

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): March 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)

Registrant's telephone number, including area code: (617) 301-9400

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, \$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

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 March 6, 2023, Quanterix Corporation (“Quanterix”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2022 (the “Earnings Release”). A copy of the Earnings Release is furnished as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure

A copy of a slide to be presented during Quanterix’s earnings call on March 6, 2023 is furnished as Exhibit 99.2 and is incorporated herein by reference.

The information in this Form 8-K (including Exhibits 99.1 and 99.2) 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 March 6, 2023.
99.2	Slide from March 6, 2023 Earnings Call.
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.

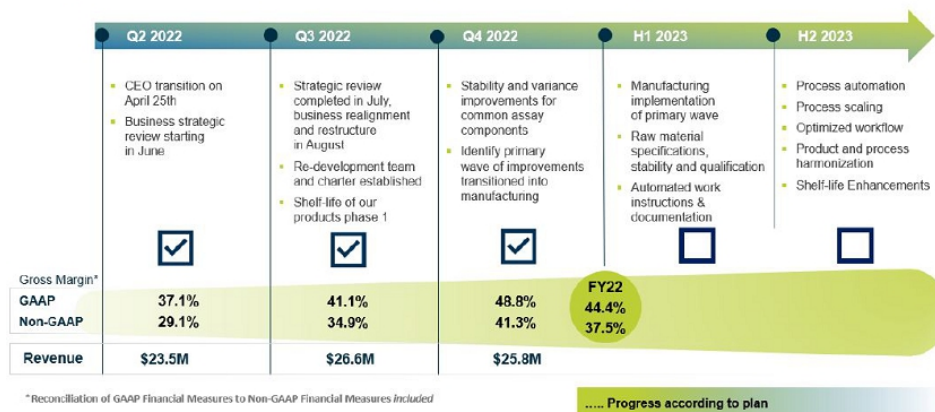
QUANTERIX CORPORATION

By: /s/ Michael Doyle
Michael Doyle
Chief Financial Officer

Date: March 6, 2023

Corporate Transformation:

Progress on Assay Redevelopment Roadmap



BILLERICA, Mass.- March 6, 2023 - Quanterix Corporation (NASDAQ: QTRX), a company fueling scientific discovery through ultrasensitive biomarker detection, today announced financial results for the fourth quarter and twelve months ended December 31, 2022.

“Our Simoa technology continues to be on the forefront of research, testing, therapeutic trials and has been an integral part of recent advances in Alzheimer’s disease. In order to best capture and lead in this area, two quarters ago we began a corporate transformation and we’re pleased announce the program is on track, with good progress quarter over quarter,” said Masoud Toloue, President and Chief Executive Officer of Quanterix.

Sequential Progress with Strategic Business Realignment

In August 2022, the Company initiated a strategic business realignment to maximize its full potential to enable access to current and future Simoa technology. As part of the realignment, the Company established an assay redevelopment program with the goal of improving its capability to manufacture high-quality assays at scale.

Quanterix’s fourth quarter and full year revenue results were in line with expectations set forth with this plan. Gross margin, a key success indicator of the Company’s strategic realignment, saw strong quarter over quarter improvement. Q4 GAAP Gross Margin was 48.8% versus Q3 GAAP gross margin of 41.1%. Q4 Non-GAAP gross margin was 41.3% versus Q3 non-GAAP gross margin of 34.9%.

GAAP Operating loss of \$22.3 million for the fourth quarter of 2022 included approximately \$10 million of restructuring and impairment related charges. As a result of the restructuring, SG&A costs were \$19.3M for the quarter, down \$9.1M from last year Q4.

Year over Year Financial Highlights

Fourth Quarter 2022

- Q4 GAAP revenue was \$25.8 million versus prior year Q4 of \$30.3 million, a decrease of 14.7%. Prior year Q4 revenue included \$1.0M of RADx revenue.
- Q4 GAAP gross margin was 48.8% versus prior year Q4 of 53.7%; Q4 non-GAAP gross margin was 41.3% versus prior year Q4 of 47.2%.
- Cash burn for Q4 was \$5 million, ended 2022 with \$338.7 million of unrestricted cash.

Full Year 2022

- FY GAAP total revenue was \$105.5 million versus prior year FY of \$110.6 million, which included RADx revenue of \$5.2 million.
- FY GAAP gross margin was 44.4% versus prior year FY of 55.8%; and FY non-GAAP gross margin was 37.5% versus prior year FY of 49.6%

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.

