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 September 30, 2022

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

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

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 November 1, 2022, the registrant had 37,054,705 shares of common stock, $0.001 par value per share, outstanding.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements 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, you can identify forward-looking statements 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 about our financial performance, including anticipated benefits and costs associated with our plan of restructuring announced in August 2022, and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A , “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 or other filings that we make with the Securities and Exchange Commission, or 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 our management 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.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events or circumstances reflected in the forward-looking statements will be achieved or occur. You should read this Quarterly Report on Form 10-Q, and the documents that we reference herein and have filed with the SEC, with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect. 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.

Unless the context otherwise requires, the terms “Quanterix,” the “Company,” “we,” “us” and “our” in this Quarterly Report on Form 10-Q refer to Quanterix Corporation and its subsidiaries. “Quanterix,” “Simoa,” “Simoa HD-X,” “Simoa HD-1,” “SR-X,” “SP-X,” “HD-X Analyzer,” “HD-1 Analyzer” 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
Condensed Consolidated Balance Sheets
(amounts in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 343,743	$ 396,465
Accounts receivable (less allowance for credit losses of $521 and $419 as of September 30, 2022 and December 31, 2021, respectively)	18,330	23,786
Inventory	18,236	22,190
Prepaid expenses and other current assets	6,475	6,514
Total current assets	386,784	448,955
Restricted cash	2,596	2,577
Property and equipment, net	21,441	17,960
Intangible assets, net	7,511	10,534
Goodwill	—	9,632
Right-of-use assets	27,165	11,491
Other non-current assets	1,200	378
Total assets	$ 446,697	$ 501,527
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,106	$ 9,209
Accrued compensation and benefits	10,503	13,252
Other accrued expenses	5,951	6,486
Deferred revenue	8,976	6,361
Short-term lease liabilities	767	1,428
Other current liabilities	268	241
Total current liabilities	28,571	36,977
Deferred revenue, net of current portion	1,591	1,099
Long-term lease liabilities	42,196	20,464
Other non-current liabilities	1,570	2,035
Total liabilities	73,928	60,575
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.001 par value:		
Authorized shares: 120,000,000 at September 30, 2022 and December 31, 2021, respectively; Issued and outstanding: 37,093,601 shares and 36,768,035 shares at September 30, 2022 and December 31, 2021, respectively	37	37
Additional paid-in capital	759,312	745,936
Accumulated other comprehensive (loss) income	(2,999)	441
Accumulated deficit	(383,581)	(305,462)
Total stockholders' equity	372,769	440,952
Total liabilities and stockholders' equity	$ 446,697	$ 501,527

See accompanying notes

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue	$ 17,693	$ 20,662	$ 53,134	$ 57,586
Service and other revenue	8,370	5,898	25,728	17,955
Collaboration revenue	301	120	479	486
Grant revenue	282	1,009	357	4,242
Total revenue	26,646	27,689	79,698	80,269
Costs of goods sold:				
Cost of product revenue	10,511	8,639	31,178	24,233
Cost of service and other revenue	5,191	3,806	14,306	10,569
Total costs of goods sold and services	15,702	12,445	45,484	34,802
Gross profit	10,944	15,244	34,214	45,467
Operating expenses:				
Research and development	6,631	6,807	20,290	20,244
Selling, general and administrative	19,966	23,670	72,723	63,913
Other lease costs	609	—	609	—
Restructuring	3,426	—	3,426	—
Goodwill impairment	8,220	—	8,220	—
Impairment expense	8,695	—	8,695	—
Total operating expenses	47,547	30,477	113,963	84,157
Loss from operations	(36,603)	(15,233)	(79,749)	(38,690)
Interest income (expense), net	1,712	(90)	2,316	(418)
Other (expense) income, net	(101)	(305)	(676)	1,478
Loss before income taxes	(34,992)	(15,628)	(78,109)	(37,630)
Income tax provision	72	33	10	32
Net loss	$ (35,064)	$ (15,661)	$ (78,119)	$ (37,662)
Net loss per share, basic and diluted	$ (0.95)	$ (0.43)	$ (2.12)	$ (1.05)
Weighted-average common shares outstanding, basic and diluted	37,004,596	36,518,177	36,926,549	35,774,455

See accompanying notes

Quanterix Corporation
Condensed Consolidated Statements of Comprehensive Loss
(amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Net loss	$ (35,064)	$ (15,661)	$ (78,119)	$ (37,662)
Other comprehensive loss:				
Foreign currency translation adjustment	(796)	(527)	(3,440)	(1,383)
Total other comprehensive loss	(796)	(527)	(3,440)	(1,383)
Comprehensive loss	$ (35,860)	$ (16,188)	$ (81,559)	$ (39,045)

See accompanying notes

Quanterix Corporation
Condensed Consolidated Statements of Cash Flows
(amounts in thousands)

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Operating activities		
Net loss	$ (78,119)	$ (37,662)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	4,186	3,566
Credit loss expense on accounts receivable	102	286
Inventory step-up amortization	—	275
Non-cash operating lease expense	1,099	364
Stock-based compensation expense	11,779	11,044
Goodwill impairment	8,220	—
Impairment expense	8,695	—
Other non-cash items	39	65
Changes in operating assets and liabilities:		
Accounts receivable	5,045	(1,556)
Inventory	3,919	(8,431)
Prepaid expenses and other assets	(262)	(1,395)
Other non-current assets	(859)	(3)
Accounts payable	(7,085)	(972)
Accrued compensation and benefits, other accrued expenses and other current liabilities	(3,021)	(2,860)
Deferred revenue	3,108	674
Operating lease liabilities	(1,156)	(902)
Other non-current liabilities	128	(108)
Net cash used in operating activities	(44,182)	(37,615)
Investing activities		
Purchases of property and equipment	(10,131)	(11,163)
Proceeds from RADx grant on assets purchased	520	7,019
Net cash used in investing activities	(9,611)	(4,144)
Financing activities		
Proceeds from stock options exercised	716	6,607
Sale of common stock in underwritten public offering, net	—	269,718
Proceeds from ESPP purchase	881	1,065
Payments on notes payable	—	(5,744)
Net cash provided by financing activities	1,597	271,646
Net (decrease) increase in cash, cash equivalents and restricted cash	(52,196)	229,887
Effect of foreign currency exchange rate on cash	(507)	(66)
Cash, cash equivalents and restricted stock at beginning of period	399,042	182,584
Cash, cash equivalents and restricted stock at end of period	$ 346,339	$ 412,405
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 263	$ 320
Noncash transactions:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 198	$ 306
Right-of-use asset obtained in exchange for lease liabilities	$ 22,239	$ —
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 343,743	$ 410,747
Restricted cash	2,596	1,658
Total cash, cash equivalents, and restricted cash	$ 346,339	$ 412,405

See accompanying notes

Quanterix Corporation
Condensed Consolidated Statements of Stockholders' Equity
(amounts in thousands, except share data)

	Three Months Ended September 30,					
	Common stock					
	Shares	Value	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balance at June 30, 2022	36,974,827	$ 37	$ 756,139	$ (2,203)	$ (348,517)	$ 405,456
Issuance of capital shares:						
−Exercised stock options	33,450	—	120	—	—	120
−Restricted units converted	45,519	—	—	—	—	—
−ESPP stock purchase	37,036	—	287	—	—	287
−Issuance of common stock	2,769	—	—	—	—	—
Stock-based compensation expense	—	—	2,766	—	—	2,766
Cumulative translation adjustment	—	—	—	(796)	—	(796)
Net loss	—	—	—	—	(35,064)	(35,064)
Balance at September 30, 2022	37,093,601	$ 37	$ 759,312	$ (2,999)	$ (383,581)	$ 372,769
Balance at June 30, 2021	36,454,369	$ 37	$ 734,170	$ 1,578	$ (269,775)	$ 466,010
Issuance of capital shares:						
−Exercised stock options	63,097	—	1,138	—	—	1,138
−Restricted units converted	43,902	—	—	—	—	—
−ESPP stock purchase	11,812	—	546	—	—	546
−Issuance of common stock	952	—	—	—	—	—
Stock-based compensation expense	—	—	4,008	—	—	4,008
Cumulative translation adjustment	—	—	—	(527)	—	(527)
Net loss	—	—	—	—	(15,661)	(15,661)
Balance at September 30, 2021	36,574,132	$ 37	$ 739,862	$ 1,051	$ (285,436)	$ 455,514

