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 6, 2023

QUANTERIX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) **001-38319** (Commission File Number) **20-8957988** (IRS Employer Identification No.)

900 Middlesex Turnpike

Billerica, MA (Address of principal executive offices)

01821 (Zip Code)

(617) 301-9400

(Registrant's telephone number, including area code)

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:

UVritten 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:

		Name of each exchange on which
Title of each class	Trading symbol(s)	registered
Common Stock, \$0.001 par value per		
share	QTRX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company \Box

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. \Box

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2023, Quanterix Corporation ("Quanterix") issued a press release announcing its financial results for the third quarter ended September 30, 2023 (the "Earnings Release"). A copy of the Earnings Release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 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

Exhibit	
No.	Description
99.1	Earnings Release dated November 6, 2023.
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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 thereunto duly authorized.

QUANTERIX CORPORATION

By: <u>/s/ Vandana Sriram</u> Vandana Sriram

Chief Financial Officer

Date: November 6, 2023

Quanterix Releases Operating Results for Third Quarter 2023

BILLERICA, Mass. – **November 6, 2023** - <u>Quanterix Corporation</u> (NASDAQ: QTRX), a company fueling scientific discovery through ultrasensitive biomarker detection, today announced financial results for the three months ended September 30, 2023.

Third Quarter Financial Highlights

- Revenue was \$31.3 million, an 18% increase from \$26.6 million for the corresponding prior year period.
- GAAP gross margin was 56.8% as compared to 41.1% for the corresponding prior year period. Non-GAAP gross margin was 48.6% as compared to 34.9% for the corresponding prior year period.
- Net loss was \$7.8 million as compared to \$35.1 million for the corresponding prior year period.
- Net cash use was approximately \$1.9 million. Cash, cash equivalents, marketable securities, and restricted cash were \$330.4 million as of September 30, 2023, as compared to \$332.2 million as of June 30, 2023.

"We're on track to achieve the six-quarter transformation plan we laid out by year end," said Masoud Toloue, President and Chief Executive Officer of Quanterix. "This will not only yield highly scaled production lines, but serve as the foundation for an accelerated innovation rate going into next year. Last month's launch of our LucentAD p-Tau 217 blood-based test puts us in a leading position to address broad-based non-invasive patient testing for Alzheimer's disease. We expect a faster release pace of pioneering, high sensitivity Simoa products going into 2024."

Operational and Business Highlights

- In October, the Company launched LucentAD p-Tau 217, a new blood-based biomarker laboratory developed test (LDT) using well-validated Johnson & Johnson Innovative Medicine (Janssen) antibodies to assist in the evaluation of patients suspected of having or developing Alzheimer's disease. p-Tau 217 is the **only** blood-based biomarker recognized in the new draft NIA-AA Revised Criteria for Diagnosis and Staging of Alzheimer's Disease capable of meeting a stringent 90% accuracy criterion necessary to diagnose Alzheimer's.
- In data presented by Eli Lilly at the CTAD conference, the Simoa® platform was used for analytical validation and initial clinical evaluation of Eli Lilly's plasma p-Tau 217 immunoassay for a new blood-based diagnostic for Alzheimer's disease. The study of over 1,000 patients from TRAILBLAZER-ALZ 2 demonstrated high positive and negative agreement to amyloid PET, with an AUC of 0.92 and the assay could prove to be a useful diagnostic test to identify the presence or absence of amyloid pathology.

Full Year Business Outlook

Management has increased full-year revenue expectations to be in the range of \$118 to \$120 million versus the prior range of \$110 to \$116 million. GAAP gross margin percentage is expected to be in the high 50's, and non-GAAP gross margin percentage is expected to be approximately 50%. Both measures increased from prior guidance of low 50's and high 40's, respectively. The Company now anticipates 2023 cash usage in the range of \$20 to \$25 million, compared to prior guidance of \$30 to \$35 million.

For additional information on the non-GAAP financial measures included in this press release, please see "Use of Non-GAAP Financial Measures" and "Reconciliation of GAAP to Non-GAAP Financial Measures" below.

Conference Call

In conjunction with this announcement, the Company will host a conference call on November 7, 2023 at 8:30 a.m. E.T. <u>Click here</u> to pre-register for the conference call and obtain your dial-in number and passcode.

Interested investors can also access the live webcast from the <u>News & Events</u> page within the Investors section of the Quanterix website at <u>http://www.quanterix.com</u>. An archived webcast replay will be available on the Company's website for one year.

