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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .

Commission File Number: 001-38319

QUANTERIX CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**20-8957988**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
900 Middlesex Turnpike **Billerica, MA**	**01821**
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Exchange 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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of May 2, 2024, the registrant had 38,270,088 shares of common stock outstanding.

QUANTERIX CORPORATION
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Unless the context otherwise requires, the terms "Quanterix," the Company," "we," "it," "us," and "our" in this Quarterly Report on Form 10-Q refer to Quanterix Corporation and its consolidated subsidiaries.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements (within the meaning of the U.S. Private Securities Litigation Reform Act of 1995) that involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, forward-looking statements can be identified by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words, or other comparable terminology. These forward-looking statements include, but are not limited to, statements related to our financial performance, and are subject to a number of risks, uncertainties, and assumptions, including those further described elsewhere in this Quarterly Report on Form 10-Q, in the section titled "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the U.S. Securities and Exchange Commission (the "SEC") on February 29, 2024, or in other filings that we make with the SEC. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Readers should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in any forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to new information, actual results, or to changes in our expectations, except as required by law.

Readers should read this Quarterly Report on Form 10-Q and any documents referenced herein that we have filed with the SEC as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

Service Marks, Trademarks and Trade Names

"Quanterix," "Simoa," "Simoa HD-X," "Simoa HD-1," "SR-X," "SP-X", "HD-X", "LucentAD," "Lucent Diagnostics," and our logo are our trademarks. All other service marks, trademarks, and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us, by these other companies.

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

QUANTERIX CORPORATION
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except per share data)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,281	$ 174,422
Marketable securities	256,640	146,902
Accounts receivable, net of allowance for expected credit losses	29,276	25,414
Inventory	26,015	22,365
Prepaid expenses and other current assets	9,551	9,291
Total current assets	366,763	378,394
Restricted cash	2,605	2,604
Property and equipment, net	17,492	17,926
Intangible assets, net	5,339	6,034
Operating lease right-of-use assets	17,748	18,251
Other non-current assets	1,802	1,802
Total assets	$ 411,749	$ 425,011
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,914	$ 5,048
Accrued compensation and benefits	6,706	13,659
Accrued expenses and other current liabilities	7,021	6,041
Deferred revenue	10,234	9,468
Operating lease liabilities	4,366	4,241
Total current liabilities	32,241	38,457
Deferred revenue, net of current portion	933	1,227
Operating lease liabilities, net of current portion	36,084	37,223
Other non-current liabilities	1,053	1,177
Total liabilities	70,311	78,084
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.001 par value per share:		
Authorized: 120,000 shares; issued and outstanding: 38,353 and 38,014 shares at March 31, 2024 and December 31, 2023, respectively	38	38
Additional paid-in capital	789,006	783,142
Accumulated other comprehensive loss	(3,038)	(1,757)
Accumulated deficit	(444,568)	(434,496)
Total stockholders' equity	341,438	346,927
Total liabilities and stockholders' equity	$ 411,749	$ 425,011

The accompanying notes are an integral part of these Consolidated Financial Statements.

QUANTERIX CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except per share data)

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Product revenue	$ 19,670	$ 19,287
Service and other revenue	11,967	8,579
Collaboration and license revenue	155	368
Grant revenue	274	222
Total revenues	32,066	28,456
Costs of goods sold and services:		
Cost of product revenue	7,145	7,033
Cost of service and other revenue	5,295	4,497
Total costs of goods sold and services	12,440	11,530
Gross profit	19,626	16,926
Operating expenses:		
Research and development	6,675	4,720
Selling, general and administrative	25,993	20,850
Other lease costs	924	776
Total operating expenses	33,592	26,346
Loss from operations	(13,966)	(9,420)
Interest income	3,948	3,449
Other income, net	206	8
Loss before income taxes	(9,812)	(5,963)
Income tax expense	(260)	(140)
Net loss	$ (10,072)	$ (6,103)
Net loss per common share, basic and diluted	$ (0.26)	$ (0.16)
Weighted-average common shares outstanding, basic and diluted	38,126	37,327

The accompanying notes are an integral part of these Consolidated Financial Statements.

QUANTERIX CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(amounts in thousands)

	Three Months Ended March 31,	
	2024	**2023**
Net loss	$ (10,072)	$ (6,103)
Other comprehensive loss, net of tax:		
Unrealized losses on marketable securities	(607)	—
Foreign currency translation	(674)	42
Total other comprehensive income (loss)	(1,281)	42
Comprehensive loss	$ (11,353)	$ (6,061)

The accompanying notes are an integral part of these Consolidated Financial Statements.

QUANTERIX CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(amounts in thousands)

	Three Months Ended March 31, 2024					
	Common Stock					
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2023	38,014	$ 38	$ 783,142	$ (1,757)	$ (434,496)	$ 346,927
Issuance of common stock under stock plans, including tax effects	274	—	599	—	—	599
Stock-based compensation expense	—	—	5,265	—	—	5,265
Unrealized loss on marketable securities, net of tax	—	—	—	(607)	—	(607)
Foreign currency translation	—	—	—	(674)	—	(674)
Net loss	—	—	—	—	(10,072)	(10,072)
Balance at March 31, 2024	38,288	$ 38	$ 789,006	$ (3,038)	$ (444,568)	$ 341,438

	Three Months Ended March 31, 2023					
	Common Stock					
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2022	37,280	$ 37	$ 763,688	$ (2,623)	$ (402,162)	$ 358,940
Issuance of common stock under stock plans, including tax effects	144	—	551	—	—	551
Stock-based compensation expense	—	—	3,902	—	—	3,902
Foreign currency translation	—	—	—	42	—	42
Net loss	—	—	—	—	(6,103)	(6,103)
Balance at March 31, 2023	37,424	$ 37	$ 768,141	$ (2,581)	$ (408,265)	$ 357,332

The accompanying notes are an integral part of these Consolidated Financial Statements.

QUANTERIX CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (10,072)	$ (6,103)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,523	1,439
Credit losses on accounts receivable	176	178
Accretion of marketable securities	(1,657)	—
Operating lease right-of-use asset amortization	478	334
Stock-based compensation expense	5,265	3,902
Other operating activity	55	270
Changes in assets and liabilities:		
Accounts receivable	(4,233)	(3,741)
Inventory	(3,670)	(89)
Prepaid expenses and other current assets	(254)	(422)
Other non-current assets	(21)	(33)
Accounts payable	(1,122)	(1,271)
Accrued compensation and benefits, accrued expenses, and other current liabilities	(6,126)	(5,983)
Deferred revenue	472	2,041
Operating lease liabilities	(988)	179
Other non-current liabilities	10	(203)
Net cash used in operating activities	(20,164)	(9,502)
Cash flows from investing activities:		
Purchases of marketable securities	(137,889)	—
Proceeds from maturities of marketable securities	29,200	—
Purchases of property and equipment	(506)	(136)
Net cash used in investing activities	(109,195)	(136)
Cash flows from financing activities:		
Proceeds from common stock issued under stock plans	2,037	564
Payments for employee taxes withheld on stock-based compensation awards	(1,438)	(13)
Net cash provided by financing activities	599	551
Net decrease in cash, cash equivalents, and restricted cash	(128,760)	(9,087)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(380)	24
Cash, cash equivalents, and restricted cash at beginning of period	177,026	341,337
Cash, cash equivalents, and restricted cash at end of period	$ 47,886	$ 332,274
Supplemental disclosure of cash flow information:		
Cash paid for taxes	$ 175	$ 246
Purchases of property and equipment in accounts payable and accrued expenses	$ 222	$ 147

The accompanying notes are an integral part of these Consolidated Financial Statements.

QUANTERIX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Organization and Nature of Business

Quanterix Corporation ("Quanterix" or the "Company") is a life sciences company that has developed next generation, ultra-sensitive digital immunoassay platforms that advance life sciences research and diagnostics. The Company's platforms are based on its proprietary digital "Simoa" detection technology and enable customers to reliably detect protein biomarkers in ultra-low concentrations in blood, serum, and other fluids that, in many cases, are undetectable using conventional, analog immunoassay technologies. The ability of the Company's Simoa platforms to detect proteins in the femtomolar range is enabling the development of novel therapies and diagnostics and has the potential to facilitate a paradigm shift in healthcare from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis, and, ultimately, prevention.

The Company also provides contract research services for customers and Laboratory Developed Test ("LDT") services through its CLIA-certified Accelerator Laboratory (the "Accelerator Laboratory"). The Accelerator Laboratory provides customers with access to its Simoa technology and its Lucent Diagnostics clinical testing services (launched in July 2023) and supports multiple projects and services, including sample testing, homebrew assay development, custom assay development, and blood-based biomarker testing. To date, the Company has completed over 2,300 projects for more than 480 customers from all over the world using its Simoa platforms.