	Nine Months Ended September 30,					
	Common stock					
	Shares	Value	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2021	36,768,035	$ 37	$ 745,936	$ 441	$ (305,462)	$ 440,952
Issuance of capital shares:						
−Exercised stock options	117,986	—	716	—	—	716
−Restricted units converted	144,553	—	—	—	—	—
−ESPP stock purchase	57,485	—	881	—	—	881
−Issuance of common stock	5,542	—	—	—	—	—
Stock-based compensation expense	—	—	11,779	—	—	11,779
Cumulative translation adjustment	—	—	—	(3,440)	—	(3,440)
Net loss	—	—	—	—	(78,119)	(78,119)
Balance at September 30, 2022	37,093,601	$ 37	$ 759,312	$ (2,999)	$ (383,581)	$ 372,769
Balance at December 31, 2020	31,796,544	$ 32	$ 451,433	$ 2,434	$ (247,774)	$ 206,125
Issuance of capital shares:						
−Exercised warrants	7,347	—	—	—	—	—
−Exercised stock options	455,476	1	6,606	—	—	6,607
−Restricted units converted	175,526	—	—	—	—	—
−ESPP stock purchase	29,037	—	1,065	—	—	1,065
−Issuance of common stock	3,060	—	—	—	—	—
Sale of common stock in underwritten public offering, net	4,107,142	4	269,714	—	—	269,718
Stock-based compensation expense	—	—	11,044	—	—	11,044
Cumulative translation adjustment	—	—	—	(1,383)	—	(1,383)
Net loss	—	—	—	—	(37,662)	(37,662)
Balance at September 30, 2021	36,574,132	$ 37	$ 739,862	$ 1,051	$ (285,436)	$ 455,514

See accompanying notes

Quanterix Corporation
Notes to condensed consolidated financial statements

1. Organization and operations

Quanterix Corporation (Nasdaq: QTRX) (the Company) is a life sciences company that has developed next generation, ultra-sensitive digital immunoassay platforms that advance precision health for life sciences research and diagnostics. The Company's platforms are based on its proprietary digital “Simoa” detection technology. The Company's Simoa bead-based and planar array platforms enable customers to reliably detect protein biomarkers in extremely low concentrations in blood, serum and other fluids that, in many cases, are undetectable using conventional, analog immunoassay technologies, and also allow researchers to define and validate the function of novel protein biomarkers that are only present in very low concentrations. These capabilities provide the Company's customers with insight into the role of protein biomarkers in human health that has not been possible with other existing technologies and enable researchers to unlock unique insights into the continuum between health and disease. The Company is currently focusing on protein detection, which it believes is an area of significant unmet need and where it has significant competitive advantages. In addition to enabling new applications and insights in protein analysis, the Company’s Simoa platforms have also demonstrated applicability across other testing applications, including detection of nucleic acids and small molecules.

The Company launched its first immunoassay platform, the Simoa HD-1 (HD-1), in 2014. The HD-1 is a fully automated immunoassay bead-based platform with multiplexing and custom assay capability, and related assay test kits and consumable materials. In the fourth quarter of 2017, the Company launched a second bead-based immunoassay platform (SR-X) with a more compact footprint than the HD-1 and less automation designed for lower volume requirements while still allowing multiplexing and custom assay capability. The Company initiated an early-access program for its third instrument (SP-X) on the new Simoa planar array platform in January 2019, with the full commercial launch commencing in April 2019. In July 2019, the Company launched the Simoa HD-X, an upgraded version of the HD-1 and phased out the HD-1. The HD-X has been designed to deliver significant productivity and operational efficiency improvements, as well as greater user flexibility. The Company began shipping and installing HD-X instruments at customer locations in the third quarter of 2019. The Company also performs research services on behalf of customers to apply the Simoa technology to specific customer needs. The Company's customers are primarily in the research use only market, which includes academic and governmental research institutions, the research and development laboratories of pharmaceutical manufacturers, contract research organizations, and specialty research laboratories.

Basis of presentation

The interim condensed consolidated financial statements are unaudited. The unaudited condensed consolidated financial statements reflect, in the opinion of the Company’s management, all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of financial position, results of operations, comprehensive loss and cash flows for each period presented and have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, certain information and disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 1, 2022.

Reclassifications

Certain amounts in the prior years’ consolidated financial statements have been reclassified to conform to the current year’s presentation.

2. Significant accounting policies

The significant accounting policies and estimates used in the preparation of the accompanying consolidated financial statements are described in the Company's audited consolidated financial statements for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K filed with the SEC on March 1, 2022. Except as noted below, there have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2022.

Goodwill

Goodwill represents the excess of the cost of acquired businesses over the fair value of identifiable net assets assumed in a business combination. Goodwill is assessed for impairment at least annually, on a reporting unit basis, or more frequently when events and circumstances occur indicating that the recorded goodwill may be impaired. Reporting units are one level below the business segment level but can be combined when reporting units within the same segment have similar economic characteristics. The Company operates within a single operating segment with one reporting unit. The process of evaluating the potential impairment of goodwill is subjective and requires significant judgment at many points during the analysis. If the book value of a reporting unit exceeds its fair value, the implied fair value of goodwill is compared with the carrying amount of goodwill. If the carrying amount of goodwill exceeds the implied fair value, an impairment loss is recorded in an amount equal to that excess. See Note 9 regarding assessment of the Company's goodwill in the three months ended September 30, 2022.

Long-lived assets

The Company accounts for long-lived assets including property and equipment and long-lived amortizable intangible assets in accordance with ASC Topic No. 360, *Property, Plant and Equipment,* (ASC 360). ASC 360 requires companies to assess whether indicators of impairment are present on a periodic basis. If such indicators are present, ASC 360 prescribes a two-step impairment test: (i) if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows, then (ii) the impairment loss is measured as the difference between the carrying amount and the fair value of the asset based on the forecasted discounted cash flows of the asset. See Note 12 for details regarding an impairment assessment of the Company's long-lived assets, including right-of-use-assets, in the three months ended September 30, 2022.

Restructuring

The Company records charges associated with approved restructuring plans to reorganize operations, to improve the efficiency of business processes, or to remove redundant headcount. Restructuring charges can include severance costs to eliminate a specific number of employees, associated legal fees and contract cancellation costs. The Company records restructuring charges when they are probable and estimable. The Company accrues for severance and other employee separation costs under these plans when employees accept the separation offers, and the amounts can be reasonably estimated. The Company implemented a restructuring plan (as defined herein) during the three months ended September 30, 2022 details of which are discussed in Note 17.

Other lease costs

As part of the Restructuring Plan, the Company is not utilizing the office and laboratory space leased in Bedford, Massachusetts, and is evaluating alternatives uses for the facilities, including terminating the lease or sub-leasing the facilities. Other lease costs on the consolidated statements of operations includes lease expenses and other facilities costs associated with these facilities for the periods after the determination the facilities would not be utilized.

3. Revenue recognition

The Company recognizes revenue when a customer obtains control of a promised good or service. The amount of revenue recognized reflects consideration that the Company expects to be entitled to receive in exchange for these goods and services, incentives and taxes collected from customers that are subsequently remitted to governmental authorities.

Customers

The Company's customers primarily consist of entities engaged in the life sciences research market that pursue the discovery and development of new drugs for a variety of neurologic, cardiovascular, oncologic and other protein biomarkers associated with diseases. The Company's customer base includes several of the largest biopharmaceutical companies, academic research organizations and distributors who serve certain geographic markets.

Product revenue

The Company's products are composed of analyzer instruments, assay kits and other consumables such as reagents. Products are sold directly to biopharmaceutical and academic research organizations or are sold through distributors in EMEA and Asia Pacific regions. The sales of instruments are generally accompanied by an initial year of implied service-type warranties and may be bundled with assays and other consumables and may also include other items such as training and installation of the instrument and/or an extended service warranty. Revenues from the sale of products are recognized at a point in time when the Company transfers control of the product to the customer, which is generally upon installation for instruments sold to direct customers, and based upon shipping terms for assay kits and other consumables. Revenue for instruments sold to distributors is generally recognized based upon shipping terms (either upon shipment or delivery).

Service and other revenue

Service revenues are composed of contract research services, initial implied one-year service-type warranties, extended services contracts and other services such as training. Contract research services are provided through the Company's Accelerator Laboratory and generally consist of fixed fee contracts. Revenues from contract research services are recognized at a point in time when the Company completes and delivers its research report on each individually completed study, or over time if the contractual provisions allow for the collection of transaction consideration for costs incurred plus a reasonable margin through the period of performance of the services. Revenues from service-type warranties are recognized ratably over the contract service period. For contract research services recognized over time, the Company uses the output method to measure the progress toward the complete satisfaction of the performance obligations. Revenues from other services are immaterial.

During the first quarter of 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. In connection with the Lilly Collaboration Agreement, the Company received a non-refundable up-front payment of $5.0 million during the first quarter of 2022, and under the Statement of Work receives $1.5 million per calendar quarter during 2022, beginning with the first quarter of 2022. The revenue will be recognized over a one-year period.

Concurrent with the execution of the Lilly Collaboration Agreement, the Company entered into a Technology License Agreement (the Lilly License) under which Lilly granted to the Company a non-exclusive license to Lilly's proprietary P-tau217 antibody technology for potential near-term use in research use only products and services and future *in vitro* diagnostics applications within the field of Alzheimer's disease. In consideration of the 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 a royalty on net sales of licensed products.

