Xeris Pharmaceuticals Announces Second Quarter 2019 Financial Results and Highlights

August 6, 2019

CHICAGO, Aug. 06, 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 second quarter and six months ended June 30, 2019.

"The second quarter saw several important highlights including the active enrollment in a number of Phase 2 clinical programs that will keep us on track to report data before the end of the year, the progress of additional preclinical programs in new therapeutic areas, and our continuing commercial preparation in advance of the FDA's decision on our Gvoke™ NDA," said Paul R. Edick, Chairman and Chief Executive Officer of Xeris Pharmaceuticals. "We look forward to the FDA decision on Gvoke in the coming weeks and, if approved, we plan to proceed with our launch late in the fourth quarter."

Second Quarter 2019 Highlights and Recent Events

- Xeris released favorable data from a Phase 1 study of XeriSol™ formulated diazepam and, based on these results, anticipates initiating a Phase 2 weight-based dosing study by year-end.
- Xeris announced that the FDA had extended its PDUFA goal date to September 10, 2019 for Gvoke. If approved, the Company anticipates launching Gvoke late in the fourth quarter of 2019.
- Xeris reported positive outcomes from a global Phase 3 study of Gvoke. This additional data will support the Marketing Authorization Application (MAA), which the Company anticipates submitting to EMA by year-end 2019.
- Xeris announced that it dosed the first subject in a Phase 2 study of ready-to-use (RTU) glucagon in patients who experience hypoglycemic episodes following bariatric surgery (NCT03770637). This randomized, placebo-controlled, double-blind study will evaluate the efficacy, safety, and tolerability of the Xeris RTU glucagon in treating symptomatic postprandial hypoglycemia among patients with post-bariatric hypoglycemia 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.
- Data was presented at American Diabetes Association's 79 th Scientific Sessions (ADA), which included preclinical data of our XeriSol™ pramlintide-insulin co-formulation and regular insulin and lispro insulin, clinical data summarizing combined safety and efficacy of Gvoke, as well as clinical data using Xeris' RTU glucagon in a dual hormone, closed-loop pump system.

Second Quarter and Year-to-Date 2019 Financial Highlights

Cash position: As of June 30, 2019, Xeris reported total cash, cash equivalents, and short-term investments (collectively, "cash and investments") of $124.5 million, compared to $112.6 million at December 31, 2018.

Research and development (R&D) expenses: R&D expenses for the three and six months ended June 30, 2019 were $19.3 million and $32.5 million, respectively, compared to $8.7 million and $17.4 million for the three and six months ended June 30, 2018, respectively. The increases were primarily driven by manufacturing costs related to Gvoke prior to FDA approval and increased personnel expenses.

Selling, general and administrative (SG&A) expenses: SG&A expenses for the three and six months ended June 30, 2019 were $15.0 million and $27.5 million, respectively, compared to $4.5 million and $7.7 million for the three and six months ended June 30, 2018, respectively. The increases were driven by increased marketing and selling expenses and increased personnel expenses primarily due to additional headcount to support Gvoke commercialization efforts.

Net loss: For the three months ended June 30, 2019, Xeris reported a net loss of $34.4 million, or $1.28 per share, compared to a net loss of $13.0 million, or $3.07 per share, for the same period in 2018. For the six months ended June 30, 2019, Xeris reported a net loss of $59.7 million, or $2.36 per share, compared to a net loss of $24.9 million, or $7.76 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 Gvoke, 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 BALANCE SHEETS
(in thousands)

	June 30, 2019	December 31, 2018
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 66,669	$ 45,716
Short-term investments	57,841	66,917
Accounts receivable, net	826	2,869
Prepaid expenses and other current assets	813	2,397
Total current assets	126,149	117,899
Property and equipment, net	7,677	2,034
Other assets	68	95
Total assets	$ 133,894	$ 120,028
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,840	$ 866
Accrued expenses	15,609	8,214
Current portion of long-term debt	3,000	-
Warrant liabilities	403	860
Deferred grant awards	156	232
Total current liabilities	21,008	10,172
Long-term debt, net of unamortized deferred costs	29,403	31,890
Other long-term liabilities	8,692	2,560
Total liabilities	59,103	44,622
Total stockholders' equity	74,791	75,406
Total liabilities and stockholders' equity	$ 133,894	$ 120,028

CONDENSED STATEMENTS OF OPERATIONS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Grant income	$ 314	$ 819	$ 529	$ 1,029
Service revenue	6	-	39	53
Cost of revenue	23	-	23	42
Gross profit	297	819	545	1,040
Operating expenses:				
Research and development	19,333	8,677	32,500	17,389
Selling, general and administrative	15,024	4,499	27,542	7,738
Expense from operations	34,357	13,176	60,042	25,127
Loss from operations	(34,060)	(12,357)	(59,497)	(24,087)
Other income (expense):				
Interest and other income	845	238	1,516	334
Interest expense	(1,062)	(562)	(2,125)	(753)
Change in fair value of warrants	(108)	(306)	444	(388)
Total other income (expense)	(325)	(630)	(165)	(807)
Net loss	$ (34,385)	$ (12,987)	$ (59,662)	$ (24,894)
Net loss per common share - basic and diluted	$ (1.28)	$ (3.07)	$ (2.36)	$ (7.76)
Weighted average common shares outstanding, basic and diluted	26,889,398	4,231,054	25,234,489	3,205,998

Source: Xeris Pharmaceuticals, Inc.