Note 2. Significant Accounting Policies

Basis of Presentation

The accompanying Consolidated Financial Statements and Notes to Consolidated Financial Statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") regarding interim financial reporting on Form 10-Q. Accordingly, certain information and disclosures required for complete financial statements prepared in accordance with U.S. GAAP are not included herein. The Consolidated Balance Sheet and related information as of December 31, 2023 included herein was derived from the audited Consolidated Financial Statements as of December 31, 2023, but does not include all disclosures required by U.S. GAAP on an annual reporting basis. Certain amounts in the prior years' Consolidated Financial Statements have been reclassified to conform to the current year's presentation.

These Consolidated Financial Statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 29, 2024. Since the date of that filing, there have been no changes or updates to the Company's significant accounting policies, other than those described below.

In the opinion of management, the Consolidated Financial Statements and Notes to Consolidated Financial Statements contain all normal, recurring adjustments necessary for a fair statement of financial position, results of operations, comprehensive loss, and cash flows as of the dates and for the interim periods presented. The results of operations for the three months ended March 31, 2024 may not be indicative of the results for the full year ended December 31, 2024, or any other period.

The Company's fiscal year is the twelve-month period from January 1 through December 31, and all references to "2024," "2023," and the like refer to the fiscal year unless otherwise noted.

Use of Estimates

The preparation of the Consolidated Financial Statements and Notes to Consolidated Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts

of assets and liabilities at the end of each fiscal period, and the reported amounts of revenues and expenses during each fiscal period. Such estimates include, but are not limited to, revenue recognition, valuation of inventory, leases, valuation and impairment of intangible and long-lived assets, recoverability of deferred tax assets, and stock-based compensation expense. The Company bases its estimates on historical experience, known trends, worldwide economic conditions, both general and specific to the life sciences industry, and other relevant factors it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates and changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Principles of Consolidation

The Consolidated Financial Statements and Notes to Consolidated Financial Statements include the accounts of Quanterix and its wholly-owned subsidiaries. All intercompany transactions have been eliminated in consolidation.

In accordance with Accounting Standards Codification ("ASC") 810 – *Consolidation*, the Company assesses the terms of non-marketable equity investments in entities to determine if any meet the definition of a variable interest entity ("VIE") and require consolidation into its Consolidated Financial Statements. Refer to Note 14 − *Variable Interest Entities* for further discussion.

Foreign Currency

The functional currency of the Company's subsidiaries is their respective local currencies. These subsidiary financial statements are translated into U.S. dollars using the period-end exchange rates for assets and liabilities, average exchange rates during the corresponding period for revenue and expenses, and historical rates for equity. The effects of foreign currency translation adjustments are recorded in accumulated other comprehensive income (loss), a component of stockholders' equity on the Consolidated Balance Sheets.

Foreign currency transaction gains (losses) are included in other income, net on the Consolidated Statements of Operations and were not material for the three months ended March 31, 2024 and 2023.

Restricted Cash

The following table summarizes the period ending cash and cash equivalents as presented on the Consolidated Balance Sheets and the total cash, cash equivalents, and restricted cash as presented on the Consolidated Statements of Cash Flows (in thousands):

	As of March 31,	
	2024	2023
Cash and cash equivalents	$ 45,281	$ 329,354
Restricted cash	2,605	2,920
Cash, cash equivalents, and restricted cash	$ 47,886	$ 332,274

Restricted cash consists of collateral for a letter of credit issued as security for two of the Company's leased facilities and to secure the Company's corporate credit card program. The short-term or long-term classification is determined in accordance with the expiration of the underlying letter of credit and security.

Recently Adopted Accounting Pronouncements

In June 2022, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions* ("ASU 2022-03"). This update clarifies the guidance in Topic 820 related to measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, as well as introduces new disclosure requirements for these types of equity securities. The new standard became effective for the Company on January 1, 2024. The Company adopted this standard on a prospective basis and such adoption did not have a material impact on the Company's Consolidated Financial Statements or related disclosures.

Recent Accounting Standards to be Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The new standard enhances the disclosures of reportable segment information, primarily with regards to significant segment expenses, and applies to entities with a single reportable segment. The new standard is effective for the Company for annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. Upon adoption, the guidance should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adoption of the standard on its Consolidated Financial Statements disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The new standard enhances income tax disclosure requirements by requiring specified categories and greater disaggregation within the tax rate reconciliation table, disclosure of income taxes paid by jurisdiction, and providing clarification on uncertain tax positions and related financial statement impacts. The new standard is effective for the Company for annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the impact of adoption of the standard on its Consolidated Financial Statements disclosures.

Note 3. Revenue and Related Matters

Revenue from Contracts with Customers

The Company's customers primarily consist of entities engaged in life sciences research that pursue the discovery and development of new drugs for a variety of neurologic, oncologic, cardiovascular, infectious disease, and other protein biomarkers associated with diseases. The Company's customer base includes pharmaceutical, biotechnology, contract research organizations, academic, and government institutions.

Disaggregated Revenue

When disaggregating revenue, the Company considers all of the economic factors that may affect its revenues. The following table disaggregates the Company's revenue from contracts with customers by geography, based on the location products and services are consumed, and revenue type (in thousands):

	Three Months Ended March 31, 2024				Three Months Ended March 31, 2023			
	North America	EMEA	Asia Pacific	Total	North America	EMEA	Asia Pacific	Total
Product revenue:								
Instruments	$ 408	$ 1,269	$ 869	$ 2,546	$ 2,144	$ 1,981	$ 1,135	$ 5,260
Consumable and other products	10,242	4,041	2,841	17,124	7,457	4,940	1,630	14,027
Total	$ 10,650	$ 5,310	$ 3,710	$ 19,670	$ 9,601	$ 6,921	$ 2,765	$ 19,287
Service revenue:								
Service-type warranties	$ 1,637	$ 852	$ 194	$ 2,683	$ 1,557	$ 706	$ 135	$ 2,398
Research services	5,762	2,802	127	8,691	5,190	234	115	5,539
Other services	318	248	27	593	381	257	4	642
Total	$ 7,717	$ 3,902	$ 348	$ 11,967	$ 7,128	$ 1,197	$ 254	$ 8,579
Collaboration and license revenue:								
Total	$ 67	$ 88	$ —	$ 155	$ 368	$ —	$ —	$ 368

For the three months ended March 31, 2024, no customer accounted for more than 10% of the Company's total revenues and for the three months ended March 31, 2023, one customer accounted for more than 10% of the Company's total revenues. At March 31, 2024 and December 31, 2023, one customer accounted for more than 10% of the Company's gross accounts receivable.

Eli Lilly and Company Service Revenue Agreements

On February 25, 2022, the Company entered into a Master Collaboration Agreement with Eli Lilly and Company ("Lilly") establishing a framework for future projects focused on the development of Simoa immunoassays (the "Lilly Collaboration Agreement"). The Company also entered into a statement of work under the Lilly Collaboration Agreement to perform assay research and development services within the field of Alzheimer's disease. Under the statement of work, the Company receives $1.5 million per calendar quarter, which began in the first quarter of 2022. The statement of work automatically renews on a quarterly basis until Lilly provides a termination notice in accordance with the terms of the Lilly Collaboration Agreement. As of March 31, 2024, the Lilly Collaboration Agreement and the statement of work were still in effect.

Concurrent with the execution of the Lilly Collaboration Agreement, the Company entered into a Technology License Agreement (the "Lilly License") under which Lilly granted the Company a non-exclusive license to Lilly's proprietary p-Tau 217 antibody technology for use in research use only products and services and future in vitro diagnostics ("IVD") applications within the field of Alzheimer's disease. In consideration of the Lilly License, the Company paid an upfront fee**,** is required to make milestone payments based on the achievement of predetermined regulatory and commercial events, and will pay royalties on net sales of licensed products.

The Company recognized $1.5 million of revenue from the Lilly Collaboration Agreement during the three months ended March 31, 2024 and 2023.

Contract Assets

There were no contract assets as of March 31, 2024 or December 31, 2023.

Deferred Revenue

During the three months ended March 31, 2024 and 2023, the Company recognized $2.7 million and $2.4 million of revenue, respectively, related to its deferred revenue balance at January 1 of each such period.

Remaining Performance Obligations

As of March 31, 2024, the aggregate amount of transaction prices allocated to performance obligations that were not yet satisfied, or were partially satisfied, was $11.2 million. Of this amount, $10.2 million is expected to be recognized as revenue in the next 12 months, with the remainder expected to be recognized thereafter. The $11.2 million primarily consists of amounts billed for undelivered services related to initial and extended service-type warranties and research services.