Fourth Quarter and Full Year Business Highlights

- In Q1 2022, Quanterix announced new agreements with Lilly to advance Alzheimer's disease diagnosis and treatment; the agreements provide Quanterix access to Lilly's P-tau217 antibody technology to create pathways for plasma-based biomarkers for use in Alzheimer's disease and establish a framework for future collaboration and supports development of Quanterix tests to advance diagnosing and treating life-threatening diseases.
 - In Q2 2022, the Company received funding from the Alzheimer's Drug Discovery Foundation to accelerate Alzheimer's disease diagnostic plasma test development. The Company is collaborating with Amsterdam University Medical Centers on four phases of clinical trials to validate Quanterix's multi-analyte test. Phase 1 training cohort was completed in Q4 with 1,200 samples and Phase 1b (independent retrospective cohort) and Phase 2 (prospective trial) are expected to start by the end of Q1 2023.
 - The Company is participating in the BioHermes trial with the Global Alzheimer's Platform Foundation. The 17 US site and 1,000 early Alzheimer's patient trial closed in November of 2022 and is expected to complete data analysis in Q2 of this year. This prospective validation trial is expected to support a regulatory filing for FDA clearance for Quanterix's pTau-181 test.
 - In Q4 2022, the Company presented findings at the 15th Clinical Trials on Alzheimer's Disease conference, revealing that Quanterix's Simoa® technology has powered critical advances in ongoing clinical trials for the treatment of Alzheimer's disease.
 - The Company expanded its LDT menu with the launch of a neurofilament light chain (NFL) LDT, which can be used as an aid in the evaluation of individuals for possible neurodegenerative conditions or other causes of neuronal or central nervous system damage. Quanterix's Simoa NFL is the most widely published NFL test with hundreds of research papers, demonstrating its validity for assessing neuronal damage, and Simoa NFL has become widely adopted in therapeutic clinical trial designs.
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Published discoveries enabled through Quanterix's Simoa technology continue to illustrate industry reliance on the Company's ultra-sensitive technology for breakthrough discovery in research and clinical applications. The technology was highlighted in 137 new publications in the fourth quarter 2022, bringing total Simoa-specific inclusions to over 2,100 as of the end of 2022.

Conference Call

In conjunction with this announcement, Quanterix Corporation will host a conference call on March 6, 2023 at 8:30 a.m. Eastern Time. Individuals interested in listening to the conference call may do so by pre-registering [here](#) and obtaining a dial-in number and passcode.

A live webcast will also be available at: <https://edge.media-server.com/mmc/p/e6rxupm5>. You may also access the live webcast by visiting the [News & Events](#) page within the Investors section of the Quanterix website at www.quanterix.com. The webcast will be available on the Company's website for one year following completion of the call.

Financial Highlights

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Product revenue	\$ 16,674	\$ 23,476	\$ 69,808	\$ 81,062
Service and other revenue	8,767	5,674	34,495	23,629
Collaboration revenue	170	162	649	648
Grant revenue	213	975	570	5,217
Total revenue	25,824	30,287	105,522	110,556
Costs of goods sold:				
Cost of product revenue	9,631	9,916	40,809	34,149
Cost of service and other revenue	3,601	4,110	17,907	14,679
Total costs of goods sold and services	13,232	14,026	58,716	48,828
Gross profit	12,592	16,261	46,806	61,728
Gross margin	48.8%	53.7%	44.4%	55.8%
Operating expenses:				
Research and development	5,600	7,734	25,890	27,978
Selling, general and administrative	19,272	28,423	91,995	92,336
Other lease costs	669	—	1,278	—
Restructuring	329	—	3,755	—
Goodwill impairment	—	—	8,220	—
Impairment expense	8,677	—	17,372	—
Total operating expenses	34,547	36,157	148,510	120,314
Loss from operations	(21,955)	(19,896)	(101,704)	(58,586)
Interest income (expense), net	2,815	15	5,131	(403)
Other income (expense), net	614	(213)	(62)	1,265
Loss before income taxes	(18,526)	(20,094)	(96,635)	(57,724)
Income tax (expense) benefit	(75)	4	(65)	36
Net loss	\$ (18,601)	\$ (20,098)	\$ (96,700)	\$ (57,760)
Net loss per share, basic and diluted	\$ (0.50)	\$ (0.55)	\$ (2.61)	\$ (1.60)
Weighted-average common shares outstanding, basic and diluted	37,160,472	36,659,254	36,990,965	35,997,473

Quanterix Corporation
Condensed Consolidated Balance Sheets
(Unaudited and in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 338,740	\$ 396,465
Accounts receivable, net	19,017	23,786
Inventory	16,786	22,190
Prepaid expenses and other current assets	6,860	6,514
Total current assets	<u>381,403</u>	<u>448,955</u>
Restricted cash	2,597	2,577
Property and equipment, net	20,162	17,960
Intangible assets, net	7,516	10,534
Goodwill	—	9,632
Right-of-use assets	21,223	11,491
Other non-current assets	1,298	378
Total assets	<u>\$ 434,199</u>	<u>\$ 501,527</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,836	\$ 9,209
Accrued compensation and benefits	10,658	13,252
Other accrued expenses	4,747	6,486
Deferred revenue	8,644	6,361
Short-term lease liabilities	2,687	1,428
Other current liabilities	386	241
Total current liabilities	<u>30,958</u>	<u>36,977</u>
Deferred revenue, net of current portion	1,415	1,099
Long-term lease liabilities	41,417	20,464
Other non-current liabilities	1,469	2,035
Total liabilities	<u>75,259</u>	<u>60,575</u>
Total stockholders' equity	358,940	440,952
Total liabilities and stockholders' equity	<u>\$ 434,199</u>	<u>\$ 501,527</u>