The Company concluded that the Lilly Collaboration Agreement (including the Statement of Work) and the Lilly License represented a single contract with a customer and is accounting for the agreements as service revenue recognized over time as the services are delivered. The transaction price for the Lilly Collaboration Agreement is $10.9 million. Contingent amounts due to Lilly represent variable consideration payable to a customer and will be recognized as reductions to service revenue up to the amount of the transaction price recognized, when probable. The Company is utilizing an input method to measure the delivery of services by calculating costs incurred at each period end relative to total costs expected to be incurred.

During the three and nine months ended September 30, 2022, the Company recognized approximately $2.7 million and $8.1 million, respectively, of revenue from the Lilly Collaboration Agreement.

Collaboration and license revenue

The Company may enter into agreements to license the intellectual property and know-how associated with its instruments and certain antibodies in exchange for license fees and future royalties (as described below). The license agreements provide the licensee with a right to use the intellectual property with the license fee revenues recognized at a point in time as the underlying license is considered functional intellectual property.

Payment terms

The Company's payment terms vary by the type and location of the customer and the products or services offered. Payment from customers is generally required in a term ranging from 30 to 45 days from date of shipment or satisfaction of the performance obligation. The Company does not provide financing arrangements to its customers.

Disaggregated revenue

When disaggregating revenue, the Company considered all of the economic factors that may affect its revenues. The following tables disaggregate the Company's revenue from contracts with customers by revenue type (in thousands):

	Three Months Ended September 30, 2022				Three Months Ended September 30, 2021			
	North America	EMEA	Asia Pacific	Total	North America	EMEA	Asia Pacific	Total
Product revenues								
Instruments	$ 2,964	3,115	1,684	$ 7,763	$ 3,492	$ 1,644	$ 1,338	$ 6,474
Consumable and other products	6,262	2,840	828	9,930	8,915	4,483	790	14,188
Total	$ 9,226	5,955	2,512	$ 17,693	$ 12,407	$ 6,127	$ 2,128	$ 20,662
Service and other revenues								
Service-type warranties	$ 1,454	$ 703	$ 125	$ 2,282	$ 1,112	$ 556	$ 66	$ 1,734
Research services	5,246	305	44	5,595	2,998	604	50	3,652
Other services	315	142	36	493	465	47	—	512
Total	$ 7,015	$ 1,150	$ 205	$ 8,370	$ 4,575	$ 1,207	$ 116	$ 5,898
Collaboration and license revenue								
Collaboration and license revenue	$ 136	$ 165	$ —	$ 301	$ 73	$ 47	$ —	$ 120

	Nine Months Ended September 30, 2022				Nine Months Ended September 30, 2021			
	North America	EMEA	Asia Pacific	Total	North America	EMEA	Asia Pacific	Total
Product revenues								
Instruments	$ 7,602	$ 7,288	$ 4,699	$ 19,589	$ 9,370	$ 6,107	$ 3,796	$ 19,273
Consumable and other products	19,814	10,854	2,877	33,545	24,638	11,227	2,448	38,313
Total	$ 27,416	$ 18,142	$ 7,576	$ 53,134	$ 34,008	$ 17,334	$ 6,244	$ 57,586
Service and other revenues								
Service-type warranties	$ 4,057	$ 2,050	$ 341	$ 6,448	$ 3,181	$ 1,452	$ 179	$ 4,812
Research services	16,853	752	65	17,670	9,285	2,095	89	11,469
Other services	916	590	104	1,610	1,271	403	—	1,674
Total	$ 21,826	$ 3,392	$ 510	$ 25,728	$ 13,737	$ 3,950	$ 268	$ 17,955
Collaboration and license revenue								
Collaboration and license revenue	$ 179	$ 248	$ 52	$ 479	$ 301	$ 185	$ —	$ 486

For the three and nine months ended September 30, 2022, two customers accounted for 14.1% and 11.1%, respectively, of the Company's total revenue. At September 30, 2022, two customers individually accounted for 13.4% and 10.1%, respectively, of the Company's gross accounts receivable.

The Company's contracts with customers may include promises to transfer multiple products and services to a customer. The Company combines any performance obligations that are immaterial with one or more other performance obligations that are material to the contract. For arrangements with multiple performance obligations, the Company allocates the contract transaction price, including discounts, to each performance obligation based on its relative standalone selling price. Judgment is required to determine the standalone selling price for each distinct performance obligation. The Company determines standalone selling prices based on prices charged to customers in observable transactions and uses a range of amounts to estimate standalone selling prices for each performance obligation. The Company may have more than one range of standalone selling price for certain products and services based on the pricing for different customer classes.

Variable consideration in the Company's contracts primarily relates to (i) sales- and usage-based royalties related to the license of intellectual property in collaboration and license contracts and (ii) certain non-fixed fee research services contracts. Accounting Standard Codification (ASC) Topic 606, *Revenue from Contracts with Customers* (ASC 606) provides for an exception to estimating the variable consideration for sales- and usage-based royalties related to the license of intellectual property, such that the sales- and usage-based royalty will be recognized in the period the underlying transaction occurs. The Company recognizes revenue from sales- and usage-based royalty revenue at the later of when the sale or usage occurs and the satisfaction or partial satisfaction of the performance obligation to which the royalty has been allocated.

Changes in deferred revenue from contracts with customers were as follows (in thousands):

	2022	2021
Balance at December 31	$ 7,460	$ 5,998
Deferral of revenue	9,559	5,486
Recognition of deferred revenue	(6,452)	(4,812)
Balance at September 30	$ 10,567	$ 6,672

As of September 30, 2022, of the performance obligations not yet satisfied or partially satisfied, $9.0 million is expected to be recognized as revenue in the next 12 months, with the remainder to be recognized within the 24 months thereafter. The $9.0 million at September 30, 2022 principally consists of amounts billed for undelivered services related to initial and extended service-type warranties and research services, as well as $0.5 million related to undelivered licenses of intellectual property for a diagnostics company (see Note 5).

Costs to obtain a contract

The Company's sales commissions are generally based on bookings of the Company. The Company has determined that certain commissions paid under its sales incentive programs meet the requirements to be capitalized as they are incremental and would not have occurred absent a customer contract. The change in the balance of costs to obtain a contract are as follows (in thousands):

	2022	2021
Balance at December 31	$ 440	$ 248
Deferral of costs to obtain a contract	1,182	558
Recognition of costs to obtain a contract	(914)	(435)
Balance at September 30	$ 708	$ 371

The Company has classified the balance of capitalized costs to obtain a contract as a component of prepaid expenses and other current assets and classifies the expense as a component of cost of goods sold and selling, general, and administrative expense over the estimated life of the contract. The Company considers potential impairment in these amounts each period.

ASC 606 provides entities with certain practical expedients and accounting policy elections to minimize the cost and burden of adoption.

The Company does not disclose the value of unsatisfied performance obligations for (i) contracts with original expected length of one year or less and (ii) contracts for which revenue is recognized at the amount to which the Company has the right to invoice for services performed.

The Company will exclude from its transaction price any amounts collected from customers related to sales and other similar taxes.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. The Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of September 30, 2022 and 2021, respectively.

The Company has elected to account for the shipping and handling as an activity to fulfill the promise to transfer the product, and therefore will not evaluate whether shipping and handling activities are promised services to its customers.

Grant revenue

The Company recognizes grant revenue as the Company performs services under the arrangement when the funding is committed. Revenues and related research and development expenses are presented gross in the consolidated statements of operations as the Company has determined it is the primary obligor under the arrangement relative to the research and development services.

Accounting for grants does not fall under ASC 606, as the grantor will not benefit directly from the Company's expansion or product development. As there is no authoritative guidance under U.S. GAAP on accounting for grants to for-profit business entities from government entities, the Company has accounted for grants obtained with the National Institute of Health (NIH) under its Rapid Acceleration of Diagnostics (RADx) program by analogy to International Accounting Standards Topic 20, *Accounting for Government Grants and Disclosure of Government Assistance* (IAS 20).

The Company accounts for grants from the Alzheimer's Drug Discovery Foundation (ADDF) under ASC Topic 958, *Not-for-Profit Entities* (ASC 958).

Under IAS 20, grants related to assets shall be presented in the consolidated balance sheets either by recognizing the grant as deferred income (which is recognized in the consolidated statements of operations on a systematic basis over the useful life of the asset), or by deducting the grant in calculating the carrying amount of the asset (which is recognized in the consolidated statements of operations over the life of the depreciable asset as a reduced depreciation expense). Both methods are acceptable under IAS 20. The Company has elected to record grants related to assets as a deduction in calculating the carrying value of the asset.