Costs to Obtain a Contract

Changes in costs to obtain a contract were as follows (in thousands):

	2024	2023
Balance at December 31 of prior year	$ 288	$ 377
Capitalization of costs to obtain a contract	97	197
Recognition of costs to obtain a contract	(95)	(191)
Balance at March 31	$ 290	$ 383

The Company evaluates potential impairment of these amounts at each balance sheet date, and no related impairments were recorded during the three months ended March 31, 2024 and 2023.

Grant Revenue

All of the Company's grant revenue is generated within North America.

NIH Grant

On September 21, 2022, the Company and the National Institutes of Health (the "NIH"), an agency of the U.S. Department of Health and Human Services, entered into a contract (the "NIH Grant") with a total award value of $1.7 million. The NIH granted the Company funding in support of the development of certain point-of-care diagnostic technologies through collaborative efforts. Grant funding is to be used solely for activities related to the point-of-care diagnostic device development project and the contract period runs through August 2025. Receipt of the award value occurs throughout the term of the contract period and after the Company submits for reimbursement of activities related to the grant. As of March 31, 2024, the Company had received $0.8 million of the total award value.

During the three months ended March 31, 2024 and 2023, grant revenue recognized and research and development expenses incurred were not material.

ADDF Grant

On March 24, 2022, the Company and the Alzheimer's Drug Discovery Foundation (the "ADDF") entered into a contract (the "ADDF Grant") with a total funding value of $2.3 million. The ADDF is a charitable venture philanthropy entity that granted the Company funding in support of certain activities for the development of an IVD test for early detection of Alzheimer's disease. The ADDF Grant restricts the Company's use of the granted funds solely for activities related to the Company's Alzheimer's diagnostic test development project and the contract period runs through June 2024. Receipt of the contract funding was subject to achievement of pre-defined milestones, and as of December 31, 2023, the Company had received the total funding value of $2.3 million.

During the three months ended March 31, 2024 and 2023 grant revenue recognized and research and development expenses incurred were not material. As of March 31, 2024, the Company had $1.0 million of deferred revenue related to the ADDF Grant.

Note 4. Allowance for Credit Losses

The change in the allowance for expected credit losses on accounts receivable is summarized as follows (in thousands):

	2024	2023
Balance at December 31 of prior year	$ 454	$ 118
Provision for expected credit losses	176	178
Write-offs and recoveries collected	(103)	(74)
Balance at March 31	$ 527	$ 222

Note 5. Marketable Securities

The amortized cost, gross unrealized gains, gross unrealized losses, and fair value of the Company's marketable securities by major security type were as follows (in thousands):

	As of March 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 42,947	$ —	$ (40)	$ 42,907
U.S. Treasuries	73,033	—	(23)	73,010
U.S. Government agency bonds	78,389	10	(149)	78,250
Corporate bonds	79,012	55	(136)	78,931
Total marketable securities	$ 273,381	$ 65	$ (348)	$ 273,098

Marketable securities are recorded in the following Consolidated Balance Sheets captions:	
Cash and cash equivalents	$ 16,458
Marketable securities	256,640
Total marketable securities	$ 273,098

	As of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 53,482	$ 23	$ (12)	$ 53,493
U.S. Treasuries	4,896	1	—	4,897
U.S. Government agency bonds	28,366	39	(7)	28,398
Corporate bonds	66,726	289	(8)	67,007
Total marketable securities	$ 153,470	$ 352	$ (27)	$ 153,795

Marketable securities are recorded in the following Consolidated Balance Sheets captions:	
Cash and cash equivalents	$ 6,893
Marketable securities	146,902
Total marketable securities	$ 153,795

The following tables show the fair value and gross unrealized losses of the Company's available-for-sale securities, with unrealized losses that are not deemed to be other-than-temporary aggregated by major security type and length of time that the individual securities have been in a continuous unrealized loss position (in thousands):

	Less Than 12 Months	
As of March 31, 2024	Fair Value	Unrealized Losses
Commercial paper	$ 38,497	$ (40)
U.S. Treasuries	73,010	(23)
U.S. Government agency bonds	69,825	(149)
Corporate bonds	48,629	(136)
Total	$ 229,961	$ (348)

	Less Than 12 Months	
As of December 31, 2023	Fair Value	Unrealized Losses
Commercial paper	$ 32,137	$ (12)
U.S. Government agency bonds	15,861	(7)
Corporate bonds	8,367	(8)
Total	$ 56,365	$ (27)

The Company did not have any individual securities in a continuous loss position for greater than 12 months, and there were no individual securities that were in a significant unrealized loss position as of March 31, 2024. For marketable securities in an unrealized loss position, the Company does not intend to sell them before recovery of their amortized cost bases, it is not more likely than not that the Company will be required to sell them before recovery of their amortized cost bases, and the unrealized losses are not credit related. Accordingly, the Company has not recorded any impairment losses or a credit loss allowance.

The Company did not sell any marketable securities or record any realized gains or losses for the three months ended March 31, 2024. At March 31, 2024 and December 31, 2023, the Company had $1.2 million and $1.0 million, respectively, of accrued interest receivable on its marketable securities, which was recorded in prepaid expenses and other current assets on the Consolidated Balance Sheets.

The following table summarizes the contractual maturities of the Company's marketable securities (in thousands):

	As of March 31, 2024		As of December 31, 2023	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due within one year	$ 209,554	$ 209,378	$ 95,188	$ 95,232
Due in one to two years	63,827	63,720	58,282	58,563
Total	$ 273,381	$ 273,098	$ 153,470	$ 153,795

Note 6. Fair Value of Financial Instruments

Recurring Fair Value Measurements

The following tables present the Company's fair value hierarchy for its financial assets that are measured at fair value on a recurring basis (in thousands):

As of March 31, 2024	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets:				
Cash equivalents: (1)				
Money market funds	$ 19,792	$ 19,792	$ —	$ —
U.S. Treasuries	16,458	—	16,458	—
Total cash equivalents	36,250	19,792	16,458	—
Marketable securities:				
Commercial paper	42,907	—	42,907	—
U.S. Treasuries	56,552	—	56,552	—
U.S. Government agency bonds	78,250	—	78,250	—
Corporate bonds	78,931	—	78,931	—
Total marketable securities	256,640	—	256,640	—
Total financial assets	$ 292,890	$ 19,792	$ 273,098	$ —

As of December 31, 2023	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets:				
Cash equivalents: (1)				
Money market funds	$ 155,367	$ 155,367	$ —	$ —
Commercial paper	1,996	—	1,996	—
U.S. Treasuries	4,897	—	4,897	—
Total cash equivalents	162,260	155,367	6,893	—
Marketable securities:				
Commercial paper	51,498	—	51,498	—
U.S. Government agency bonds	28,398	—	28,398	—
Corporate bonds	67,006	—	67,006	—
Total marketable securities	146,902	—	146,902	—
Total financial assets	$ 309,162	$ 155,367	$ 153,795	$ —

(1) Included in cash and cash equivalents on the Consolidated Balance Sheets.

Cash equivalents and marketable securities classified as Level 2 financial assets are initially valued at their purchase price and subsequently valued at the end of each reporting period utilizing third party pricing services or other observable data. The pricing services utilize industry standard valuation methods, including both income and market-based approaches, and observable market inputs to determine the fair value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates, and other industry and economic events.

Nonrecurring Fair Value Measurements

The Company has a non-marketable equity investment in an entity that is evaluated under the VIE guidance (refer to Note 14 - *Variable Interest Entities* for further discussion). Pursuant to ASC 321 – *Investments – Equity Securities*, the Company uses the measurement alternative for equity investments without readily determinable fair values and recognizes its non-marketable equity investment at cost, less any impairment, and adjusted for any observable price changes in orderly transactions. The Company's investment is classified as a Level 3 financial asset. Changes in the inputs and assumptions used to determine the fair value would result in a higher or lower fair value measurement.

The Company's non-marketable equity investment contains certain restrictions related to the sale or transfer of the securities. The restrictions are in place indefinitely and cannot lapse. No adjustment to the fair value was required as a result of adopting ASU 2022-03 on January 1, 2024.

During the three months ended March 31, 2024 and 2023, the Company did not record any fair value adjustments to its non-marketable equity investment and to date, the cumulative fair value adjustments have not been material. As of March 31, 2024 and December 31, 2023, the carrying value of the non-marketable equity investment was $0.8 million, and is recorded in other non-current assets on the Consolidated Balance Sheets.

Other Fair Value Disclosures

During the three months ended March 31, 2024 and 2023, the Company did not transfer financial assets between levels of the fair value hierarchy. Additionally, there have been no changes to the valuation techniques for Level 2 or Level 3 financial assets.

