

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 10, 2021

XERIS BIOPHARMA HOLDINGS, INC.

Delaware
(State or other jurisdiction of
incorporation)

(Exact name of registrant as specified in its charter)

001-40880
(Commission
File Number)

87-1082097
(I.R.S. Employer
Identification No.)

180 N. LaSalle Street, Suite 1600
Chicago, Illinois 60601
(Address of principal executive offices, including zip code)

(844) 445-5704
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	XERS	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On November 10, 2021, Xeris Biopharma Holdings, Inc. (the “Company”) issued a press release containing information about the Company’s results of operations and business highlights for the three and nine months ended September 30, 2021. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by Xeris Biopharma Holdings, Inc. dated November 10, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 10, 2021

Xeris Biopharma Holdings, Inc.

By: /s/ Steven M. Pieper
Name: Steven M. Pieper
Title: *Chief Financial Officer*



XERIS BIOPHARMA REPORTS THIRD QUARTER 2021 FINANCIAL RESULTS AND OTHER HIGHLIGHTS

Acquisition of Strongbridge Biopharma closed October 5, 2021; integration complete

Q3 pro forma net sales of \$22.5M: Gvoke® and Keveyis® \$11.0M and \$11.5M, respectively

Gvoke and Keveyis net sales grew 19% compared to Q2 2021 and combined are on track to achieve \$76M to \$80M full year 2021 net sales

On track to realize \$50M in synergies; anticipates year-end cash, cash equivalents, and investments of approximately \$100M

Achieved 12-month interest-only extension on Oxford/SVB debt facility, deferring approximately \$17M in principal repayment to 2023

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

CHICAGO, IL; November 10, 2021 – Xeris Biopharma Holdings, Inc. (Nasdaq: XERS), a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology, neurology, and gastroenterology, and Xeris Pharmaceuticals, Inc., today announced financial results for the third quarter and first nine months ended September 30, 2021, and recent highlights, including the completion of the Strongbridge Biopharma plc acquisition on October 5, 2021.

"Continued strong demand for both Gvoke and Keveyis resulted in outstanding growth in third quarter, recording pro forma net sales of \$22.5 million. Our two commercial brands are now on track to achieve a combined \$76-80 million in full year revenue," said Paul R. Edick, Chairman and CEO of Xeris Biopharma. "Since the closing of the Strongbridge acquisition in early October, we have completed integration of the operations. We are operating as one company and are on track to realize \$50 million in synergies, while at the same time intensely preparing for the potential commercial launch of Recorlev. We are in a strong cash position to drive continued growth of Gvoke and Keveyis, prepare for and launch Recorlev in Q1 2022, if approved, and continue to advance our pipeline products."

Third Quarter 2021 Highlights and Recent Events

Marketed Products

- **Gvoke:** Third quarter 2021 prescriptions topped 27,000 for the first time, growing more than 28% from the prior quarter and 95% compared to the same period in 2020. Gvoke's NRx share of the retail glucagon market grew to approximately 18% during the third quarter. Gvoke YTD revenue more than doubled to \$27.9 million when compared to the same nine-month period in 2020. Also in the third quarter, the FDA approved the sNDA for the Gvoke Kit, which will be available in Q1 2022, as well as an extended room temperature shelf-life of the Gvoke 1mg HypoPen and PFS from 24 months to 30 months.

- Keveyis®: Third quarter 2021 net sales of \$11.5 million represent a 42% increase in revenue compared to \$8.1 million during third quarter 2020. YTD 2021 net sales of \$29.9 million represent a 33% increase versus same period last year. Xeris anticipates full year 2021 net sales for Keveyis to be in the range of \$38 to \$40 million, exceeding previously given full year estimates of \$34 to \$36 million.
- Ogluo®: In July, Xeris entered into an exclusive agreement with Tetris Pharma to commercialize Ogluo® in the European Economic Area, United Kingdom, and Switzerland. Tetris is on track to launch Ogluo in the UK before year-end 2021.

Pipeline Programs

- Recorlev®: The NDA is under review with the FDA for the treatment of endogenous Cushing's syndrome with a PDUFA goal date of January 1, 2022. Assuming approval, Xeris anticipates launching Recorlev in the first quarter of 2022.
- Exercise-induced Hypoglycemia (EIH): Xeris plans to submit an IND in the first half of 2022, and upon clearance, expects to continue to generate more clinical data addressing the management of EIH in 2022.
- Levothyroxine: Xeris has successfully enrolled all participants in a Phase 1 study of levothyroxine (XP-8121) to evaluate the pharmacokinetics, safety and tolerability, and potential for weekly dosing of the investigational, novel, subcutaneous (SC) injection for the treatment of hypothyroidism.
- XeriJect™ Technology Platform Collaborations: In October, Xeris announced a collaboration agreement with Merck, with an option to license Xeris' suspension-based formulation technology, XeriJect™, for use with undisclosed monoclonal antibodies (mAbs) for the purpose of engineering ultra-high concentration, ready-to-use formulations.