Under IAS 20, grants related to income are presented as part of the consolidated statements of operations, either separately or under a general heading. Both methods are acceptable under IAS 20. The Company has elected to record grants related to income separately on the consolidated statements of operations as grant revenue. The related expenses are recorded within operating expenses.

Under ASC 958, grants related to income are presented as part of the consolidated statements of operations, either separately or under a general heading. Both methods are acceptable under ASC 958. The Company has elected to record grants related to income separately on the consolidated statements of operations as grant revenue. The related expenses are recorded within operating expenses.

RADx grant

On September 29, 2020, the Company entered into a contract with RADx (the RADx Grant), which had a total award value of $18.2 million and accelerated the continued development, scale-up, and deployment of the novel SARS-CoV-2 antigen detection test using the Company's Simoa technology. The RADx Grant provided funding to expand assay kit manufacturing capacity and commercial deployment readiness. Release of the $18.2 million of funding under the RADx Grant was based on the achievement of certain milestones. Contract funding was subject to achievement of these pre-defined milestones and the contract period ran through September 2021, with one milestone extending to May 31, 2022. The Company has received the full $18.2 million under the RADx Grant and the Company has no future obligations under the RADx Grant.

During the three and nine months ended September 30, 2022, the Company recognized no grant revenue and incurred no research and development expense related to the RADx Grant. During the three months ended September 30, 2021, the Company recognized $1.0 million in grant revenue and incurred $0.5 million in research and development expense related to the RADx grant. During the nine months ended September 30, 2021, the Company recognized $4.2 million in grant revenue and incurred $3.4 million in research and development expense related to the RADx Grant.

The RADx Grant contains both monetary amounts granted related to assets and monetary amounts granted related to income, which are grants other than those related to assets. The grants related to assets are for the expansion and increase of manufacturing capacity. The grants related to income are for additional research and development, as well as other non-asset related scale up costs.

The following table summarizes the cumulative activity under the RADx Grant (in thousands):

	September 30, 2022	December 31, 2021
Grant revenue from research and development activities	$ 9,576	$ 9,576
Proceeds used for assets	8,624	8,104
Deferred proceeds for assets	—	—
Deferred grant revenue	—	—
Total recognized	$ 18,200	$ 17,680
Recognized	$ 18,200	$ 17,680
Amount accrued	—	—
Total cash received	$ 18,200	$ 17,680
Proceeds received	$ 18,200	$ 17,680
Proceeds reasonably assured	—	520
Total RADx Grant amount	$ 18,200	$ 18,200

ADDF

On March 24, 2022, the Company entered into a contract with the Alzheimer’s Drug Discovery Foundation (ADDF) (the ADDF Grant). ADDF is a charitable venture philanthropy entity that has granted the Company funding in support of certain activities for the development of an in vitro diagnostic (IVD) test for early detection of Alzheimer's disease. The ADDF Grant, which has a total funding value of $2.3 million, restricts the Company’s use of the granted funds to be used solely for activities related to the Alzheimer’s diagnostic test development project. Contract funding is subject to achievement of these pre-defined milestones and the contract period runs through June 2024. The Company recognizes revenue over time as the related services are performed. As of September 30, 2022, the Company had received $1.3 million of the total funding value of $2.3 million under the ADDF Grant. During the three months ended September 30, 2022, the Company recognized $0.3 million in grant revenue and incurred $0.3 million in research and development expense related to the ADDF Grant. During the nine months ended September 30, 2022, the Company recognized $0.4 million in grant revenue and incurred $0.4 million in research and development expense related to the ADDF Grant.

4. Allowance for credit losses

The Company is exposed to credit losses primarily through sales of products and services. The Company’s expected loss allowance methodology for accounts receivable is developed using historical collection experience, current and future economic and market conditions, and a review of the current status of customers’ trade accounts receivable. Due to the short-term nature of such receivables, the estimated accounts receivable that may not be collected is based on aging of the accounts receivable balances.

Customers are assessed for credit worthiness upfront through a credit review, which includes assessment based on the Company’s analysis of customers’ financial statements when a credit rating is not available. The Company evaluates contract terms and conditions, country, and political risk, and may require prepayment to mitigate risk of loss. Specific allowance amounts are established to record the appropriate provision for customers that have a higher probability of default. The Company monitors changes to the receivables balance on a timely basis, and balances are written off as they are determined to be uncollectable after all collection efforts have been exhausted.

Activity related to the allowance for credit losses was as follows (in thousands):

	2022	2021
Balance at January 1	$ 419	$ 370
Provision for credit losses, net of recoveries	102	275
Balance at September 30	$ 521	$ 645

5. Collaboration and license arrangements

The Company has entered into certain licenses with other companies for use of the Company's technology. These licenses have royalty components which the Company earns and recognizes as collaboration and license revenue throughout the year. At both September 30, 2022 and December 31, 2021, the Company had $0.5 million of deferred revenue related to ongoing negotiations with a diagnostics company.

Abbott Laboratories

On September 29, 2020, the Company entered into a Non-Exclusive License Agreement (the Abbott License Agreement) with Abbott Laboratories (Abbott). Under the terms of the Abbott License Agreement, the Company granted Abbott a non-exclusive, worldwide, royalty-bearing license, without the right to sublicense, under the Company's bead-based single molecule detection patents (Licensed Patents) in the field of *in vitro* diagnostics. Abbott agreed to pay the Company an initial license fee of $10.0 million in connection with the execution of the Abbott License Agreement, which was recognized as license revenue during the 2020 fiscal year. Abbott has also agreed to pay the Company milestone fees subject to the achievement by Abbott of certain development, regulatory and commercialization milestones and low single-digit royalties on net sales of licensed products.

The Abbott License Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature. The Abbott License Agreement became effective upon signing and will continue until expiration of the last-to-expire Licensed Patent, or the agreement is earlier terminated. Under the terms of the Abbott License Agreement, the Company and Abbott each have the right to terminate the agreement for uncured material breach by, or insolvency of, the other party. Abbott may also terminate the Abbott License Agreement at any time without cause upon 60 days' notice.

During the three and nine months ended September 30, 2022 and 2021, the Company did not recognize any revenue under the Abbott License Agreement.

6. Net loss per share

The following common share equivalents have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	2,503,077	2,244,295	2,423,296	2,244,295
Unvested restricted stock and stock units	902,220	607,118	807,360	607,118

7. Fair value of financial instruments

Fair value measurements are as follows (in thousands):

September 30, 2022	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets				
Cash equivalents - money market funds	$ 333,716	$ 333,716	$ —	$ —

December 31, 2021	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Financial assets				
Cash equivalents - money market funds	$ 332,093	$ 332,093	$ —	$ —

8. Inventory

Inventory consists of the following (in thousands):

	September 30, 2022	December 31, 2021
Raw materials	$ 7,467	$ 7,892
Work in process	3,485	4,923
Finished goods	7,284	9,375
Total net inventory	$ 18,236	$ 22,190

9. Goodwill

During the third quarter of 2022, the Company identified certain indicators of impairment, including the significant decline in the Company's stock price, actions taken under the Restructuring Plan and the reduction of forecasted sales and profitability. As a result, the Company performed an interim goodwill impairment test. It was determined that the Company's goodwill was impaired as the carrying amount of the Company's sole reporting unit exceeded the estimated fair value. The Company concluded that the entire goodwill balance was impaired and recognized a non-cash impairment charge during the third quarter of 2022.

The changes in the carrying value of goodwill are as follows (in thousands):

	2022	2021
Balance at January 1	$ 9,632	$ 10,460
Impairment losses	(8,220)	—
Foreign exchange adjustments	(1,412)	(557)
Balance at September 30	$ —	$ 9,903

10. Other accrued expenses

Other accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Royalties	$ 734	$ 1,250
Professional and outside services	1,219	2,126
Tax liabilities	787	430
Other	3,211	2,680
Total accrued expenses	$ 5,951	$ 6,486

11. Stock-based compensation

Stock-based compensation expense for all stock awards consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of product revenue	$ 199	$ 96	$ 424	$ 282
Cost of service and other revenue	159	115	530	347
Research and development	320	440	1,200	1,248
Selling, general, and administrative	2,088	3,357	9,625	9,167
Total stock-based compensation	$ 2,766	$ 4,008	$ 11,779	$ 11,044

As of September 30, 2022, there was $37.1 million of total unrecognized compensation cost related to unvested restricted stock units and stock options, which is expected to be recognized over the remaining weighted-average vesting period of 3.1 years.

12. Leases

The Company is a lessee under leases of offices, lab spaces, and certain office equipment. Some of the Company's leases include options to extend the lease, and these options are included in the lease term to the extent they are reasonably certain to be exercised.