Note 7. Inventory

Inventory, net of inventory reserves, consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	$ 6,369	$ 5,114
Work in process	7,371	4,466
Finished goods	12,275	12,785
Total inventory	$ 26,015	$ 22,365

Note 8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Accrued professional services	$ 1,947	$ 1,596
Accrued royalties	1,631	1,689
Accrued tax liabilities	1,485	808
Other accrued expenses	1,958	1,948
Total accrued expenses and other current liabilities	$ 7,021	$ 6,041

Note 9. Stock-Based Compensation

Stock Options

Stock option activity for the three months ended March 31, 2024 is presented below (in thousands, except per share and contractual life amounts):

	Number of options	Weighted-average exercise price per share	Weighted-average remaining contractual life (in years)	Aggregate intrinsic value
Outstanding at December 31, 2023	2,774	$ 19.62	7.9	$ 26,941
Granted	1,179	22.74		
Exercised	(104)	12.34		
Forfeited/expired	(181)	20.24		
Outstanding at March 31, 2024	3,668	$ 20.80	8.3	$ 17,741
Exercisable at March 31, 2024	1,297	$ 22.24	6.6	$ 7,615
Vested and expected to vest at March 31, 2024	3,668	$ 20.80	8.3	$ 17,741

Restricted Stock Units

Restricted stock unit ("RSU") activity for the three months ended March 31, 2024 is presented below (in thousands, except per share amounts):

	Number of shares	Weighted-average grant date fair value per share
Unvested at December 31, 2023	1,328	$ 17.87
Granted	446	24.40
Vested	(197)	17.57
Forfeited	(96)	20.52
Unvested at March 31, 2024	1,481	$ 19.71

Employee Stock Purchase Plan ("ESPP")

In December 2017, the Company adopted the 2017 Employee Stock Purchase Plan (the "2017 ESPP"). The 2017 ESPP provides for six-month offering periods commencing and ending as follows: March 1 through August 31, and September 1 through February 28. During the three months ended March 31, 2024, employees purchased 36 thousand shares of the Company's common stock pursuant to the 2017 ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense was recorded in the following categories on the Consolidated Statements of Operations (in thousands):

	Three Months Ended March 31,	
	2024	2023
Cost of product revenue	$ 281	$ 187
Cost of service and other revenue	308	350
Research and development	543	370
Selling, general and administrative	4,133	2,995
Total stock-based compensation expense	$ 5,265	$ 3,902

As of March 31, 2024, there was $56.0 million of total unrecognized stock-based compensation expense related to unvested RSUs and stock options, which is expected to be recognized over the remaining weighted-average vesting period of 3.1 years.

Note 10. Net Loss Per Share

The following table presents the computation of basic and diluted net loss per share (in thousands, except per share data):

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss	$ (10,072)	$ (6,103)
Denominator:		
Weighted average common shares outstanding, basic and diluted	38,126	37,327
Net loss per share, basic and diluted	$ (0.26)	$ (0.16)

As the Company was in a net loss position for all periods listed in the table below, the following common share equivalents (calculated on a weighted average basis) were excluded from the calculation of diluted net loss per share (in thousands):

	Three Months Ended March 31,	
	2024	2023
Stock options	3,520	2,720
Common stock and RSUs	1,497	1,489
Estimated ESPP purchases	19	26
Total dilutive shares	5,036	4,235

Note 11. Income Taxes

The Company's effective tax rates were (2.6)% and (2.4)% for the three months ended March 31, 2024 and 2023, respectively. The income tax provision and effective tax rate is driven primarily by a valuation allowance in the United States, partially offset by income taxes in foreign jurisdictions.

The Company maintains a valuation allowance on the majority of its deferred tax assets, and it has concluded that it is more likely than not that the deferred assets will not be utilized.

Note 12. Commitments and Contingencies

Purchase Commitments

STRATEC

During 2022, the Company and STRATEC Consumables GmbH ("STRATEC") entered into an amendment to the supply agreement with STRATEC (as amended, the "STRATEC Supply Agreement"), related to the supply of discs used in Simoa bead-based instruments. As part of the STRATEC Supply Agreement, the Company agreed to purchase a total of 515 thousand discs to be shipped at various points starting in 2022 and continuing through 2024 at an agreed purchase price per disc.

The total purchase commitment under the STRATEC Supply Agreement is $3.7 million, of which $2.1 million has been paid, and $1.6 million is due within one year from March 31, 2024.

During the three months ended March 31, 2024 and 2023, STRATEC shipped 35 thousand and 75 thousand discs, respectively, to the Company. The Company recorded cost of product revenue related to these shipments of $0.3 million and $0.5 million for the three months ended March 31, 2024 and 2023, respectively. During 2024, STRATEC is

required to ship 222 thousand discs to the Company. During the three months ended March 31, 2024, 35 thousand discs were shipped.

Other Purchase Commitments

The Company's other non-cancellable purchase commitments primarily consist of purchases of raw materials for manufacturing operations under annual and multi-year agreements, some of which have minimum quantity requirements. As of March 31, 2024, the Company's total purchase commitments under these agreements were $3.8 million, most of which the Company expects to incur in the year ending December 31, 2024.

License Agreements

Harvard University

In August 2022, the Company and Harvard University ("Harvard") entered into an exclusive license agreement (the "Harvard License Agreement") for certain intellectual property owned by Harvard. Pursuant to the Harvard License Agreement, the Company paid an upfront fee of $0.6 million, which was recorded in research and development expenses on the Consolidated Statements of Operations. Under this license, the Company is required to pay Harvard low single-digit royalties on net sales of products and services using the licensed technology, as well as a portion of its applicable sublicense revenues. The Company incurred no royalty expense under the Harvard License Agreement for the three months ended March 31, 2024 and 2023.

Refer to Note 13 − *Related Party Transactions* for a discussion of a related party relationship with Harvard.

Tufts University

In June 2007, the Company and Tufts University ("Tufts") entered into a license agreement (the "Tufts License Agreement") for certain intellectual property owned by Tufts. The Tufts License Agreement, which was subsequently amended, is exclusive and sub-licensable, and will continue in effect on a country-by-country basis as long as there is a valid claim of a licensed patent in a country. The Company is required to pay license and maintenance fees that are creditable against royalties, in addition to low single-digit royalties on direct sales and services, and a royalty on sublicense income. The Company incurred royalty expenses related to the Tufts License Agreement of $0.5 million and $0.4 million during the three months ended March 31, 2024 and 2023, respectively, which was recorded in cost of product revenue on the Consolidated Statements of Operations.

Refer to Note 13 − *Related Party Transactions* for a discussion of a related party relationship with Tufts.

Legal Contingencies

The Company is subject to claims in the ordinary course of business; however, the Company is not currently a party to any pending or threatened litigation, the outcome of which would be expected to have a material adverse effect on its financial condition or results of operations. The Company records contingent liabilities when losses are probable and estimable. If an estimate of a probable loss is a range and no amount within the range is more likely than any other amount in the range, the Company records the minimum amount of the range.

Leases

The undiscounted future lease payments for non-cancelable operating leases were as follows (in thousands):

Maturity of lease liabilities	As of March 31, 2024
2024 (remainder)	$ 5,340
2025	7,254
2026	7,408
2027	7,641
2028	7,880
2029	8,126
Thereafter	7,612
Total lease payments	51,261
Less: imputed interest	10,811
Total operating lease liabilities	$ 40,450

The Company's lease agreement for office and laboratory facilities in Bedford, Massachusetts included a tenant improvement allowance with the landlord that offset a portion of the Company's construction costs. During the first quarter of 2023, the Company received the final tenant improvement allowance reimbursement of $0.9 million.

Note 13. Related Party Transactions

In June 2007, the Company entered into the Tufts License Agreement for certain intellectual property owned by Tufts (refer to Note 12 − *Commitments and Contingencies*). A member of the Company's Board of Directors was previously affiliated with Tufts and continues to receive compensation from Tufts on a formulaic basis based on royalties and license payments the Company makes to Tufts. At March 31, 2024 and December 31, 2023, open payable balances to Tufts were not material.

In August 2022, the Company entered into the Harvard License Agreement for certain intellectual property owned by Harvard (refer to *Note 12 − Commitments and Contingencies*). Harvard is required to pay a portion of the payments received from the Company under the Harvard License Agreement to a member of the Company's Board of Directors. A member of the Company's Board of Directors is also affiliated with Harvard and Mass General Brigham. Revenue recorded from sales of products and services to Harvard and its affiliates and to Mass General Brigham and its affiliates was $0.3 million for both the three months ended March 31, 2024 and 2023. Cost of product revenue and operating expenses with Harvard and Mass General Brigham were not material for the three months ended March 31, 2024 and 2023. At March 31, 2024 and December 31, 2023, open payables to and receivable balances from Harvard and Mass General Brigham were not material.

