



Xeris Pharmaceuticals Reports Second Quarter 2021 Financial Results and Recent Highlights

August 5, 2021

Gvoke® prescription volume up 32% versus prior quarter

Gvoke unit sales to wholesalers and other direct customers up 36% versus prior quarter

Gvoke quarterly net sales up 10% to \$8.8 million versus prior quarter

Strong cash position of \$116 million

FDA approved Gvoke 1mg shelf-life extension to 30 months

EIH program to move forward in early 2022 with a Phase 2 study in broader patient populations

Proposed acquisition of Strongbridge Biopharma plc on track to close early Q4

Conference call and webcast today at 8:30 a.m. ET

CHICAGO--(BUSINESS WIRE)--Aug. 5, 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 financial results for the second quarter and first six months ended June 30, 2021, and recent highlights.

"The second quarter was extremely busy and very successful, highlighted by the proposed acquisition of Strongbridge Biopharma. We continued to see strong demand for Gvoke, driven by HypoPen sales, as evidenced by impressive increases from the first quarter in prescription volume, unit sales to wholesalers, and net sales of 32%, 36%, and 10% respectively, as well as our market share growth, which outpaced the overall glucagon market. While our net sales were somewhat negatively impacted by the continuation of the \$0 copay and an adjustment related to the return reserve for PFS inventory from prior years' sales, we don't see that as an ongoing situation, especially for the 1mg HypoPen now with 30-month dating," said Paul R. Edick, Chairman and CEO of Xeris. "We also found a great partner to prioritize and commercialize Ogluo in the UK and Europe in Tetris Pharma; we renegotiated our debt facility to extend our cash runway; and based on FDA feedback, we determined it was best to terminate the PBH program and advance EIH into a broader Phase 2 study."

Mr. Edick continued, "Our near-term focus continues to be on driving Gvoke during this important back-to-school season, closing the Strongbridge transaction and integrating the organization and its products, anticipating a potential approval and launch of Recorlev, and re-prioritizing the pipeline as we position the company for long-term product development and commercial success."

Second Quarter 2021 Highlights and Recent Events

Marketed and Approved Products

- In the second quarter, Gvoke prescriptions topped 21,000 for the first time, growing more than 32% from the prior quarter and 272% compared to the same period in 2020. Gvoke's NRx share of the retail glucagon market grew to approximately 16% during the second quarter.
- Xeris recently received approval of a Prior Approval Supplement to extend the shelf life of Gvoke 1mg from 24 months to 30 months from date of manufacture.
- In July, Xeris announced it entered into an exclusive agreement with Tetris Pharma to commercialize Ogluo® in the European Economic Area, the United Kingdom, and Switzerland. Subject to the terms and conditions set forth in the agreements, over the next several years 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. It is anticipated that Ogluo will be available in the United Kingdom in the fourth quarter of 2021 and launched subsequently in additional countries.

Ready-to-use Glucagon Programs

- Xeris received additional written feedback from the FDA on its micro dose development program in Exercise-Induced Hypoglycemia (EIH) requiring a very extensive clinical program to advance EIH. Due to the design and scope that the FDA is requiring, Xeris will not move forward with a Phase 3 study at this time. Based on FDA feedback, however, Xeris anticipates initiating a Phase 2 study in the first quarter of 2022 to examine the efficacy and safety of long-term use of RTU glucagon in a broader range of T1D and T2D patients that exercise at least twice per week.
- Following feedback from the FDA at a Type C meeting in July on its mini-dose development program in Post-Bariatric Hypoglycemia (PBH), Xeris has determined it will not advance this program due to the complexity and cost of a Phase 3 study design as proposed by the FDA.

Other Pipeline Programs

- With the intensified focus on the commercial business, especially with the anticipated closing of the Strongbridge acquisition, the Company is re-prioritizing its pipeline and will discontinue any early-stage development programs that were designed for out-license and focus development efforts solely on products for its own potential commercialization. In particular:
 - Xeris will continue to advance two undisclosed programs in endocrinology and gastroenterology.
 - Xeris will continue to partner and/or license its unique technologies with companies for whom its formulation science may create a competitive advantage, with three current programs that continue to advance in proof of concept.
 - Xeris continues to seek a development and commercialization partner to advance its XeriSol pramlintide-insulin co-formulation program but will otherwise discontinue any further internal development.
 - Xeris also continues to seek a partner to further develop and commercialize its XeriSol diazepam program but will otherwise discontinue any further internal development.

Corporate Highlights

- In May, Xeris announced a definitive agreement to acquire Strongbridge Biopharma plc in a stock and CVR transaction. A special meeting of stockholders is scheduled for September 14, 2021 for Xeris stockholders of record as of July 21, 2021. The transaction is anticipated to close early in the fourth quarter.
- In May, the Company amended its existing loan agreement with Oxford Finance and Silicon Valley Bank to extend the interest-only period up to 12 months upon achievement of certain revenue targets, which we currently expect to achieve.
- In July, Xeris announced that Barry Deutsch has decided to step down as CFO and his planned successor, Steven Pieper, was promoted to the role. Mr. Deutsch will remain with the Company through the close of the Strongbridge acquisition to ensure a smooth transition.