Corporate & Financial Highlights

- Xeris ended with a cash position of \$93 million as of September 30, 2021. and received an additional \$38 million from Strongbridge at close of acquisition putting Xeris in a healthy cash position. Xeris anticipates year-end cash, cash equivalents, and investments of approximately \$100 million, which is after incurring approximately \$40 million in acquisition-related one-time costs and debt extinguishment by Strongbridge. The Company believes that its cash resources are sufficient to sustain operations through at least the end of 2022.
- Due to the continued strong performance of both Gvoke and Keveyis, Xeris has achieved a full 12-month interest-only extension on our debt facility with Oxford and Silicon Valley Bank, which pushes out principal repayment to start Q1 2023 and avoids approximately \$17.4 million in principal payments in 2022.
- In the third quarter, Strongbridge and its existing lender, Avenue Venture Opportunities Fund, LP ("Avenue") entered into an amendment to its existing term loan agreement, whereby \$10.0 million of the \$20.0 million aggregate principal amount outstanding would automatically convert into Strongbridge ordinary shares immediately prior to the completion of the acquisition of Strongbridge by Xeris. The remaining Avenue aggregate principal amount of \$10.0 million was repaid in full by Strongbridge upon the completion of the acquisition of Strongbridge by Xeris.
- In conjunction with the close of the Strongbridge acquisition, John H. Johnson and Garheng Kong, M.D., PhD, MBA, joined the Board of Directors of Xeris Biopharma.

- Senior Management will participate in the upcoming investor conferences:
 - Jefferies London Healthcare Conference, November 18-19, 2021
 - Piper Sandler 33rd Annual Healthcare Conference, November 30-December 2, 2021
 - H.C. Wainwright BioConnect Conference 2022, January 10-13, 2022

Third Quarter and Year-to-Date 2021 Financial Highlights (Xeris Pharmaceuticals, Inc. stand-alone without impact of Strongbridge acquisition)

Net sales: Net sales for Gvoke HypoPen® and Gvoke pre-filled syringe for the three- and nine-month periods ending September 30, 2021 were \$11.0 million and \$27.9 million, respectively. Net sales for Gvoke, comprised primarily of Gvoke PFS, for the same periods ending September 30, 2020 were \$9.4 million and \$13.1 million, respectively. The increases in net sales for both periods were primarily due to increased demand for Gvoke.

Cost of goods sold: Cost of goods sold was \$3.2 million and \$8.4 million for the three and nine months ended September 30, 2021.

Research and development (R&D) expenses: R&D expenses was \$5.7 million and \$15.1 million for the three and nine months ended September 30, 2021.

Selling, general and administrative (SG&A) expenses: SG&A expenses for the three and nine months ended September 30, 2021 were \$26.5 million and \$71.5 million. These figures include transaction-related expenses of \$2.3 million and \$6.2 million for the three and nine months ended September 30, 2021, respectively.

Net loss: For the three months ended September 30, 2021, Xeris reported a net loss of \$26.0 million, or \$0.39 per share, and a net loss of \$71.9 million, or \$1.11 per share, for the nine months ended September 30, 2021. The net loss and per share figures include transaction-related expenses of \$2.3 million (or \$0.03 per share) and \$6.2 million (or \$0.10 per share) for the three and nine months ended September 30, 2021, respectively.

Cash position: As of September 30, 2021, Xeris reported total cash, cash equivalents, and investments of \$93.0 million, compared to \$133.8 million at December 31, 2020. Total shares outstanding as of October 31, 2021 is 124,708,935.

Conference Call and Webcast Details

Xeris will host a conference call and webcast today, Wednesday, November 10, 2021, at 8:30 a.m. Eastern Time. To register for this conference call, please use this link: <https://www.incommglobalevents.com/registration/q4inc/9056/xeris-biopharma-third-quarter-2021-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. Following the conference call, a replay will be available until Wednesday, November 24, 2021, at US Toll Free: 1 866 813 9403, UK: 0204 525 0658, Canada: 1 226 828 7578, or all other locations: +44 204 525 0658 Access Code: 508975

About Xeris Biopharma

Xeris (Nasdaq: XERS), is a biopharmaceutical company developing and commercializing unique therapies for patient populations in endocrinology, neurology, and gastroenterology. Xeris has two commercially available products, Gvoke®, a ready-to-use liquid glucagon for the treatment of severe hypoglycemia and Keveyis®, the first and only FDA-approved therapy for primary periodic paralysis. In addition to Recorlev®, which is filed and under review by the FDA, Xeris also has a robust pipeline of development programs to extend the current marketed products into important new indications

and uses and bring new products forward using its proprietary formulation technology platforms, XeriSol™ and XeriJect™, supporting long-term product development and commercial success.