Use of Non-GAAP Financial Measures

To supplement its financial statements presented on a GAAP basis, the Company presents non-GAAP gross profit and non-GAAP gross margin, 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 the Company's operating performance in a manner that allows for meaningful period-to-period comparison and analysis of trends between the Company's business and its competitors. Management believes that presentation of non-GAAP gross margin provides useful information to investors in assessing the Company's operating performance within its industry and in order to allow comparability to the presentation of other companies in its industry where shipping and handling costs are included in cost of goods sold for products. Management also uses non-GAAP gross margin as a factor in assessing the Company's progress against the strategic business realignment 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 GAAP. Investors are encouraged to review the reconciliation of these pro-forma measures to their most directly comparable GAAP financial measures set forth below.

Reconciliation of GAAP to Non-GAAP Financial Measures

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

	Three Months Ended December 31,		Three Months Ended September 30,		Three Months Ended June 30,		Year Ended December 31,	
	2022	2021	2022	2022	2022	2022	2021	2021
GAAP gross profit	\$ 12,592	\$ 16,261	\$ 10,944	\$ 8,711	\$ 46,806	\$ 61,728		
Shipping and handling costs (1)	(1,926)	(1,976)	(1,636)	(1,868)	(7,206)	(6,892)		
Non-GAAP gross profit	\$ 10,666	\$ 14,285	\$ 9,308	\$ 6,843	\$ 39,600	\$ 54,836		
GAAP Revenue	25,824	30,287	26,646	23,500	105,522	110,556		
GAAP Gross margin (GAAP gross profit as % of revenue)	48.8%	53.7%	41.1%	37.1%	44.4%	55.8%		
Non-GAAP gross margin (non-GAAP gross profit as % of revenue)	41.3%	47.2%	34.9%	29.1%	37.3%	49.6%		
GAAP total operating expenses	\$ 34,547	\$ 36,157	\$ 47,547	\$ 33,670	\$ 148,510	\$ 120,314		
Shipping and handling costs (1)	(1,926)	(1,976)	(1,636)	(1,868)	(7,206)	(6,892)		
Non-GAAP total operating costs	\$ 32,621	\$ 34,181	\$ 45,911	\$ 31,802	\$ 141,304	\$ 113,422		
GAAP loss from operations	\$ (21,955)	\$ (19,896)	\$ (36,603)	\$ (24,959)	\$ (101,704)	\$ (58,586)		
Non-GAAP loss from operations	\$ (21,955)	\$ (19,896)	\$ (36,603)	\$ (24,959)	\$ (101,704)	\$ (58,586)		

(1) Shipping and handling costs, which include freight and other activities costs associated with product shipments, net of charges passed on to the customer, are captured within operating expenses in our consolidated statements of operations. During the three months and year ended December 31, 2022, we incurred \$1.9 million and \$7.2 million, respectively, of shipping and handling costs recorded within operating expenses. During the three months and year ended December 31, 2021, we incurred \$2.0 million and \$6.9 million, respectively, of shipping and handling costs recorded within operating expenses. During the three months ended September 30, 2022, we incurred \$1.6 million of shipping and handling costs within operating expenses. During the three months ended June 30, 2022, we incurred \$2.1 million 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). 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 2,000 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

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' financial performance, including anticipated progress associated with Quanterix' strategic business alignment plan, and are subject to a number of risks, uncertainties and assumptions. Forward-looking statements in this news release are based on Quanterix' 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' 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 "Part I, Item 1A, "Risk Factors" in Quanterix' Annual Report on Form 10-K for the year ended December 31, 2022, to be filed with the SEC 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.

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Quanterix Corporation
Supplemental Schedule of Operating Expenses
(Unaudited and in thousands)

	Three Months Ended December 31	
	2022	2021
Operating expenses:		
Research and development	\$ 5,600	\$ 7,734
Selling, general and administrative	<u>19,272</u>	<u>28,423</u>
Subtotal	\$ 24,872	\$ 36,157
Other lease costs	669	—
Restructuring	329	—
Goodwill impairment	—	—
Impairment expense	<u>8,677</u>	<u>—</u>
Subtotal	<u>\$ 9,675</u>	<u>\$ —</u>
Total operating expenses	<u>\$ 34,547</u>	<u>\$ 36,157</u>