Second Quarter and Year-to-Date 2021 Financial Highlights

Net sales: Net sales for Gvoke HypoPen® and Gvoke pre-filled syringe (PFS) for the three- and six-month periods ending June 30, 2021 were \$8.8 million and \$16.9 million, respectively. Net sales for Gvoke, comprised primarily of Gvoke PFS, for the same periods ending June 30, 2020 were \$2.0 million and \$3.7 million, respectively. The \$8.8 million of Gvoke net sales for the three-month period ending June 30, 2021 was driven by a 36% increase in unit sales to wholesalers and other direct customers and included adjustments to the accrued returns reserve related to prior years' sales and based on actual returns experience that decreased revenue by \$0.9 million. During the three months ended March 31, 2021, the Company made adjustments to rebate and patient assistance copay accruals which were recorded in prior years based on actual claims experience to date, which increased revenue by \$0.9 million. For the six months ended June 30, 2021, these adjustments offset and together had no impact on net sales.

Cost of goods sold: Cost of goods sold were \$3.4 million and \$5.2 million for the three- and six-month periods ending June 30, 2021, respectively, which included primarily standard cost for product sold. Cost of goods sold for the same periods ending June 30, 2020 were \$1.3 million and \$3.1 million, respectively, which included under-absorbed overhead costs of \$0.7 million and \$1.5 million related to the establishment of a reserve for excess and obsolete inventory, respectively.

Research and development (R&D) expenses: R&D expenses for the three months ended June 30, 2021 were \$5.4 million compared to \$5.3 million for the same period ended June 30, 2020. The increase was primarily driven by higher pharmaceutical process development costs of \$1.1 million, partially offset by lower personnel-related costs of \$0.8 million due to lower headcount.

R&D expenses for the six months ended June 30, 2021 were \$9.4 million compared to \$11.9 million for the same period ended June 30, 2020. The decrease was primarily driven by declines in expenses associated with our clinical trials of \$2.1 million and lower personnel-related costs of \$1.2 million due to lower headcount, partially offset by higher pharmaceutical process development costs of \$0.5 million.

Selling, general and administrative (SG&A) expenses: SG&A expenses for the three months ended June 30, 2021 were \$25.9 million compared to \$17.6 million for the same period ended June 30, 2020. The increase was primarily driven by transaction-related expenses of \$3.9 million related to the pending acquisition of Strongbridge Biopharma plc, an increase of \$1.8 million in personnel-related costs due primarily to an increase in sales force headcount, and an increase in marketing and selling expenses of \$1.2 million.

SG&A expenses for the six months ended June 30, 2021 were \$45.0 million compared to \$39.3 million for the same period ended June 30, 2020. The increase was primarily driven by transaction-related expenses of \$3.9 million related to the pending acquisition of Strongbridge and an increase of \$3.8 million in personnel-related costs due primarily to an increase in sales force headcount. The increase was partially offset by a decrease in marketing and selling expenses of \$4.0 million due to a decrease in advertising.

Net loss: For the three months ended June 30, 2021, Xeris reported a net loss of \$27.5 million, or \$0.41 per share, compared to a net loss of \$24.1 million, or \$0.63 per share, for the same period in 2020. For the six months ended June 30, 2021, Xeris reported a net loss of \$45.9 million, or \$0.72 per share, compared to a net loss of \$53.3 million, or \$1.51 per share, for the same period in 2020.

Cash position: As of June 30, 2021, Xeris reported total cash, cash equivalents, and investments of \$116.0 million, compared to \$133.8 million at December 31, 2020. Total shares outstanding as of July 31, 2021 is 66,497,370.

Conference Call and Webcast Details

Xeris Pharmaceuticals will host a conference call and webcast today, Thursday, August 5, 2021 at 8:30 a.m. Eastern Time. To register for this conference call, please use this link: <https://www.incommglobevents.com/registration/q4inc/8310/xeris-pharmaceuticals-second-quarter-financial-results/>. After registering, a confirmation email will be sent, including dial-in details and a unique code for entry. The Company recommends registering a minimum of ten minutes prior to the start of the call. A replay will be available until Thursday, August 19, 2021, at (929) 458-6194 (US), 0204 525 0658 (UK) or +44 204 525 0658 (all other locations) Access Code: 743899.

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 a novel technology platform that enables ready-to-use, room-temperature stable formulations of injectable, the company is advancing a portfolio of solutions in various therapeutic categories, including its first commercial product, Gvoke® in the U.S. 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 designed 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 www.xerispharma.com, or follow us on Twitter, LinkedIn or Instagram.

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, expectations regarding clinical data or results from planned clinical trials, the timing or likelihood of regulatory approval and commercialization of its product candidates, the timing and likelihood of the consummation of the Strongbridge Biopharma acquisition, the timing or likelihood of expansion into additional markets, the timing or likelihood of identifying potential development and commercialization partnerships, 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 United States Securities and Exchange Commission (the "SEC"), as well as discussions of potential risks, uncertainties, and other important factors in Xeris' subsequent filings with the SEC. 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 Profit Forecast/Asset Valuations

No statement in this communication is intended to constitute a profit forecast for any period, nor should any statements be interpreted to mean that earnings or earnings per share will necessarily be greater or lesser than those for the relevant preceding financial periods for Strongbridge Biopharma plc ("Strongbridge"), Xeris Pharmaceuticals, Inc ("Xeris") or Xeris Biopharma Holdings, Inc. (being the entity under which Xeris and Strongbridge will be combined), as appropriate.