In May 2022, the Company and UltraDx Limited ("UltraDx"), a company formed by ARCH Venture Partners ("ARCH"), entered into an agreement (the "UltraDx Agreement"). Under the UltraDx Agreement, the Company agreed to supply UltraDx with HD-X instruments (both fully assembled and disassembled), assays and assay components, and granted a co-exclusive license to manufacture, seek Chinese regulatory approval of (including performance of any necessary research and development activities), and commercialize, HD-X instruments assembled in China and related assays in the Chinese IVD market. At contract inception, the Company determined that UltraDx was a related party because a member of the Company's Board of Directors was affiliated with ARCH and UltraDx. As of June 7, 2023, this individual was no longer a member of the Company's Board of Directors. Revenue recorded from sales of products and services to UltraDx totaled $1.1 million for the three months ended March 31, 2024. Cost of product revenue and services was not material for the three months ended March 31, 2024. At March 31, 2024 there was $1.2 million in open receivable balances and no open payable balances to UltraDx.

Revenue and cost of product revenue and services for three months ended March 31, 2023 were not material. At December 31, 2023, there were no open payable balances to UltraDx and open receivable balances from UltraDx were not material.

Note 14. Variable Interest Entities

The Company enters into relationships with, or has investments in, other entities that may be VIEs. The Company assesses the criteria in ASC 810 – *Consolidation* to determine if any of these entities meet the definition of a VIE and require consolidation into its financial statements. The Company's analysis determines whether it has a controlling financial interest and also identifies the primary beneficiary of a VIE as the enterprise that has both (1) the power to direct activities of a VIE that most significantly impact the entity's economic performance and (2) the obligation to absorb losses of, or the right to receive benefits from, the entity that could potentially be significant to that entity.

Based on the Company's assessments, it does not have any controlling financial interests in any VIE, and therefore did not consolidate any VIE into its Consolidated Financial Statements during the three months ended March 31, 2024 and 2023.

As of March 31, 2024 and December 31, 2023, the carrying value of the Company's investment in VIEs was $0.8 million, which was recorded in other non-current assets on the Consolidated Balance Sheets. Refer to Note 6 − *Fair Value of Financial Instruments* for the Company's related valuation disclosures. Maximum exposure to losses related to the VIE is limited to its carrying value and the Company does not have any future funding commitments to any VIE.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited Consolidated Financial Statements and Notes to Consolidated Financial Statements in the section titled "Part I. Item 1. Financial Statements (Unaudited)" in this Quarterly Report on Form 10-Q and our audited Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the U.S. Securities and Exchange Commission (the "SEC") on February 29, 2024 (the "Annual Report on Form 10-K"). Certain columns and rows may not add due to the use of rounded numbers. Percentages presented are calculated from the underlying unrounded numbers. In addition to historical information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results, performance, or experience may differ materially from those discussed below due to various important factors, risks, and uncertainties, including, but not limited to, those set forth under the sections titled "Part II, Item 1A. Risk Factors" and "Note Regarding Forward-Looking Statements" included in this Quarterly Report on Form 10-Q or under the section titled "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K, as may be updated by Part II, Item 1A. Risk Factors in our subsequently filed Quarterly Reports on Form 10-Q. Unless the context otherwise requires, the terms "Quanterix," the "Company," "we," "it," "us, "and "our" in this Quarterly Report on Form 10-Q refer to Quanterix Corporation and its consolidated subsidiaries.

Overview

We are a life sciences company that has developed next-generation, ultra-sensitive digital immunoassay platforms that advance life sciences research and diagnostics. Our platforms are based on our proprietary digital "Simoa" detection technology and enable customers to reliably detect protein biomarkers at ultra-low concentrations in blood, serum, and other fluids that, in many cases, are undetectable using conventional, analog immunoassay technologies. The ability of our Simoa platforms to detect proteins in the femtomolar range is enabling the development of novel therapies and diagnostics and has the potential to facilitate a paradigm shift in healthcare from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis, and, ultimately, prevention. Our Simoa platforms have achieved significant scientific validation and commercial adoption, and our Simoa technology has been cited in more than 2,900 scientific publications in areas of high unmet medical need and research interest such as neurology, oncology, cardiology, infectious disease, and inflammation.

Our instruments are designed to be used either with assays fully developed by us, including all antibodies and supplies required to run the assays, or with "homebrew" assay kits where we supply some of the components required for testing and the customer supplies the remaining required elements. Accordingly, our installed instruments generate a recurring revenue stream. As the installed base of our Simoa instruments increases, we expect total consumables revenue to increase.

We commercially launched our HD-X instrument in the second half of 2019. The HD-X is an upgraded version of the Simoa HD-1 (our first Simoa instrument, launched in January 2014), collectively "HD Instruments", that is designed to deliver significant productivity and operational efficiency improvements, as well as greater user flexibility. The HD-X uses our bead-based technology and assays run on the HD-X are fully automated. By March 31, 2024, approximately 83% of the HD Instrument installed base were HD-X instruments.

Further, we launched our SR-X instrument in 2017 as a compact desktop instrument with a lower price point, more flexible assay preparation, and a wider range of applications. The SR-X utilizes the same Simoa bead-based technology and assay kits as the HD-X.

With our acquisition of Aushon BioSystems, Inc. in 2018, we acquired a CLIA certified laboratory and proprietary sensitive planar array detection technology. The Clinical Laboratory Improvement Amendments of 1988 ("CLIA") are federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States (with the exception of research testing that does not report patient specific results). Leveraging our proprietary

sophisticated Simoa image analysis and data analysis algorithms, we further refined the planar array technology to develop the SP-X instrument to provide sensitivity similar to that found in our Simoa bead-based platform. We commercially launched the SP-X instrument in 2019.

Our wholly-owned subsidiary UmanDiagnostics AB ("Uman"), a company located in Umeå, Sweden, supplies neurofilament light ("NfL"), antibodies, and enzyme-linked immunoassay ("ELISA") kits, which are used by researchers and biopharmaceutical and diagnostics companies world-wide in the detection of NfL to advance the development of therapeutics and diagnostics for neurodegenerative conditions.

We also provide contract research services for customers and Laboratory Developed Test ("LDT") services through our CLIA-certified Accelerator Laboratory (the "Accelerator Laboratory"). The Accelerator Laboratory provides customers with access to our Simoa technology and our Lucent Diagnostics clinical testing services (launched in July 2023), and supports multiple projects and services, including sample testing, homebrew assay development, custom assay development, and blood-based biomarker testing. To date, we have completed over 2,300 projects for more than 480 customers from all over the world using our Simoa platforms.

We have an extensive base of customers including pharmaceutical, biotechnology, contract research organizations, academic and governmental research institutions. We sell our instruments, consumables, and services through a direct field sales force and support organizations in North America and Europe, and through our own sales force and distributors in additional countries, including Australia, Brazil, China, Czech Republic, India, Hong Kong, Israel, Japan, New Zealand, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, and the United Arab Emirates. In addition, we sell NfL antibodies and NfL ELISA kits directly, and through distributors, worldwide.

As of March 31, 2024, we had cash, cash equivalents, and marketable securities of $301.9 million. Since our inception, we have incurred annual net losses, including net losses of $10.1 million and $6.1 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $444.6 million and stockholders' equity of $341.4 million.

We expect to incur significant expenses and operating losses at least through the next 24 months and we expect our expenses to increase substantially as we:

- expand our sales and marketing efforts to further commercialize our products;
- expand our research and development efforts to improve our existing products and develop and launch new products, particularly if any of our products become subject to additional or more burdensome regulation by the U.S. Food and Drug Administration (the "FDA");
- invest in Lucent Diagnostics, additional LDTs, and other diagnostics initiatives including entry into translational pharma and clinical diagnostic markets;
- seek Premarket Approval ("PMA"), de novo classification, or 510(k) clearance from the FDA for our existing products or new products if or when we decide to market products for use in the prevention, diagnosis, or treatment of a disease or other condition;
- hire additional personnel to support our growth and research and development;
- strategically acquire and integrate companies or technologies that may be complementary to our business;
- enter into collaboration arrangements, or in-license other products and technologies; and
- add operational, financial, and management information systems.

Recent Business Developments

In March 2024, our Lucent AD p-Tau 217 blood test was granted Breakthrough Device designation by the FDA. This designation is granted to products that have the potential to offer more effective diagnosis of life-threatening diseases with an unmet medical need. Proposed indications for this blood test include use of the test results in patients presenting with cognitive impairment who are being evaluated for Alzheimer's disease risk to aid in diagnostic evaluation. The test is not intended as a stand-alone diagnostic test and test results will be interpreted in conjunction with other diagnostic tools to establish a final clinical diagnosis. This test has not been otherwise cleared or approved by the FDA and Breakthrough Device designation does not guarantee that the FDA review and approval process will be shortened or that an application will be approved. We do not expect material revenue from this test, or other Lucent Diagnostics tests, until late 2024 or later, if at all.