On January 28, 2022, the Company executed a lease for 85,800 square feet of office and laboratory space in Bedford, Massachusetts. The lease commencement date was February 1, 2022, when the Company gained access to the underlying facilities. The Company has negotiated a tenant improvement allowance with the landlord which will offset a portion of the Company's construction costs. The Company has assessed whether improvements made to the premises are landlord-owned or company-owned, with payments made by the Company for landlord-owned assets accounted for as lease incentives. The initial term of the lease's payment schedule is eight years and nine months beginning on May 1, 2022. The Company has the option to extend the lease for two additional five-year periods. As part of the Restructuring Plan, the Company decided not to utilize these facilities as part of its own operations. During the third quarter of 2022, the Company recorded an impairment of $7.7 million related to the Bedford facilities, including $5.5 million relating to the right-of-use assets and $2.2 million associated with property and equipment.

The components of lease expense were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Operating leases	2022	2021	2022	2021
Lease costs (1)				
Operating lease costs	$ 1,500	$ 663	$ 3,733	$ 1,997
Total lease cost	$ 1,500	$ 663	$ 3,733	$ 1,997

(1) Short-term lease costs and variable lease costs incurred by the Company for the three and nine months ended September 30, 2022 were not material.

Supplemental balance sheet and cash flow information was as follows (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Supplemental balance sheet information:				
Weighted average remaining lease term	8.2 years	8.9 years	8.2 years	8.9 years
Weighted average discount rate	7.2%	9.7%	7.2%	9.7%
Supplemental cash flow information:				
Operating cash flows used for operating leases	$ 1,398	$ 849	$ 2,792	$ 2,532

Future minimum commitments under the Company's operating leases were as follows (in thousands):

Twelve months ending September 30,	
2023	$ 6,356
2024	6,992
2025	7,173
2026	7,328
2027	7,561
Thereafter	25,603
Total lease payments	61,013
Less: imputed interest	18,050
Total operating lease liabilities	$ 42,963

13. Income taxes

The Company recorded provisions for income taxes of $72 thousand and $33 thousand for the three months ended September 30, 2022 and 2021, respectively, and provisions of $10 thousand and $32 thousand for the nine months ended September 30, 2022 and 2021, respectively. The Company's effective tax rates were 0.21% for both the three months ended September 30, 2022 and 2021, respectively, 0.01% and 0.09% for the nine months ended September 30, 2022 and 2021, respectively. The income tax provisions and the effective tax rates are primarily driven by state and international taxes.

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.

14. Commitments and contingencies

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 the results of its operations. The Company accrues for contingent liabilities to the extent that the liability is probable and estimable.

15. Related party transactions

One of the Company's Directors is affiliated with Harvard University and Mass General Brigham. Revenue recorded from sales to Harvard University and its affiliates and to Mass General Brigham and its affiliates totaled $0.2 million and $0.5 million for the three and nine months ended September 30, 2022, respectively, and $0.2 million for both the three and nine months ended September 30, 2021, respectively. The Company recorded cost of goods sold of $0.1 million for the three months ended September 30, 2022 related to Harvard University and its affiliates and to Mass General Brigham and its affiliates. The Company had $0.2 million in accounts receivable from Harvard University and its affiliates and Mass General Brigham and its affiliates at both September 30, 2022 and December 31, 2021. Deferred revenue from Harvard University and its affiliates and Mass General Brigham and its affiliates was $0.1 million at both September 30, 2022 and December 31, 2021.

On May 26, 2022, the Company entered into an agreement with UltraDx Limited (the UltraDx Agreement), a new company formed by ARCH Venture Partners (ARCH). Under the UltraDx Agreement, the Company will supply HD-X instruments (both fully assembled and disassembled) as well as assays and assay components to UltraDx, and UltraDx has the non-exclusive right to seek Chinese regulatory approval of and to commercialize the HD-X instrument and related assays in the Chinese neurological in vitro diagnostic market. The Company has determined that UltraDx is a related party because one of the Company's directors is affiliated with ARCH and UltraDx. Under the terms of the UltraDx Agreement, the Company shipped a total of ten fully assembled and disassembled HD-X instruments to UltraDx on June 30, 2022 at a purchase price of approximately $1.9 million. Because UltraDx was formed during the second quarter of 2022, the Company recognized revenue on these shipments upon receipt of payment during the three months ended September 30, 2022.

16. Accumulated other comprehensive loss

The following shows the changes in the components of accumulated other comprehensive loss (in thousands):

	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2020	$ 2,434	$ 2,434
Foreign currency translation adjustments	(1,993)	(1,993)
Balance at December 31, 2021	$ 441	$ 441
Foreign currency translation adjustments	(3,440)	(3,440)
Balance at September 30, 2022	$ (2,999)	$ (2,999)

17. Restructuring

Following a strategic review and assessment of the Company's operations and cost structure, on August 8, 2022, the Company announced a plan of restructuring and strategic re-alignment (the Restructuring Plan). As part of the Restructuring Plan, the Company began an assay redevelopment program with the ultimate objective of improving its ability to manufacture and deliver high-quality assays at scale. The Restructuring Plan aligns the Company's investments to best serve the needs of its customers, focuses the Company's innovation efforts on key platforms and provides a foundation for the Company's entry into translational pharma and clinical markets, which it believes will be required to access new growth categories. In accordance with the Restructuring Plan, the Company implemented a workforce reduction, which was substantially completed by the end of the third quarter of 2022. The Company recorded charges in the three months ended September 30, 2022, consisting of one-time termination benefits for employee severance, benefits and related costs, all of which were cash expenditures.

The following shows the number of positions by function and by location eliminated in connection with the Restructuring Plan:

	North America	EMEA	Asia Pacific	Total
Cost of goods sold	21	—	—	21
Research and development	34	1	—	35
Selling, general and administrative	50	9	4	63
Total headcount	105	10	4	119

As part of the Restructuring Plan, the Company also performed an assessment of impairment for long-lived assets, including right-of-use assets, and recorded an impairment charge of $8.7 million. The impairment expense includes $7.7 million associated with the right-of-use and property and equipment at the Bedford facilities (see Note 12). Additionally, the Company recorded an impairment charge of $1.0 million for software costs related to projects that have been rationalized as part of the Restructuring Plan.

The following presents a rollforward of the restructuring reserve and provision activity (in thousands):

	Severance and Employee Benefit Costs	Other Restructuring Charges	Total
Balance at June 30, 2022	$ —	$ —	$ —
Charges	3,325	101	3,426
Cash payments	(2,995)	(101)	(3,096)
Foreign exchange	7	—	7
Balance at September 30, 2022	$ 337	$ —	$ 337

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited 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, 2021, filed with the Securities and Exchange Commission (the SEC) on March 1, 2022. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results, performance or experience could differ materially from what is indicated by any forward-looking statement due to various important factors, risks and uncertainties, including, but not limited to, those set forth under Item 1A of Part II, "Risk Factors" and "Special Note Regarding Forward-Looking Statements" included elsewhere in this Quarterly Report on Form 10-Q or under "Risk Factors" in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2021.

Overview

We are a life sciences company that has developed next generation, ultra-sensitive digital immunoassay platforms that advance precision health for life sciences research and diagnostics. Our platforms are based on our proprietary digital "Simoa" detection technology. Our Simoa bead-based and planar array platforms enable customers to reliably detect protein biomarkers in extremely low concentrations in blood, serum and other fluids that, in many cases, are undetectable using conventional, analog immunoassay technologies, and also allow researchers to define and validate the function of novel protein biomarkers that are only present in very low concentrations. These capabilities provide our customers with insight into the role of protein biomarkers in human health that has not been possible with other existing technologies and enable researchers to unlock unique insights into the continuum between health and disease. We believe this greater insight will enable the development of novel therapies and diagnostics and facilitate a paradigm shift in healthcare from an emphasis on treatment to a focus on earlier detection, monitoring, prognosis and, ultimately, prevention.

Our instruments are designed to be used either with assays fully developed by us, including all antibodies and supplies required to run the tests, or with "homebrew" 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 the Simoa instruments increases, total consumables revenue overall is expected to increase. We believe that consumables revenue should be subject to less period-to-period fluctuation than our instrument sales revenue and will become an increasingly important contributor to our overall revenue.

We commercially launched our first immunoassay platform, the Simoa HD-1, in January 2014. The HD-1 is based on our bead-based technology, and assays run on the HD-1 are fully automated. We initiated commercial launch of the SR-X instrument in December 2017. The SR-X utilizes the same Simoa bead-based technology and assay kits as the HD-1 in a compact benchtop form with a lower price point, more flexible assay preparation, and a wider range of applications. In July 2019, we launched the Simoa HD-X, an upgraded version of the Simoa HD-1, which replaces the HD-1. The HD-X has been designed to deliver significant productivity and operational efficiency improvements, as well as greater user flexibility. We began shipping and installing HD-X instruments at customer locations in 2019, and by the end of 2021, approximately 68% of the HD instrument installed base was HD-X instruments.

