



Xeris Pharmaceuticals Announces Third Quarter 2018 Financial Results and Highlights Pipeline Progress

November 7, 2018

Glucagon pen NDA accepted for review by FDA

Continuing to execute commercial build and launch readiness for glucagon pen

Advancing pipeline of preclinical and clinical development-stage products

CHICAGO, Nov. 07, 2018 (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 third quarter ended September 30, 2018, as well as pipeline and corporate highlights.

"A major achievement in the third quarter was the planned submission to the FDA of our NDA for the glucagon pen for the treatment of severe hypoglycemia. With a PDUFA goal date of June 10, 2019, we are actively preparing for a commercial launch in the US in the fourth quarter of 2019," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "In addition, we continue to advance several other preclinical and clinical programs for which we anticipate topline data in the first half of 2019."

Third Quarter 2018 Highlights and Recent Events

- **Glucagon pen NDA accepted for review by FDA:** As previously announced, the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) of Xeris' lead product candidate, glucagon pen, for the treatment of severe hypoglycemia in people with diabetes. The FDA has assigned a PDUFA goal date of June 10, 2019. *(Severe hypoglycemia is characterized by sweating, trembling, anxiousness, confusion, and combativeness, often requiring external assistance for recovery. These events can be extremely frightening for patients and caregivers and can result in seizure or coma, and, if left untreated, death.)*
- **Strengthened commercial organization:** 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-US commercial plans and partnering.
- **New Investigational New Drug (IND) application enables Phase 2 trial of ready-to-use glucagon for post-bariatric hypoglycemia (PBH):** A new glucagon IND went into effect and authorized Xeris to proceed with a Phase 2 study with its ready-to-use, room-temperature stable liquid glucagon formulation for patients who experience hyperinsulinemic hypoglycemia after bariatric surgery. Xeris expects to initiate the study before the end of 2018. *(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.)*
- **Concluded Phase 2 clinical trial in congenital hyperinsulinism (CHI) (NCT02937558).** Xeris recently concluded enrollment in the Phase 2 study and expects the randomized controlled data will support initiation of a Phase 3 program for continuous subcutaneous infusion of glucagon for the treatment of congenital hyperinsulinism. *(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 artificial pancreas trial:** In August, 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. *(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.)*

Upcoming Events

- Xeris will present three abstracts at the upcoming 18th Annual Diabetes Technology Meeting from November 8-10, 2018 in North Bethesda, Maryland.
- Xeris' senior management will be participating in the following upcoming investor conferences:
 - Jefferies London Healthcare Conference on November 14-15, 2018 in London, UK
 - Global Mizuho Investor Conference on December 3-4, 2018 in New York, NY

Third Quarter 2018 Financial Highlights

Cash position: As of September 30, 2018, Xeris reported total cash, cash equivalents, and short-term investments (collectively, "cash and investments") of \$131.0 million, compared to \$42.0 million at December 30, 2017. Xeris' cash and investments at September 30, 2018 included \$15.0 million from the Company's draw-down in the third quarter of the second tranche of its Loan and Security Agreement. The second tranche was contingent on the Company submitting the glucagon pen NDA prior to September 30, 2018. The Company's cash and investments at September 30, 2018 also included the \$89.0 million in net proceeds from the Company's initial public offering completed in June 2018.

Research and development (R&D) expenses: R&D expenses for the three months and nine months ended September 30, 2018 were \$10.9 million and \$28.3 million, respectively, compared to \$5.7 million and \$13.6 million for the same periods in 2017. The increases for both the three-month and nine-month periods were primarily due to increased product development expenses in support of the glucagon pen NDA filing and additional pipeline programs, as well as increased personnel expenses. Additionally, the increase for the nine-month period was due to increased expenses associated with clinical programs and trials.

General and administrative (G&A) expenses: G&A expenses for the three months and nine months ended September 30, 2018 were \$4.7 million and \$12.4 million, respectively, compared to \$2.0 million and \$4.9 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 three and nine months ended September 30, 2018, Xeris reported a net loss of \$14.8 million, or \$0.71 per share, and \$39.7 million, or \$4.36 per share, respectively, compared to a net loss of \$7.5 million, or \$3.72 per share, and \$17.4 million, or \$8.63 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 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.

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XERIS PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Grant income	\$ 582	\$ 170	\$ 1,611	\$ 1,073
Service revenue	-	-	53	16
Cost of revenue	-	-	42	4
Gross profit	582	170	1,622	1,085
Operating expenses:				

Research and development	10,875	5,725	28,264	13,588
General and administrative	4,650	2,017	12,388	4,917
Expense from operations	15,525	7,742	40,652	18,505
Loss from operations	(14,943)	(7,572)	(39,030)	(17,420)
Other income (expense):				
Interest income	462	45	796	45
Interest expense	(737)	-	(1,490)	(1)
Change in fair value of warrants	451	-	63	(32)
Total other income (expense)	176	45	(631)	12
Net loss	<u>\$ (14,767)</u>	<u>\$ (7,527)</u>	<u>\$ (39,661)</u>	<u>\$ (17,408)</u>
Net loss per common share - basic and diluted	<u>\$ (0.71)</u>	<u>\$ (3.72)</u>	<u>\$ (4.36)</u>	<u>\$ (8.63)</u>
Weighted average common shares outstanding, basic and diluted	<u>20,714,475</u>	<u>2,024,355</u>	<u>9,104,491</u>	<u>2,016,112</u>

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

	September 30, 2018	December 31, 2017
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 75,745	\$ 42,045
Short-term investments	55,296	
Accounts receivable, net	1,731	1,199
Prepaid expenses and other current assets	2,898	809
Total current assets	135,670	44,053
Property and equipment, net	1,826	788
Other assets	95	157
Total assets	<u>\$ 137,591</u>	<u>\$ 44,998</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 622	\$ 1,976
Accrued expenses	6,260	2,557
Warrant liabilities	1,042	93
Deferred grant award	284	234
Total current liabilities	8,208	4,860
Long-term debt, net of unamortized deferred costs	31,642	-
Other long-term liabilities	2,621	90
Total liabilities	42,471	4,950
Total convertible preferred stock	-	97,878
Total stockholders' equity (deficit)	95,120	(57,830)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 137,591</u>	<u>\$ 44,998</u>



Source: Xeris Pharmaceuticals, Inc.