During the fourth quarter of 2023, we substantially completed our six-quarter assay redevelopment program. The objective of this operational program was to improve our ability to manufacture and deliver high-quality assays at scale. We have now launched five new Simoa Advantage PLUS assays, which have been developed using improved protocols, by leveraging manufacturing efficiencies and reagent improvements to provide more consistent results and improved lot-to-lot consistency, and through enabling production of larger lot sizes with extended shelf lives. These assays began shipping to customers in the first quarter of 2024. We expect to continue to apply these improved protocols and manufacturing efficiencies to other existing assays as well as assays that we may develop in the future.

Comparison of Results of Operations for Three Months Ended March 31, 2024 and 2023:

The following table sets forth select Consolidated Statements of Operations data, and such data as a percentage of total revenues (in thousands, except percentages):

	Three Months Ended March 31,				Increase (Decrease)	
	2024	% of revenue	2023	% of revenue	Amount	%
Revenues:						
Product revenue	$ 19,670	61 %	$ 19,287	68 %	$ 383	2 %
Service and other revenue	11,967	37 %	8,579	30 %	3,388	39 %
Collaboration and license revenue	155	— %	368	1 %	(213)	(58)%
Grant revenue	274	1 %	222	1 %	52	23 %
Total revenues	32,066	100 %	28,456	100 %	3,610	13 %
Costs of goods sold and services:						
Cost of product revenue	7,145	22 %	7,033	25 %	112	2 %
Cost of service and other revenue	5,295	17 %	4,497	16 %	798	18 %
Total costs of goods sold and services	12,440	39 %	11,530	41 %	910	8 %
Gross profit	19,626	61 %	16,926	59 %	2,700	16 %
Operating expenses:						
Research and development	6,675	21 %	4,720	17 %	1,955	41 %
Selling, general and administrative	25,993	81 %	20,850	73 %	5,143	25 %
Other lease costs	924	3 %	776	3 %	148	19 %
Total operating expenses	33,592	105 %	26,346	93 %	7,246	28 %
Loss from operations	(13,966)	(44)%	(9,420)	(33)%	4,546	48 %
Interest income	3,948	12 %	3,449	12 %	499	14 %
Other income, net	206	1 %	8	— %	198	2,475 %
Loss before income taxes	(9,812)	(31)%	(5,963)	(21)%	3,849	65 %
Income tax expense	(260)	(1)%	(140)	— %	120	86 %
Net loss	$ (10,072)	(31)%	$ (6,103)	(21)%	$ 3,969	65 %

Revenues

Total revenues increased $3.6 million, or 13%, to $32.1 million for the three months ended March 31, 2024, compared to $28.5 million for the three months ended March 31, 2023.

Product revenue of $19.7 million for the three months ended March 31, 2024 consisted of instrument sales of $2.6 million and sales of consumables and other products of $17.1 million. This represented an increase of $0.4 million, or 2%, compared to product revenue of $19.3 million for the three months ended March 31, 2023. The increase in product revenue was primarily due to a $3.1 million increase in sales of consumables from increases in both customer demand and selling prices. This increase was partially offset by a $2.7 million decrease in instrument sales due to reduced demand in what we believe is a constrained capital funding environment. Based on this, we expect softness in instrument sales to continue for the remainder of 2024.

Service revenue was $12.0 million for the three months ended March 31, 2024, compared to $8.6 million for the three months ended March 31, 2023, an increase of $3.4 million, or 39%. This increase was primarily due to a $3.2 million increase in Accelerator Laboratory revenue driven by higher volumes of sample testing and assay development services. We expect to see continued growth in Accelerator Laboratory services through 2024.

Cost of Goods Sold and Services

Total cost of goods sold and services increased $0.9 million, or 8%, to $12.4 million for the three months ended March 31, 2024, compared to $11.5 million for the three months ended March 31, 2023.

Cost of product revenue increased $0.1 million, or 2%, to $7.1 million for the three months ended March 31, 2024, compared to $7.0 million for the three months ended March 31, 2023. This increase was primarily due to consumables related revenue increases, including compensation and benefit costs from increased headcount, and was partially offset by decreased costs due to lower instrument revenue.

Cost of service and other revenue increased $0.8 million, or 18%, to $5.3 million for the three months ended March 31, 2024, compared to $4.5 million for the three months ended March 31, 2023. This increase was primarily due to the increase in Accelerator Laboratory revenue, including compensation and benefit costs from increased headcount and increased volume of lab supplies used.

Research and Development

Research and development expense increased $2.0 million, or 41%, to $6.7 million for the three months ended March 31, 2024, compared to $4.7 million for the three months ended March 31, 2023. This increase was primarily due to a $1.2 million increase in compensation and benefits costs related to increased headcount, and a $0.4 million increase in professional services and research lab supplies and equipment to enable product development. We expect research and development expense to continue to increase throughout 2024 due to continued investments in product development and new offerings.

Selling, General and Administrative

Selling, general and administrative expense increased $5.1 million, or 25%, to $26.0 million for the three months ended March 31, 2024, compared to $20.9 million for the three months ended March 31, 2023. The primary reason for the increase is additional headcount to expand the size of our sales team. More specifically, the increase was primarily due to (1) a $3.5 million increase in personnel related costs, primarily compensation and benefits related to increased headcount, (2) a $1.1 million increase in stock-based compensation expense due to increased headcount, and (3) a $0.6 million increase in travel related expenses. Included within selling, general, and administrative expense are $2.1 million and $1.8 million of shipping and handling costs for product sales for the three months ended March 31, 2024 and 2023, respectively.

Other Lease Costs

Other lease costs increased $0.1 million, or 19% to $0.9 million for the three months ended March 31, 2024, compared to $0.8 million for the three months ended March 31, 2023. Following our restructuring in 2022, we are not using two leased office and laboratory facilities and are evaluating alternatives, including sub-leasing the facilities. Other lease costs include amortization of the related operating lease right-of-use assets and other leased facility operating expenses from periods after the restructuring and determination that the facilities would not be used.

Interest Income

Interest income increased $0.5 million, or 14%, to $3.9 million for the three months ended March 31, 2024, as compared to $3.4 million for the three months ended March 31, 2023. This increase was primarily due to higher interest rates earned on cash, cash equivalents, and marketable securities, and the accretion of discounts from the purchase of marketable securities.

Other Income, Net

Other income, net was $0.2 million for the three months ended March 31, 2024, as compared to less than $0.1 million for the three months ended March 31, 2023.

Income Tax Expense

Income tax expense was $0.3 million for the three months ended March 31, 2024, as compared to $0.1 million for the three months ended March 31, 2023. The increase was primarily due to estimated foreign income taxes.

Liquidity and Capital Resources

Our principal sources of liquidity are cash, cash equivalents, marketable securities, and funds generated from sales of our products and services. As of March 31, 2024, we had cash and cash equivalents of $45.3 million and $256.6 million of available for sale marketable securities. Historically we have also financed our operations through equity offerings and borrowings from credit facilities.

We believe our cash, cash equivalents, and marketable securities, along with funds generated from sales of our products and services, will be sufficient to meet our anticipated operating cash requirements for at least 12 months from the date of this Quarterly Report on Form 10-Q.

Our liquidity requirements have consisted, and we expect that they will continue to consist, of sales and marketing expenses, research and development expenses, working capital, and general corporate expenses. Our future capital requirements will depend on many factors, including, but not limited to, our pace of growth, expansion and introduction of new products and services, including Lucent Diagnostics, and advancing access to our diagnostic tests, market acceptance of our products and services, regulatory requirements, regulatory approval of our products or services, and the effects of competition, technological developments, and broader market and economic trends.

We regularly assess potential acquisitions and pursue acquisitions of complementary businesses, services, and technologies. To the extent our existing cash, cash equivalents, and marketable securities are insufficient to fund future activities or requirements to continue operating our business, we may need to raise additional capital. If the conditions for raising capital are favorable, we may seek to finance future cash needs through public or private equity, debt offerings, or other financings.

If needed, we cannot guarantee that we will be able to obtain additional funds on acceptable terms, or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt or equity financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise

additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If we do not have or are not able to obtain sufficient funds, if needed, we may have to delay development or commercialization of our products and services. We also may have to reduce marketing, customer support, or other resources devoted to our products, or cease operations.

Cash Flows

The following table summarizes our cash flows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (20,164)	$ (9,502)
Net cash used in investing activities	(109,195)	(136)
Net cash provided by financing activities	599	551
Net decrease in cash, cash equivalents, and restricted cash	$ (128,760)	$ (9,087)

Net Cash Used in Operating Activities

We derive cash flows from operations primarily from the sale of our products and services. Our cash flows from operating activities are also significantly influenced by our use of cash for operating expenses to develop new products and services, invest in process and product improvements, and increase our sales and marketing efforts. We have historically experienced negative cash flows from operating activities as we have developed our technology, expanded our business, and built our infrastructure. We expect negative cash flows from operating activities will continue in the future.