We also provide contract research services for customers through our CLIA-certified Accelerator Laboratory. The Accelerator Laboratory provides customers with access to Simoa technology, and supports multiple projects and services, including sample testing, homebrew assay development and custom assay development. To date, we have completed over 1,900 projects for approximately 440 customers from all over the world using our Simoa platforms.

We sell our instruments, consumables and services to the life science, pharmaceutical and diagnostics industries through a direct sales force and support organizations in North America and Europe, and through distributors or sales agents in other select markets, including Australia, Brazil, China, Czech Republic, India, Hong Kong, Israel, Japan, New Zealand, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan, and UAE. In addition, Uman sells Nf-L antibodies and Nf-L ELISA kits directly, and in conjunction with us and another distributor worldwide. We have an extensive base of customers in world class academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies.

As of September 30, 2022, we had cash and cash equivalents of $343.7 million. Since inception, we have incurred annual net losses. Our net losses were $57.7 million, $31.5 million, and $40.8 million for the years ended December 31, 2021, 2020, and 2019, respectively, and $78.1 million and $37.7 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $383.6 million and stockholders' equity of $372.8 million.

Recent Business Developments

On March 24, 2022, we entered into a contract with the Alzheimer’s Drug Discovery Foundation (ADDF). ADDF is a charitable venture philanthropy entity that has granted us funding in support of certain activities for the development of an in vitro diagnostic (IVD) test for early detection of Alzheimer's disease (ADDF Grant). The ADDF Grant, which has a total funding value of $2.3 million, restricts our use of the granted funds to be used solely for activities related to the Alzheimer’s diagnostic test development project. Contract funding is subject to achievement of pre-defined milestones and the contract period runs through June 2024. As of September 30, 2022, we had received $1.3 million out of the full $2.3 million funding value under the ADDF Grant. During the three months ended September 30, 2022, we recognized $0.3 million in grant revenue and incurred $0.3 million in research and development expense related to the ADDF Grant. During the nine months ended September 30, 2022, we recognized $0.4 million in grant revenue and incurred $0.4 million in research and development expense related to the ADDF Grant.

During the first quarter of 2022, we 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). We also entered into a statement of work (the Statement of Work) under the Lilly Collaboration Agreement to perform assay research and development services within the field of Alzheimer’s disease. In connection with the Lilly Collaboration Agreement, we received a non-refundable up-front payment of $5.0 million during the first quarter of 2022, and under the Statement of Work receive $1.5 million per calendar quarter during 2022, beginning with the three months ended March 31, 2022. The revenue will be recognized over a one-year period.

Concurrent with the execution of the Lilly Collaboration Agreement, we entered into a Technology License Agreement (the Lilly License) under which Lilly granted to us a non-exclusive license to Lilly’s proprietary P-tau217 antibody technology for potential near-term use in research-use-only products and services and future *in vitro* diagnostics applications within the field of Alzheimer’s disease. In consideration of the Lilly License, we paid an upfront fee, are required to make milestone payments based on the achievement of predetermined regulatory and commercial events, and will pay a royalty on net sales of licensed products.

We concluded that the Lilly Collaboration Agreement and the Lilly License represented a single contract with a customer and are accounting for the agreements as service revenue recognized over time as the services are delivered. The transaction price for the Lilly Collaboration Agreement is $10.9 million. Contingent amounts due to Lilly represent variable consideration payable to a customer and will be recognized as reductions to service revenue up to the amount of the transaction price recognized, when probable. We are utilizing an input method to measure the delivery of services by calculating costs incurred at each period end relative to total costs expected to be incurred.

During the three and nine months ended September 30, 2022, we recognized approximately $2.7 million and $8.1 million, respectively, of revenue from the Lilly Collaboration Agreement as service revenue.

Restructuring and Strategic Re-Alignment

Following a strategic review and assessment of our operations and cost structure, on August 8, 2022, we announced a plan of restructuring and strategic re-alignment (the Restructuring Plan). As part of this plan, we began an assay redevelopment program with the ultimate objective of improving our ability to manufacture and deliver high-quality assays at scale. The plan aligns our investments to best serve the needs of customers, focuses innovation efforts on key platforms and provides the foundation for our entry into translational pharma and clinical markets, which we believe will be required to access new growth categories. The restructuring included the elimination of 119 positions across the Company and other cost-saving measures. The workforce reduction was substantially completed by the end of the third quarter of 2022. We recorded a $3.3 million charge in the third quarter of 2022 as a result of the workforce reduction, consisting of one-time termination benefits for employee severance, benefits and related costs. As part of the Restructuring Plan, we are also reviewing alternative uses of the additional facility space that we currently lease in Bedford, Massachusetts. These alternatives may include terminating the lease or the sub-lease of all or a portion of the leased facility. During the three months ended September 30, 2022, we recorded an impairment expense of $7.7 million on our long-lived assets related to the Bedford facilities, as well as a $1.0 million impairment expense related to software projects. Overall, as a result of the Restructuring Plan, we expect to realize estimated annualized operating expense savings of approximately $25 million.

Despite the Restructuring Plan, we expect to continue to incur significant expenses and operating losses at least through the next 24 months as we:

- execute the Restructuring Plan;
- expand our sales and marketing efforts to further commercialize our products;
- pursue strategic acquisitions of companies or technologies that may be complementary to our business;
- expand our research and development efforts to improve our existing products and develop and launch new products, particularly if any of our products are deemed by FDA to be medical devices or otherwise subject to additional regulation by FDA;
- seek PMA or 510(k) clearance from 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; and
- enter into additional collaboration arrangements or in-license other products and technologies.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and September 30, 2021 (dollars in thousands):

	Three Months Ended September 30,				Increase (Decrease)	
	2022	% of revenue	2021	% of revenue	Amount	%
Product revenue	$ 17,693	66 %	$ 20,662	75 %	$ (2,969)	(14)%
Service and other revenue	8,370	31 %	5,898	21 %	2,472	42 %
Collaboration and license revenue	301	1 %	120	— %	181	151 %
Grant revenue	282	1 %	1,009	4 %	(727)	(72)%
Total revenue	26,646	99 %	27,689	100 %	(1,043)	(4)%
Cost of goods sold:						
Cost of product revenue	10,511	39 %	8,639	31 %	1,872	22 %
Cost of service revenue	5,191	19 %	3,806	14 %	1,385	36 %
Total costs of goods sold and services	15,702	58 %	12,445	45 %	3,257	26 %
Gross profit	10,944	41 %	15,244	55 %	(4,300)	(28)%
Operating expenses:						
Research and development	6,631	25 %	6,807	25 %	(176)	(3)%
Selling, general, and administrative	19,966	75 %	23,670	85 %	(3,704)	(16)%
Other lease costs	609	2 %	—	— %	609	—
Restructuring	3,426	13 %	—	— %	3,426	—
Goodwill impairment	8,220	31 %	—	— %	8,220	—
Impairment expense	8,695	33 %	—	— %	8,695	—
Total operating expenses	47,547	178 %	30,477	110 %	17,070	56 %
Loss from operations	(36,603)	(137)%	(15,233)	(55)%	(21,370)	(140)%
Interest income (expense), net	1,712	6 %	(90)	— %	1,802	2,002 %
Other (expense) income, net	(101)	1 %	(305)	(1)%	204	(67)%
Loss before income taxes	(34,992)	(131)%	(15,628)	(56)%	(19,364)	(124)%
Income tax provision	72	— %	33	— %	39	118 %
Net loss	$ (35,064)	(131)%	$ (15,661)	(56)%	$ (19,403)	(124)%

Revenue

Total revenue decreased $1.1 million, or 4%, to $26.6 million for the three months ended September 30, 2022, compared to $27.7 million for the three months ended September 30, 2021. Product revenue of $17.7 million for the three months ended September 30, 2022 consisted of instrument sales of $7.8 million and sales of consumables and other products of $9.9 million. This represented a decrease of $3.0 million, or 14%, as compared to product revenue of $20.7 million for the three months ending September 30, 2021, which consisted of $6.5 million in instrument sales and $14.2 million in consumables and other. The decrease in product revenue was primarily due to our management of production levels as we address the quality challenges affecting our consumables.

Service and other revenue was $8.4 million for the three months ended September 30, 2022, compared to $5.9 million for the three months ended September 30, 2021, an increase of $2.7 million, or 42%, primarily due to revenue recognized from the Lilly Collaboration Agreement which was new in 2022. Grant revenue decreased 72% period over period. Grant revenue of $0.3 million in the third quarter of 2022 was related to the ADDF Grant which was new in 2022 and grant revenue of $1.0 million in the third quarter of 2021, was related to the RADx Grant which ended in 2021.

Cost of Goods Sold and Services

Cost of goods sold and services increased $3.3 million, or 26%, to $15.7 million for the three months ended September 30, 2022 compared to $12.4 million for the three months ended September 30, 2021, primarily due to increased cost of product revenue. Cost of product revenue increased 22% as a result of an increase our inventory reserve to address manufacturing and quality challenges and discontinued products. This increase was partially offset by the reduction in headcount due to the Restructuring Plan.