Quanterix Corporation Consolidated Statements of Operations (Unaudited and in thousands, except per share data)

	Three Months Ended September 30,		, Nine Months Ende		ded S	ed September 30,		
		2023		2022		2023		2022
Revenues:								
Product revenue	\$	19,660	\$	17,693	\$	58,639	\$	53,134
Service revenue		10,938		8,370		30,069		25,728
Collaboration and license revenue		237		301		1,234		479
Grant revenue		499		282		877		357
Total revenues		31,334		26,646		90,819		79,698
Costs of goods sold and services:								
Cost of product revenue		8,342		10,511		22,611		31,178
Cost of service and other revenue		5,209		5,191		14,361		14,306
Total costs of goods sold and services		13,551		15,702		36,972		45,484
Gross profit		17,783		10,944		53,847		34,214
Operating expenses:								
Research and development		7,200		6,631		17,866		20,290
Selling, general, and administrative		23,595		19,966		66,069		72,723
Other lease costs		758		609		2,696		609
Impairment and restructuring				20,341		(33)		20,341
Total operating expenses		31,553		47,547		86,598		113,963
Loss from operations		(13,770)		(36,603)		(32,751)		(79,749)
Interest income, net		4,185		1,712		11,520		2,316
Other income (expense), net		2,030		(101)		1,884		(676)
Loss before income taxes		(7,555)		(34,992)		(19,347)		(78,109)
Income tax expense		(203)		(72)		(578)		(10)
Net loss	\$	(7,758)	\$	(35,064)	\$	(19,925)	\$	(78,119)
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Net loss per common share, basic and diluted	\$	(0.21)	\$	(0.95)	\$	(0.53)	\$	(2.12)
Weighted-average common shares outstanding, basic and								
diluted		37,657		37,005		37,494		36,927
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Quanterix Corporation Consolidated Balance Sheets (Unaudited and in thousands)

	Septen	nber 30, 2023	December 31, 2022		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	201,261	\$	338,740	
Marketable securities		126,449		_	
Accounts receivable		24,083		19,017	
Inventory		19,945		16,786	
Prepaid expenses and other current assets		9,273		6,860	
Total current assets		381,011		381,403	
Restricted cash		2,647		2,597	
Property and equipment, net		17,517		20,162	
Intangible assets, net		6,003		7,516	
Operating lease right-of-use assets		19,860		21,223	
Other non-current assets		2,004		1,298	
Total assets	\$	429,042	\$	434,199	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	4,786	\$	3,836	
Accrued compensation and benefits		9,775		10,658	
Accrued expenses and other current liabilities		6,672		5,133	
Deferred revenue		9,827		8,644	
Operating lease liabilities		4,093		2,687	
Total current liabilities		35,153		30,958	
Deferred revenue, net of current portion		1,126		1,415	
Operating lease liabilities, net of current portion		38,306		41,417	
Other non-current liabilities		1,105		1,469	
Total liabilities		75,690		75,259	
Total stockholders' equity		353,352		358,940	
Total liabilities and stockholders' equity	\$	429,042	\$	434,199	

Quanterix Corporation Consolidated Statements of Cash Flows (Unaudited and in thousands)

]	Nine Months Ended Sep	
		2023	2022
Cash flows from operating activities:	¢	(10,025) 作	(70.110
Net loss	\$	(19,925) \$	(78,119
Adjustments to reconcile net loss to net cash used in operating activities:		4 700	1 100
Depreciation and amortization expense		4,788	4,186
Credit losses on accounts receivable		311	102
Foreign currency losses		359	167
Unrealized losses on marketable securities		(241)	
Amortization of (discount) premium on marketable securities		(1,249)	
Operating lease right-of-use asset amortization		1,518	1,099
Stock-based compensation expense		12,438	11,779
Impairment		—	16,915
Deferred income taxes		242	(134
Loss on disposal of fixed assets		46	6
Changes in assets and liabilities:			
Accounts receivable		(5,615)	5,045
Inventory		(2,966)	3,919
Prepaid expenses and other current assets		(2,829)	(262
Other non-current assets		(716)	(859
Accounts payable		948	(7,085
Accrued compensation and benefits, accrued expenses, and other current liabilities		876	(3,021
Deferred revenue		894	3,108
Operating lease liabilities		(1,690)	(1,156
Other non-current liabilities		(107)	128
Net cash used in operating activities		(12,918)	(44,182
Cash flows from investing activities:			
Purchases of marketable securities		(125,200)	
Purchases of property and equipment		(1,572)	(10,131
Proceeds from RADx grant on assets purchased		_	520
Net cash used in investing activities		(126,772)	(9,611
Cash flows from financing activities:			
Proceeds from common stock issued under stock plans		2,632	1,597
Payments for employee taxes withheld on stock-based compensation awards		(142)	· · · ·
Net cash provided by financing activities		2,490	1,597
Net decrease in cash, cash equivalents, and restricted cash		(137,200)	(52,196
Effect of exchange rate changes on cash, cash equivalents, and restricted cash		(137,200)	(507
Cash, cash equivalents, and restricted cash at beginning of period		341,337	399,042
	\$	203,908 \$	346,339
Cash, cash equivalents, and restricted cash at end of period	<u>а</u>	203,908 \$	346,339