Net cash used in operating activities was $20.2 million and $9.5 million for the three months ended March 31, 2024 and 2023, respectively. The $10.7 million increase in net cash used in operating activities was primarily driven by an overall increase in our net loss, adjusted for non-cash items including stock-based compensation and the accretion of our marketable securities. The increase was further driven by changes in working capital items, primarily (1) an increase in accounts receivable and deferred revenue from sales timing and revenue growth, (2) an increase in inventory as a result of completing the assay development program and manufacturing and stocking new assays, and (3) a decrease in accrued compensation.

Net Cash Used in Investing Activities

Our primary investing activities consist of purchases of marketable securities to increase the interest income we would otherwise earn in cash accounts. Additionally, we use funds towards capital expenditures for the purchase of property and equipment to support our expanding infrastructure and work force. We expect to continue to incur additional capital expenditures related to these efforts in future periods.

Net cash used in investing activities was $109.2 million during the three months ended March 31, 2024, which consisted of the purchase of $137.9 million of marketable securities and $0.5 million of purchases of property and equipment, offset by proceeds from the maturities of marketable securities of $29.2 million.

Net cash used in investing activities was not material during the three months ended March 31, 2023.

Net Cash Provided by Financing Activities

Financing activities provided $0.6 million of cash during both the three months ended March 31, 2024 and 2023, from sales of our common stock under our employee stock purchase plan and from the exercise of options under our equity incentive plan.

Future Cash Obligations

As of March 31, 2024, there have been no material changes to our contractual obligations and commitments from those described in the section titled "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K.

In addition to the cash commitments disclosed in our Annual Report on Form 10-K, we may have other payables and liabilities that may be legally enforceable but are not considered contractual commitments.

Critical Accounting Policies and Estimates

Our critical accounting policies and significant estimates that involve a higher degree of judgment and complexity are described in the section titled "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies, Significant Judgments and Estimates" included in our Annual Report on Form 10-K.

There have been no material changes to our critical accounting policies and estimates as previously disclosed in that report.

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. These non-GAAP measures are calculated by including shipping and handling costs for product sales within cost of product revenue instead of within selling, general and administrative expenses. We use 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. We believe that presentation of these non-GAAP measures provides useful information to investors in assessing our operating performance within our industry and 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. 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 (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
GAAP gross profit	$ 19,626	$ 16,926
Shipping and handling costs	(2,142)	(1,829)
Non-GAAP gross profit	$ 17,484	$ 15,097
GAAP revenue	$ 32,066	$ 28,456
GAAP gross margin (gross profit as % of revenue)	61.2%	59.5%
Non-GAAP gross margin (non-GAAP gross profit as % of revenue)	54.5%	53.1%
GAAP total operating expenses	$ 33,592	$ 26,346
Shipping and handling costs	(2,142)	(1,829)
Non-GAAP total operating expenses	$ 31,450	$ 24,517
GAAP loss from operations	$ (13,966)	$ (9,420)
Non-GAAP loss from operations	$ (13,966)	$ (9,420)

Recent Accounting Pronouncements

Refer to Note 2 − *Significant Accounting Policies* in the Notes to Consolidated Financial Statements included in this Quarterly Report on Form 10-Q for a full description of recent accounting pronouncements, including the expected dates of adoption and effects on our Consolidated Financial Statements and related disclosures.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of March 31, 2024, there have been no material changes to the market risk information from those described in the section titled "Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk" included in our Annual Report on Form 10-K.

ITEM 4. CONTROLS AND PROCEDURES

As previously disclosed in the section titled "Part II, Item 9A. Controls and Procedures" in our Annual Report on Form 10-K, management concluded that our internal control over financial reporting was not effective at a reasonable assurance level as of December 31, 2023 due to deficiencies in the operating effectiveness of our internal controls associated with the valuation of our inventory, including excess and obsolescence reserves (the "Inventory Valuation MW"), and the accounting for property and equipment, net (the "Property and Equipment MW"). These deficiencies constituted material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Through the date of this Quarterly Report on Form 10-Q, we have not identified any material misstatements as a result of these material weaknesses.

Management has been actively engaged in the implementation of remediation efforts to address the material weaknesses, as well as other identified areas of risk. For a complete description of management's remediation plan, refer to the section titled "Part II, Item 9A. Controls and Procedures" in our Annual Report on Form 10-K, as may be updated in the section titled "Part I. Item 4. Controls and Procedures" of our subsequently filed Quarterly Reports on Form 10-Q. For updates on management's remediation plan as of March 31, 2024, refer to the section titled "Management's Implementation of Remediation Plan" below.

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to ensure that such information is accumulated and communicated to management, including our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), to allow timely decisions regarding required disclosures. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide a reasonable assurance of achieving their objectives. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of March 31, 2024. Because our efforts to remediate the material weaknesses in our internal control over financial reporting are still underway and we have not had a sufficient period of time to test the operating effectiveness of our internal control over financial reporting, which we view as an integral part of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of March 31, 2024.

Nevertheless, based on a number of factors, including the performance of additional procedures by management designed to ensure the reliability of our financial reporting, we believe that the Consolidated Financial Statements and Notes to Consolidated Financial Statements in this Quarterly Report on Form 10-Q fairly present, in all material

respects, our financial position, results of operations, and cash flows as of the dates, and for the periods, presented, in conformity with U.S. GAAP.

Management's Implementation of Remediation Plan

Management, with oversight from the Audit Committee of our Board of Directors, previously commenced implementing changes to our internal control over financial reporting in order to remediate the control deficiencies that resulted in the Inventory Valuation MW and Property and Equipment MW disclosed in our Annual Report on Form 10-K. As of March 31, 2024, we believe that we are on track with the remediation plan disclosed therein. Our ongoing efforts for remediation include, but are not limited to, the following:

- we have engaged accounting advisory consultants to implement new software systems to automate manual key inventory valuation processes and outputs;
- we continue to strengthen and document our existing controls and, starting in the first quarter of 2024, have implemented additional compensating controls and will continue to do so throughout the remainder of fiscal year 2024;
- we continue to execute controls that we worked to improve during fiscal year 2023 that did not have a sufficient period of time to demonstrate operating effectiveness as of December 31, 2023;
- we continue to evaluate, enhance, and add personnel in the finance organization with a focus on the requisite experience in the areas of accounting, SEC financial reporting, and associated internal controls. Additionally, for key additions or vacancies on our team, we have engaged accounting consultants to provide additional depth and breadth in our period end closes, financial reporting capabilities, and internal controls compliance until we have filled the positions with qualitied personnel for a sufficient period of overlap to ensure successful transition of responsibilities;
- we have engaged a third-party consulting firm to perform an assessment of our remediation plan and provide recommendations to enhance the effectiveness of the related controls; and
- we continue to provide trainings on a regular basis related to internal control over financial reporting for all control owners.

We will continue our efforts to remediate, and test the remediation of, the Inventory Valuation MW and Property and Equipment MW through fiscal year 2024. We believe that the implementation of the above steps will allow us to address the deficient controls within our internal control environment, which will facilitate the remediation of these material weaknesses. As we continue to evaluate and work to improve our internal control over financial reporting, we will take additional measures to address control deficiencies and we may modify certain of the remediation measures described above. Given that many of the remediation efforts described above are in the process of being implemented and our controls continue to undergo independent testing, we will not be able to consider the material weaknesses as described in our Annual Report on Form 10-K remediated until the applicable remedial controls operate for a sufficient period of time and our management has concluded, through testing, that our controls are operating effectively. We, along with our Audit Committee, will continue to monitor and evaluate the effectiveness of these remedial actions and take further actions as we deem appropriate.

Changes in Internal Control over Financial Reporting

Other than the changes outlined above to remediate the material weaknesses, there have been no changes in our internal control over financial reporting during the quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings and threats of litigation consisting of intellectual property, contractual, employment, and other matters. While the outcome of any such actions or proceedings cannot be predicted with certainty, as of March 31, 2024, we were not party to any legal proceedings, the outcome of which would be expected to have a material adverse effect on our financial condition or results of operations. Regardless of any outcome, litigation can have a material adverse effect on us due to defense and settlement costs, diversion of management resources, and other factors.

ITEM 1A. RISK FACTORS

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition, results of operations, or the price of our common stock. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risk factors described in the section titled "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 29, 2024 (the "Annual Report on Form 10-K"). Those risk factors are not the only risks we face. Additional risks and uncertainties not currently known to us or that we deem to be not material also may adversely affect our business, financial condition, and results of operations.