No statement in this communication constitutes an asset valuation.

Responsibility Statement Required by the Irish Takeover Rules

The Xeris directors accept responsibility for the information contained in this communication. To the best of the knowledge and belief of the Xeris directors (who have taken all reasonable care to ensure that such is the case) the information contained in this communication is in accordance with the facts and does not omit anything likely to affect the import of such information.

Dealing Disclosure Requirements

Under the provisions of Rule 8.3 of the Irish Takeover Rules, if any person is, or becomes, 'interested' (directly or indirectly) in 1% or more of any class of 'relevant securities' of Strongbridge or Xeris, all 'dealings' in any 'relevant securities' of Strongbridge or Xeris (including by means of an option in respect of, or a derivative referenced to, any such 'relevant securities') must be publicly disclosed by not later than 3:30 pm (New York time) on the 'business' day following the date of the relevant transaction. This requirement will continue until the date on which the 'scheme of arrangement' under Irish law pursuant to which Xeris will acquire Strongbridge becomes effective or on which the 'offer period' otherwise ends. If two or more persons co-operate on the basis of any agreement, either express or tacit, either oral or written, to acquire an 'interest' in 'relevant securities' of Strongbridge or Xeris, they will be deemed to be a single person for the purpose of Rule 8.3 of the Irish Takeover Rules.

Under the provisions of Rule 8.1 of the Irish Takeover Rules, all 'dealings' in 'relevant securities' of Strongbridge by Xeris or 'relevant securities' of Xeris by Strongbridge, or by any party acting in concert with either of them, must also be disclosed by no later than 12 noon (New York time) on the 'business' day following the date of the relevant transaction.

A disclosure table, giving details of the companies in whose 'relevant securities' 'dealings' should be disclosed, can be found on the Irish Takeover Panel's website at www.irishtakeoverpanel.ie.

'Interests in securities' arise, in summary, when a person has long economic exposure, whether conditional or absolute, to changes in the price of securities. In particular, a person will be treated as having an 'interest' by virtue of the ownership or control of securities, or by virtue of any option in respect of, or derivative referenced to, securities.

Terms in single quotation marks are defined in the Irish Takeover Rules, which can also be found on the Irish Takeover Panel's website. If you are in any doubt as to whether or not you are required to disclose a dealing under Rule 8, please consult the Irish Takeover Panel's website at www.irishtakeoverpanel.ie or contact the Irish Takeover Panel on telephone number +353 1 678 9020.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net sales	\$ 8,835	\$ 1,986	\$ 16,886	\$ 3,662
Grant and other income	71	41	215	153
Cost of goods sold	3,383	1,299	5,209	3,089
Gross profit	5,523	728	11,892	726
Operating expenses:				
Research and development	5,383	5,289	9,415	11,935
Selling, general and administrative	25,927	17,644	45,004	39,250
Total operating expenses	31,310	22,933	54,419	51,185
Loss from operations	(25,787)	(22,205)	(42,527)	(50,459)
Other income (expense):				
Interest and other income	77	277	177	711
Interest expense	(1,795)	(2,242)	(3,586)	(3,741)
Change in fair value of warrants	(10)	(39)	10	96
Total other income (expense)	(1,728)	(2,004)	(3,399)	(2,934)
Net loss before benefit from income taxes	(27,515)	(24,209)	(45,926)	(53,393)
Benefit from income taxes	—	110	—	110
Net loss	\$ (27,515)	\$ (24,099)	\$ (45,926)	\$ (53,283)
Net loss per common share - basic and diluted	\$ (0.41)	\$ (0.63)	\$ (0.72)	\$ (1.51)
Weighted average common shares outstanding - basic and diluted	66,367,125	37,973,123	63,820,321	35,381,720

XERIS PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 63,599	\$ 37,598
Short-term investments	52,381	96,190
Trade accounts receivable, net	12,295	6,875
Inventory	12,299	8,353
Prepaid expenses and other current assets	4,014	3,196
Total current assets	144,588	152,212
Property and equipment, net	6,697	6,707
Other assets	211	232
Total assets	\$ 151,496	\$ 159,151
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,185	\$ 3,117
Other accrued liabilities	19,965	15,895
Accrued trade discounts and rebates	6,799	5,984
Accrued returns reserve	3,301	2,889
Other current liabilities	214	322
Total current liabilities	35,464	28,207
Long-term debt, net of unamortized debt issuance costs	87,478	87,021
Deferred rent	6,769	6,629
Other liabilities	1,897	3,533
Total liabilities	131,608	125,390

Total stockholders' equity	19,888	33,761
Total liabilities and stockholders' equity	<u>\$ 151,496</u>	<u>\$ 159,151</u>

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