Use of Non-GAAP Financial Measures

To supplement our financial statements presented on a U.S. GAAP basis, we present non-GAAP gross profit, non-GAAP gross margin, non-GAAP total operating expenses, and non-GAAP loss from operations, which are calculated by including shipping and handling costs for product sales within cost of goods sold instead of within selling, general, and administrative expenses. Management uses these non-GAAP measures to evaluate our operating performance in a manner that allows for meaningful period-to-period comparison and analysis of trends in our business and our competitors. Management believes that presentation of these non-GAAP measures provides useful information to investors in assessing our operating performance within our industry and in order to allow comparability to the presentation of other companies in our industry where shipping and handling costs are included in cost of goods sold for products. Management also uses these non-GAAP measures as a factor in assessing our progress against our restructuring plan. The non-GAAP financial information presented here should be considered in conjunction with, and not as a substitute for, the financial information presented in accordance with U.S. GAAP.

Set forth below is a reconciliation of non-GAAP gross profit, non-GAAP gross margin, non-GAAP total operating expenses, and non-GAAP loss from operations to their most directly comparable GAAP financial measures.

Reconciliation of GAAP to Non-GAAP Financial Measures

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	Three Months Ended September 30,				Nine Months Ended September 30,				
		2023		2022		2023		2022	
GAAP gross profit	\$	17,783	\$	10,944	\$	53,847	\$	34,214	
Shipping and handling costs (1)		(2,553)		(1,639)		(6,004)		(5,288)	
Non-GAAP gross profit	\$	15,230	\$	9,305	\$	47,843	\$	28,926	
GAAP revenue	\$	31,334	\$	26,646	\$	90,819	\$	79,698	
GAAP gross margin (gross profit as % of revenue)		56.8%		41.1%		59.3%		42.9%	
Non-GAAP gross margin (non-GAAP gross profit									
as % of revenue)		48.6%		34.9%		52.7%		36.3%	
GAAP total operating expenses	\$	31,553	\$	47,547	\$	86,598	\$	113,963	
Shipping and handling costs (1)		(2,553)		(1,639)		(6,004)		(5,288)	
Non-GAAP total operating expenses	\$	29,000	\$	45,908	\$	80,594	\$	108,675	
CAAD loss from operations	¢	(13,770)	\$	(36,603)	\$	(32,751)	\$	(79,749)	
GAAP loss from operations	\$		ф ф		ф ф		ф		
Non-GAAP loss from operations	\$	(13,770)	\$	(36,603)	\$	(32,751)	\$	(79,749)	

Quanterix Corporation Reconciliation of GAAP Financial Measures to Non-GAAP Financial Measures (Unaudited and in thousands, except percentages)

(1) Shipping and handling costs, which include freight and other activities costs associated with product shipments, are captured within operating expenses in our consolidated statements of operations. During the three months ended September 30, 2023 and 2022, we incurred \$2.6 million and \$1.6 million, respectively, of shipping and handling costs recorded within operating expenses. During the nine months ended September 30, 2023 and 2022, we incurred \$6.0 million and \$5.3 million, respectively, of shipping and handling costs within operating expenses.

About Quanterix

From discovery to diagnostics, Quanterix's ultrasensitive biomarker detection is driving breakthroughs only made possible through its unparalleled sensitivity and flexibility. The Company's Simoa technology has delivered the gold standard for earlier biomarker detection in blood, serum or plasma, with the ability to quantify proteins that are far lower than the Level of Quantification (LoQ) of conventional analog methods. Its industry-leading precision instruments, digital immunoassay technology and CLIA-certified Accelerator laboratory have supported research that advances disease understanding and management in neurology, oncology, immunology, cardiology and infectious disease. Quanterix has been a trusted partner of the scientific community for nearly two decades, powering research published in more than 2,200 peer-reviewed journals. Find additional information about the Billerica, Massachusetts-based company at https://www.quanterix.com or follow us on Twitter and LinkedIn.

Forward-Looking Statements

Quanterix's current financial results, as discussed in this press release, are preliminary and unaudited, and subject to adjustment. This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements about Quanterix's financial performance, including statements under the header "Full Year Business Outlook" set forth above, and are subject to a number of risks, uncertainties and assumptions. Forward-looking statements in this press release are based on Quanterix's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause Quanterix's actual results to differ from those expressed or implied in the forward-looking statements in this press release include, but are not limited to, those described in the section titled "Part I, Item 1A, "Risk Factors" in Quanterix' Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the U.S. Securities and Exchange Commission on March 6, 2023. Except as required by law, Quanterix assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Contacts

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