As of the date of this Quarterly Report on Form 10-Q, there were no material changes to the risk factors described in our Annual Report on Form 10-K, except that the risk factors entitled "*If the FDA determines that our products are subject to regulation as medical devices, if the FDA modifies its regulations to require that our LDTs are subject to regulation as devices, or if we seek to market our products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance(s) or approval(s). Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome.*" and "*U.S. legislative, FDA or global regulatory reforms may make it more difficult and costly for us to obtain any required regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.*" are replaced as follows:

> ***If the FDA determines that our products are subject to regulation as medical devices or if we seek to market our products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance(s) or approval(s). Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome.***

We focused initially on the life sciences research market. This includes offering products for use by laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Accordingly, the majority of our products are labeled as "Research Use Only". While we focused initially on the life sciences research market and RUO products only, our strategy includes expanding our product line to encompass products that are intended to be used for the diagnosis of disease, including LDTs and IVD devices, either alone or in collaboration with third parties. IVD products and LDTs are subject to regulation by the FDA, or comparable international agencies, as medical devices, including requirements for regulatory clearance or approval of such products before they can be marketed.

The process of obtaining regulatory clearances to market a medical device can be costly and time consuming, and we or our collaborators may not be able to obtain these clearances or approvals on a timely basis, if at all. In general, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FDCA"), de novo classification, or is the subject of an approved Premarket Approval ("PMA"), unless the device is specifically exempt from those requirements. The FDA will clear marketing of a moderate risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to a legally marketed predicate device, which can include pre-amendment, 510(k)-exempt, 510(k) cleared products, or PMA-approved products that have subsequently been down-classified. If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is novel, it is automatically classified into Class III, and the device sponsor must then fulfill the much more rigorous premarketing

requirements of the PMA approval process, or seek classification of the device through the de novo classification process. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. Even where our products are labeled for research use only, the FDA may consider a product to be intended for clinical diagnostic use and subject to medical device regulation by the FDA as described above.

If any of our products are subject to medical device regulation, we would be subject to a substantial number of additional requirements for medical devices, including establishment registration, device listing, quality system requirements ("QSRs") —which cover the design, testing, production, control, quality assurance, labeling, packaging, servicing, sterilization (if required), and storage and shipping of medical devices (among other activities) —product labeling, advertising, recordkeeping, post-market surveillance, post-approval studies, adverse event reporting, and correction and removal (recall) regulations. One or more of the products we may develop using our technology may also require clinical trials in order to generate the data required for a PMA, de novo classification request or 510(k) premarket notification. Complying with these requirements may be time-consuming and expensive. We may be required to expend significant resources to ensure ongoing compliance with the FDA regulations. Failure to comply with these requirements may subject us to a range of enforcement actions, such as warning letters, injunctions, civil monetary penalties, criminal prosecution, recall and/or seizure of products, and revocation of marketing authorization, as well as significant adverse publicity. If we fail to obtain, or experience significant delays in obtaining, regulatory approvals for IVD products, such products may not be able to be launched or successfully commercialized in a timely manner, or at all.

LDTs are a subset of IVD tests that are offered as services by CLIA-certified high complexity clinical laboratories and designed, manufactured and used within a single laboratory. In 2022 and 2023, we launched three LDTs to quantitatively measure p-Tau 181 and p-Tau 217 in plasma as an aid in diagnostic evaluation of Alzheimer's disease and NfL in serum as an aid in the evaluation of individuals for possible neurodegenerative conditions or other causes of neuronal or central nervous system damage. The FDA maintains that LDTs are medical devices but has, for the most part, historically exercised enforcement discretion for most LDTs, meaning that the FDA has not historically required LDTs to obtain premarket approval or clearance or comply with post-market medical device requirements. However, the FDA significantly changed its approach to LDTs and on April 29, 2024, issued a final rule regarding LDTs that makes explicit that IVD products are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer is a laboratory. The rule describes a policy under which the FDA will provide greater oversight of LDTs, including by phasing out its general enforcement discretion approach and phasing in medical device regulation for LDTs over a period of four years. The FDA has indicated that it intends to continue to exercise enforcement discretion for several categories of tests, including exercising enforcement discretion with regard to premarket review and most QSRs with respect to LDTs that were first marketed before the issuance of the final rule, provided that such LDTs are not modified or are only subject to limited modification. This new regulatory approach for LDTs by the FDA will lead to an increased regulatory burden on us, including additional costs and delays in introducing new tests. The FDA's new rule could also impact our business more broadly, given that some of our current and/or future customers and collaboration partners will be subject to additional regulation and delays, which could potentially affect the development of new diagnostics that incorporate our instruments or consumables. This also may increase costs and regulatory burdens on laboratories that develop LDTs, thereby reducing the financial incentive for laboratories to develop new LDTs or invest in instruments, which could reduce demand for our instruments and our other products.

Foreign jurisdictions have laws and regulations similar to those described above, which may adversely affect our ability to market our products as planned in such countries. The number and scope of these requirements are increasing. As in the United States, the cost and time required to comply with regulatory requirements may be substantial, and there is no guarantee that we will obtain the necessary authorization(s) required to make our products commercially viable. In addition, the imposition of foreign requirements may also have a material adverse effect on the commercial viability of our operations.

U.S. legislative, FDA or global regulatory reforms may make it more difficult and costly for us to obtain any required regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. For example, in December 2022, Congress enacted the Food and Drug Omnibus Reform Act of 2022 ("FDORA"). FDORA reauthorized the FDA to collect device user fees and contained substantive amendments to the device provisions of the FDCA, including imposing new cybersecurity and clinical trial requirements for devices. Congress has also considered, but not yet passed, legislation to impose a new FDA regulatory framework for all diagnostics, including IVD devices and LDTs. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. For example, on April 29, 2024, the FDA issued a final rule regarding LDTs that makes explicit that in vitro diagnostic products that are devices under the Federal Food, Drug, and Cosmetic Act include when the manufacturer of the IVD is a laboratory. The rule describes a policy under which the FDA will provide greater oversight of LDTs, including by phasing out its general enforcement discretion approach and phasing in medical device regulation for LDTs over a period of four years. This new rule will lead to an increased regulatory burden on us, including additional costs and delays in introducing new tests. Any other changes in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

In addition, in the E.U. new regulations recently entered into force that result in greater regulation of medical devices and IVDs. The IVD Regulation is significantly different from the IVD Directive that it replaces in that it ensures that the new requirements apply uniformly and on the same schedule across the member states, includes a risk-based classification system and increases the requirements for conformity assessment. The CE registration for Uman's NfL ELISA assay kit for cerebral spinal fluid was approved in March 2014 under the IVD Directive. Under the IVD Directive, the assay is classified as a general IVD product, and required self-certification with no involvement of a notified body/authority. The IVD Regulation introduces a new classification system for IVDs and assessment by a notified body is required for class B, C and D products. Uman's NfL ELISA assay kit for CSF is classified as a class B product and must fully comply with (and have a CE mark issued under) the IVD Regulation by May 2027 (subject to proposed extension of the transitional periods in the IVD Regulation). The new requirements include an ISO 13485 certification of the quality system (which Uman received in July 2018) and increased technical evidence and follow-up of performance of the specific product (e.g., clinical evidence and post-market activities). The work to evaluate and to meet the new technical requirements is on-going.

Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the European Economic Area ("EEA") countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our notified body, which could impair our ability to market products in the EEA in the future.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Securities Trading Plans of Directors and Executive Officers

On March 13, 2024, The Martin D. Madaus GST Exempt 2012 Irrevocable Trust, of which Martin Madaus, a member of our Board of Directors, is a trust advisor who shares voting and investment power over the shares held by the trust, adopted a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Securities Exchange Act of 1934. The Rule 10b5-1 trading plan provides for the potential sale of up to 82,500 shares of our common stock beginning on June 17, 2024. The plan will terminate at the earlier of the execution of all trading orders under the plan or December 27, 2024.

During the three months ended March 31, 2024, none of our other directors or officers adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K).

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
3.1	Amended and Restated Certificate of Incorporation.		8-K	12/15/2017	001-38319
3.2	Restated Bylaws.		10-Q	8/8/2023	001-38319
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certifications of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X			
101.SCH	XBRL Taxonomy Extension Schema Document.	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	XBRL Taxonomy Extension Definition.	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	X			

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

Dated: May 8, 2024

By: /s/ Masoud Toloue
Masoud Toloue
President and Chief Executive Officer
(principal executive officer)

Dated: May 8, 2024

By: /s/ Vandana Sriram
Vandana Sriram
Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Masoud Toloue, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Quanterix Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2024

/s/ Masoud Toloue
Masoud Toloue
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Vandana Sriram, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Quanterix Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2024

/s/ Vandana Sriram
Vandana Sriram
Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Quanterix Corporation, a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the period ended March 31, 2024 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2024

/s/ Masoud Toloue
Masoud Toloue
President and Chief Executive Officer

Dated: May 8, 2024

/s/ Vandana Sriram
Vandana Sriram
Chief Financial Officer