Research and Development Expense

Research and development expense decreased $0.2 million, or 3%, for the three months ended September 30, 2022, as compared to the same period in 2021, primarily due to the reduction in headcount in connection with the implementation of the Restructuring Plan.

Selling, General, and Administrative Expense

Selling, general and administrative expense decreased $3.7 million, or 16%, for the three months ended September 30, 2022, as compared to the same period in 2021, mainly due to the reduction in headcount in connection with the implementation of the Restructing Plan and a decrease in contracted services.

Other Lease Costs

As part of the Restructuring Plan, we are not utilizing the office and laboratory space leased in Bedford, Massachusetts and are evaluating alternatives, including termination of the lease or sub-leasing the facilities. Other lease costs represent the depreciation expense of the right-of-use asset and the accretion of the lease facility for periods after the impairment and the determination that the facilities would not be utilized. There were no similar charges in the same period in 2021.

Restructuring, Goodwill Impairment, and Impairment Expense

During the three months ended September 30, 2022, we incurred restructuring expense of $3.4 million, and non-cash impairment expenses of $8.7 million and $8.2 million for long-lived assets, and goodwill, respectively. Included in restructuring expense were costs for severance and one-time termination benefits in connection with the elimination of 119 positions across the Company, associated legal fees and contract cancellation costs due to the implementation of the Restructuring Plan. Impairment expense of $8.7 million includes $7.7 million associated with the Bedford, Massachusetts facilities and $1.0 million associated with the impairment of software costs for projects that have been rationalized as part of the Restructuring Plan. As part of the Restructuring Plan, we are not utilizing the Bedford, Massachusetts facilities and are evaluating alternatives, including terminating the lease or sub-leasing the facilities. The entire goodwill balance was written off during the three months ended September 30, 2022, following the assessment of our interim goodwill impairment test. There were no similar charges in the same period in 2021.

Interest Income (Expense), Net

Interest income (expense), net was income of $1.7 million for the three months ended September 30, 2022, as compared to an expense of $0.1 million in the same period in 2021, due to the maturity of our note payable in the fourth quarter of 2021 and higher interest income on our cash equivalents during the three months ended September 30, 2022.

Other (Expense) Income, Net

Other (expense) income, net was an expense of $0.1 million in the three months ended September 30, 2022, as compared to income of $0.3 million in the same period in 2021, mainly due to the impact of foreign currency exchange rates.

Income Tax Provision

Income tax provision was $0.1 million for the three months ended September 30, 2022, and less than $0.1 million for the three months ended September 30, 2021, consisting primarily of provisions recorded on the operating results of our foreign subsidiaries.

Comparison of the Nine Months Ended September 30, 2022 and September 30, 2021 (dollars in thousands):

	Nine Months Ended September 30,				Increase (Decrease)	
	2022	% of revenue	2021	% of revenue	Amount	%
Product revenue	$ 53,134	67 %	$ 57,586	72 %	$ (4,452)	(8)%
Service and other revenue	25,728	32 %	17,955	22 %	7,773	43 %
Collaboration and license revenue	479	1 %	486	1 %	(7)	(1)%
Grant revenue	357	— %	4,242	5 %	(3,885)	(92)%
Total revenue	79,698	100 %	80,269	100 %	(571)	(1)%
Cost of goods sold:						
Cost of product revenue	31,178	39 %	24,233	30 %	6,945	29 %
Cost of service revenue	14,306	18 %	10,569	13 %	3,737	35 %
Total costs of goods sold and services	45,484	57 %	34,802	43 %	10,682	31 %
Gross profit	34,214	43 %	45,467	57 %	(11,253)	(25)%
Operating expenses:						
Research and development	20,290	25 %	20,244	25 %	46	0 %
Selling, general and administrative	72,723	91 %	63,913	80 %	8,810	14 %
Other lease costs	609	1 %	—	— %	609	—
Restructuring	3,426	4 %	—	— %	3,426	—
Goodwill impairment	8,220	10 %	—	— %	8,220	—
Impairment expense	8,695	11 %	—	— %	8,695	—
Total operating expenses	113,963	142 %	84,157	102 %	29,806	35 %
Loss from operations	(79,749)	(99)%	(38,690)	(48)%	(41,059)	(106)%
Interest income (expense), net	2,316	3 %	(418)	(1)%	2,734	654 %
Other (expense) income, net	(676)	(1)%	1,478	2 %	(2,154)	(146)%
Loss before income taxes	(78,109)	(97)%	(37,630)	(47)%	(40,479)	(108)%
Income tax provision	10	— %	32	— %	(22)	(69)%
Net loss	$ (78,119)	(97)%	$ (37,662)	(47)%	$ (40,457)	(107)%

Revenue

Total revenue was $79.7 million for the nine months ended September 30, 2022 compared to $80.3 million for the nine months ended September 30, 2021, a decrease of $0.6 million, or 1%. Product revenue of $53.1 million for the nine months ended September 30, 2022, which consisted of instrument sales of $19.6 million and sales of consumables and other products of $33.5 million. This represented a decrease of $4.5 million, or 8%, as compared to $57.6 million for the nine months ended September 30, 2021, which consisted instrument sales of $19.3 million and sales of consumables and other products of $38.3 million. This decrease in revenue was primarily due to quality issues with our consumables product and, in the third quarter of 2022, the management of production levels as we ensure we deliver quality products to our customers while we address the quality challenges affecting our consumables.

Service and other revenue was $25.7 million for the nine months ended September 30, 2022 compared to $18.0 million for the nine months ended September 30, 2021, an increase of $7.8 million, or 43% ,primarily due to revenue recognized from the Lilly Collaboration Agreement which was new in 2022. Grant revenue decreased 92% period over period. Grant revenue of $0.4 million in the nine months ended September 30, 2022 was related to the ADDF grant which was new in 2022 and grant revenue of $4.2 million in the same period of 2021 was related to the RADx grant which ended in 2021.

Cost of Goods Sold and Services

Cost of goods sold and service increased $10.7 million, or 31%, to $45.5 million for the nine months ended September 30, 2022 compared to $34.8 million for the nine months ended September 30, 2021. Cost of product revenue increased 29% as a result of increasing our inventory reserve to reflect the ongoing efforts to address manufacturing and quality challenges, and discontinued products. Cost of service revenue increased by 35% mainly due to a change in the way certain costs are allocated in the nine months ended September 30, 2022.

Research and Development Expense

Research and development expense was consistent at $20.3 million for the nine months ended September 30, 2022 and $20.2 million for the same period in 2021.

Selling, General, and Administrative Expense

Selling, general and administrative expense increased $8.8 million, or 14%, for the nine months ended September 30, 2022, as compared to the same period in 2021, mainly due to additional headcount driving increased cash compensation expense, stock-based compensation expense, and other general and administrative expenses prior to the implementation of our Restructuring Plan. Rent expense increased for the nine months ended September 30, 2022 due to the new leased facilities in Bedford, Massachusetts that commenced on February 1, 2022 when we gained access to the underlying facilities prior to the implementation of our Restructuring Plan.

Other Lease Costs

As part of the Restructuring Plan implemented during the third quarter of 2022, we are not utilizing the office and laboratory space leased in Bedford, Massachusetts and are evaluating alternatives, including termination of the lease or sub-leasing the facilities. Other lease costs represent the depreciation expense of the right-of-use asset and the accretion of the lease facility for periods after the impairment and determination the facilities would not be utilized.

Restructuring, Goodwill Impairment, and Impairment Expense

During the nine months ended September 30, 2022, we incurred restructuring expense of $3.4 million, and non-cash impairment expenses of $8.7 million and $8.2 million for long-lived assets, and goodwill, respectively. Included in restructuring expense were costs for severance and one-time termination benefits in connection with the elimination of 119 positions across the Company, associated legal fees and contract cancellation costs due to the implementation of the Restructuring Plan. Impairment expense of $8.7 million includes $7.7 million associated with the Bedford, Massachusetts facilities and $1.0 million associated with the impairment of software costs for projects that have been rationalized as part of the Restructuring Plan. As part of the Restructuring Plan, we are not utilizing these facilities and are evaluating alternatives, including termination of the lease or sub-leasing the facilities. The entire goodwill balance was written off during the nine months ended September 30, 2022, following the assessment of our interim goodwill impairment test. There were no similar charges in the same period in 2021.

Interest Income (Expense), Net

Interest income (expense), net was income of $2.3 million in the nine months ended September 30, 2022, as compared to an expense of $0.4 million in the same period in 2021, due to the maturity of our note payable in the fourth quarter of 2021 and higher interest income on our cash equivalents during the nine months ended September 30, 2022.