Xeris Biopharma Holdings 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 Biopharma Holdings, 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, estimates and projections about the potential benefits of the Strongbridge Biopharma acquisition, the future performance of the combined company and estimated synergies, estimates and expectations regarding potential collaborations, the timing or likelihood of regulatory approval and commercialization of its product candidates, 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. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, reliance on third-party suppliers for Gvoke®, Ogluo®, Keveyis and Recorlev (if approved), the regulatory approval of its product candidates, its ability to market and sell its products, failure to realize the expected benefits of the acquisition, failure to promptly and effectively integrate Strongbridge’s businesses, general economic and business conditions that affect the combined company following the consummation of the acquisition, the impact of the COVID-19 pandemic on the combined company following the consummation of the transaction, changes in global, political, economic, business, competitive, market and regulatory forces, future exchange and interest rates, changes in tax laws, regulations, rates and policies, future business acquisitions or disposals and competitive developments and the other risks described in our Quarterly Report on Form 10-Q and other reports we file from time to time with the SEC. These forward-looking statements are based on numerous assumptions and assessments made in light of Xeris’ experience and perception of historical trends, current conditions, business strategies, operating environment, future developments, and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The factors described in the context of such forward-looking statements in this communication could cause Xeris’ plans with respect to Strongbridge, Xeris’ plans with respect to its products and product candidates, Xeris’ actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements. Although it is believed that the expectations reflected in such forward-looking statements are reasonable, no assurance can be given that such expectations will prove to have been correct and persons reading this communication are therefore cautioned not to place undue reliance on these forward-looking statements which speak only as at the date of this communication. Additional information about economic, competitive, governmental, technological, and other factors that may affect Xeris is set forth in Item 1A, “Risk Factors,” in Xeris’ 2020 Annual Report on Form 10-K, which has been filed with the SEC and other important factors in Xeris’ subsequent filings with the SEC, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Additional information about economic, competitive, governmental, technological, and other factors that may affect Strongbridge is set forth in Item 1A, “Risk Factors,” in Strongbridge’s 2020 Annual Report on Form 10-K, which has been filed with the SEC, the contents of which are not incorporated by reference into, nor do they form part of, this communication. Any forward-looking statements in this communication are based upon information available to Xeris, as of the date of this communication and, while believed to be true when made, may ultimately prove to be incorrect. Subject to any obligations under applicable law, Xeris does not undertake any obligation to update any forward-looking statement whether as a result of new

information, future developments or otherwise, or to conform any forward-looking statement to actual results, future events, or to changes in expectations. All subsequent written and oral forward-looking statements attributable to Xeris or any person acting on behalf of any of them are expressly qualified in their entirety by this paragraph.

Investor Contact

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XERIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data; unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net sales	\$ 11,035	\$ 9,404	\$ 27,921	\$ 13,066
Grant and other income	25	44	240	197
Cost of goods sold	3,220	2,832	8,429	5,921
Gross profit	7,840	6,616	19,732	7,342
Operating expenses:				
Research and development	5,663	3,876	15,078	15,811
Selling, general and administrative	26,535	16,484	71,539	55,734
Total operating expenses	32,198	20,360	86,617	71,545
Loss from operations	(24,358)	(13,744)	(66,885)	(64,203)
Other income (expense):				
Interest and other income	66	232	243	943
Interest expense	(1,798)	(2,328)	(5,384)	(6,069)
Change in fair value of warrants	81	(160)	91	(64)
Total other income (expense)	(1,651)	(2,256)	(5,050)	(5,190)
Net loss before benefit from income taxes	(26,009)	(16,000)	(71,935)	(69,393)
Benefit from income taxes	—	—	—	110
Net loss	\$ (26,009)	\$ (16,000)	\$ (71,935)	\$ (69,283)
Other comprehensive loss, net of tax:				
Unrealized gains (losses) on investments	(5)	(125)	(34)	1
Foreign currency translation adjustments	(1)	17	2	12
Comprehensive loss	\$ (26,015)	\$ (16,108)	\$ (71,967)	\$ (69,270)
Net loss per common share - basic and diluted	\$ (0.39)	\$ (0.35)	\$ (1.11)	\$ (1.78)
Weighted average common shares outstanding - basic and diluted	66,497,593	46,145,116	64,722,552	38,995,707

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

	September 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,492	\$ 37,598
Short-term investments	33,491	96,190
Trade accounts receivable, net	13,561	6,875
Inventory	14,241	8,353
Prepaid expenses and other current assets	3,582	3,196
Total current assets	124,367	152,212
Property and equipment, net	6,682	6,707
Other assets	211	232
Total assets	\$ 131,260	\$ 159,151
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	\$ 4,290	\$ 3,117
Other accrued liabilities	22,957	15,895
Accrued trade discounts and rebates	6,782	5,984
Accrued returns reserve	3,161	2,889
Other current liabilities	95	322
Total current liabilities	37,285	28,207
Long-term debt, net of unamortized debt issuance costs	87,713	87,021
Deferred rent	6,826	6,629
Other liabilities	1,897	3,533
Total liabilities	133,721	125,390
Total stockholders' (deficit) equity	(2,461)	33,761
Total liabilities and stockholders' (deficit) equity	\$ 131,260	\$ 159,151