Other (Expense) Income, Net

Other (expense) income, net was an expense of $0.7 million in the nine months ended September 30, 2022, as compared to income of $1.5 million in the same period in 2021. Other expense, net for the nine months of 2022 was mainly due to the impact of foreign currency exchange rates. Other income, net for the nine months of 2021 was mainly due to a $2.1 million employee retention tax credit established under the Coronavirus Aid, Relief, and Economic Security Act.

Income Tax Provision

Income tax provision was less than $0.1 million in both the nine months ended September 30, 2022 and 2021, consisting primarily of provisions recorded on the operating results of our foreign subsidiaries.

Liquidity and Capital Resources

To date, we have financed our operations principally through equity offerings, borrowings from credit facilities and revenue from our commercial operations.

Cash Flows

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

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net cash used in operating activities	$ (44,182)	$ (37,615)
Net cash used in investing activities	(9,611)	(4,144)
Net cash provided by financing activities	1,597	271,646
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (52,196)	$ 229,887

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 invest in process improvements. We have historically experienced negative cash flows from operating activities as we have developed our technology, expanded our business and built our infrastructure and this may continue in the future.

Net cash used in operating activities was $44.2 million during the nine months ended September 30, 2022. The net cash used in operating activities primarily consisted of the net loss of $78.1 million offset by non-cash charges of $11.8 million of stock-based compensation expense, impairment of long-lived assets of $8.7 million, impairment of goodwill of $8.2 million and $4.2 million of depreciation.

Net cash used in operating activities was $37.6 million during the nine months ended September 30, 2021. The net cash used in operating activities primarily consisted of the net loss of $37.7 million offset by non-cash charges of $11.0 million of stock-based compensation expense and $3.6 million of depreciation and amortization expense. Cash used as a result of changes in operating assets and liabilities of $15.6 million was primarily due to an increase in inventory of $8.4 million, a decrease in accrued compensation and benefits, other accrued expenses and other current liabilities of $2.7 million, and an increase in accounts receivable of $1.6 million.

Net Cash Used in Investing Activities

Historically, our primary investing activities have consisted of capital expenditures for the purchase of capital equipment to support our expanding infrastructure and work force. We expect to continue to incur additional costs for capital expenditures related to these efforts in future periods.

We used $10.1 million in cash during the nine months ended September 30, 2022 primarily related to purchases of property and equipment for the new leased facility in Bedford, Massachusetts, offset by $0.5 million of grant proceeds.

We used $4.1 million in cash during the nine months ended September 30, 2021 primarily related to $11.2 million in purchases of property and equipment, offset by $7.0 million in grant proceeds related to the RADx Grant.

Net Cash Provided by Financing Activities

Historically, we have financed our operations principally through sales of our stock, borrowings from credit facilities and revenues from our commercial operations.

Financing activities provided $1.6 million of cash during the nine months ended September 30, 2022, from proceeds from employee stock purchases and stock option exercises.

Financing activities provided $271.6 million of cash during the nine months ended September 30, 2021, primarily from $269.7 million in net proceeds from our underwritten public offering during the first quarter of 2021, and $6.6 million in proceeds from common stock option exercises, offset by $5.7 million in payments on notes payable.

Capital Resources

Since inception, we have incurred annual net losses. Our liquidity requirements have historically consisted, and we expect that they will continue to consist, of sales and marketing expenses, research and development expenses, working capital, debt service and general corporate expenses.

We believe cash generated from commercial sales, our current cash and cash equivalents, and interest income we earn on these balances will be sufficient to meet our anticipated operating cash requirements for at least the next 12 months. Our estimates of the period of time through which our financial resources will be adequate to support our operations and the costs to support research and development and our sales and marketing activities are forward-looking statements and involve risks and uncertainties and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part II, Item 1A. “Risk Factors”, of this Quarterly Report on Form 10-Q, and Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021 We have based our estimates on assumptions that may prove to be wrong and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- our ability to successfully execute and realize the intended benefits of the Restructuring Plan;
- market acceptance of our products and our ability to introduce new products;
- the cost and timing of establishing additional sales, marketing and distribution capabilities;
- the cost of our research and development activities;
- our ability to enter into collaborations in the future, and the success of any such collaborations;
- the cost and timing of potential regulatory clearances or approvals that may be required in the future for our products; and
- the effect of competing technological and market developments.

If the conditions for raising capital are favorable, we may seek to finance future cash needs through public or private equity or debt offerings or other financings. We cannot assure you 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, we may have to delay development or commercialization of our products. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations.

Contractual Obligations and Commitments

As of September 30, 2022, except for the Bedford, Massachusetts lease detailed in Note 12 to our unaudited condensed consolidated financial statements, there have been no material changes to our contractual obligations and commitments from those described under “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, 2021.

Critical Accounting Policies, Significant Judgments and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States, or U.S. GAAP, requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of assets and liabilities in our financial statements and accompanying notes. The most significant assumptions used in the financial statements are the underlying assumptions used in revenue recognition and valuation of inventory. We base estimates and assumptions on historical experience when available and on various factors that we determined to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and significant estimates that involve a higher degree of judgment and complexity are described under “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 for the year ended December 31, 2021.

There have been no material changes to our critical accounting policies and estimates as disclosed therein.

Recent Accounting Pronouncements

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

At September 30, 2022, there have been no material changes to the market risk information, except for concentrations noted below, described under “Quantitative and Qualitative Disclosures About Market Risk” included in the Annual Report on Form 10-K for the year ended December 31, 2021.

For the three and nine months ended September 30, 2022, there was one customer that accounted for 14.1% and 11.1%, respectively, of our total revenue.

At September 30, 2022, two customers individually accounted for 13.4% and 10.1%, respectively, of our gross accounts receivable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. 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.

Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our principal executive officer and principal financial officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended September 30, 2022 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

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 1, 2022, except that the following risk factor replaces the risk factor with the same title as set forth in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 8, 2022:

We may fail to achieve the expected cost savings and related benefits from our Restructuring Plan.

In August 2022, we announced a plan of restructuring and strategic re-alignment, which included the elimination of approximately 119 current positions, or 25% of our workforce, and other cost-savings measures (the Restructuring Plan). We incurred expenses of approximately $3.4 million related to the Restructuring Plan in the third quarter of 2022, substantially all of which were cash expenditures for severance and other costs relating to the Restructuring Plan.

Overall, we expect to realize estimated annualized operating expense savings of approximately $25.0 million. These estimates are subject to a number of assumptions, and actual results may differ. There is no guarantee that the Restructuring Plan will achieve its intended benefits. For example, our cost restructuring and business re-alignment efforts may not result in the anticipated savings or other economic benefits, or could result in total costs and expenses that are greater than expected, which could require us to seek potentially dilutive financing alternatives, disrupt or restrain the scope of our business activities and make it more difficult to attract and retain qualified personnel, each of which could have an adverse effect on our business. We may implement other cost savings measures as part of the Restructuring Plan, and may incur termination and other costs in connection with such measures, which could be material. As part of the Restructuring Plan, we are also reviewing our alternatives with respect to additional facility space that we currently lease in Bedford, Massachusetts. These alternatives may include the termination of the lease or the sub-lease of all or a portion of the leased facility.

We may fail to effectively execute on the Restructuring Plan. The Restructuring Plan may cause disruption to our business operations. For example, the Restructuring Plan resulted in the loss of a number of long-term employees, resulting in the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across our organization, all of which could adversely affect our operations. In addition, we may not be able to effectively realize all the cost savings anticipated by the Restructuring Plan and we may incur unanticipated charges or make cash payments that were not previously contemplated, which could result in an adverse effect on our business or results of operations. In connection with the Restructuring Plan, we have set in motion an assay improvement program with the ultimate objective of improving our ability to manufacture and deliver high-quality assays at scale. We expect to make initial progress toward this initiative in 2022 and that the program will be completed in 2023. We may be unable to obtain the anticipated product and quality-related benefits from these efforts in the timeframe anticipated, or at all, which could have an adverse effect on our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q.

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.		8-K	12/15/2017	001-38319
10.1	Employment Agreement between Dan Pikora and the Company dated March 28, 2022.		8-K	9/8/2022	001-38319
10.2	Separation Agreement between E. Kevin Hrusovsky and the Company, effective August 8, 2022.		8-K	8/8/2022	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: November 9, 2022

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

Dated: November 9, 2022

By: /s/ Michael A. Doyle
Michael A. Doyle
Chief Financial Officer
(principal financial officer and principal accounting officer)

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: November 9, 2022

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

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Michael A. Doyle, 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: November 9, 2022

/s/ Michael A. Doyle
Michael A. Doyle
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 September 30, 2022 (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: November 9, 2022	/s/ Masoud Toloue Masoud Toloue President and Chief Executive Officer
Dated: November 9, 2022	/s/ Michael A. Doyle Michael A. Doyle Chief Financial Officer