Quanterix Corporation Releases Operating Results for Fourth Quarter and Full Year 2021

March 1, 2022

Company strengthens balance sheet ending FY with GAAP total revenue growth increase of 28% led by strong performance in neuro-related studies and applications

Executive leadership succession plan effective April 25, 2022, to build on the Company's foundation for growth

BILLERICA, Mass.--(BUSINESS WIRE)--Mar. 1, 2022-- Quanterix Corporation (NASDAQ: QTRX), a company digitizing biomarker analysis with the goal of advancing the science of precision health, today announced financial results for the fourth quarter and twelve months ending December 31, 2021.

“We‘ve reached an important inflection point with the achievement of several key milestones, namely, our license and collaboration agreements with Eli Lilly, FDA Breakthrough Device Designation for plasma pTau-181 for Alzheimer’s disease (AD), and ending a strong 2021 with another record quarter. We have nearly $400 million on our balance sheet and the recruitment of several key executives that strengthen both RUO and diagnostics potential,” said Kevin Hrusovsky, Chairman and Chief Executive Officer, Quanterix. “With our new agreements in place, we now have access to Lilly’s marquis P-tau217 antibody technology for AD and a collaboration framework for future projects across all disease categories. As we build our franchise in 2022, we look forward to partnering with other bio-pharmaceuticals, payors, researchers, and investors to unlock the massive opportunity for asymptomatic medicine using precision health proteomics.”

For more information on the new agreements with Lilly to advance diagnosis and treatment of Alzheimer’s disease, please see the press release issued today.

Quanterix also announced the Company’s executive leadership succession plan. Effective April 25, 2022, President Masoud Toloue will succeed Chairman & Chief Executive Officer Kevin Hrusovsky as CEO and join Quanterix’ Board of Directors. Hrusovsky will move into an active Executive Chairman role, continuing to serve on the Board and support key strategic initiatives and important customer, partner and investor relationships. For more information on the succession plan, please see the full release issued today.

Fourth Quarter 2021 Financial Highlights

Key financial results for the fourth quarter of 2021 are shown below:

- Q4 GAAP total revenue, which includes grant revenue of $1.0M, was $30.3M versus prior year Q4 of $26.1M, which included grant revenue of $4.5M, an increase of 16%;
- Q4 non-GAAP total revenue was $29.3M versus prior year Q4 of $21.6M, an increase of 35%;
- Q4 GAAP product revenue was $23.5M versus prior year Q4 of $15.7M, an increase of 49%;
- Q4 GAAP service and other revenue was $5.7M versus prior year Q4 of $5.5M, an increase of 3%;
- Q4 GAAP gross margin was 53.7% versus prior year Q4 of 57.6%; and
- Q4 non-GAAP gross margin was 53.5% versus prior year Q4 of 50.8%.

Full Year 2021 Financial Highlights

Key financial results for FY 2021 are shown below:

- FY GAAP total revenue, which includes grant revenue of $5.2M, was $110.6M versus prior year FY of $86.4M; which included one-time license revenue of $11.2M and grant revenue of $6.4M, an increase of 28%;
- FY non-GAAP total revenue was $105.3M versus prior year FY of $68.8M, an increase of 53%;
- FY GAAP product revenue was $81.1M versus prior year FY of $44.0M, an increase of 84%;
- FY GAAP service and other revenue was $23.6M versus prior year FY of $24.1M, a decrease of 2%;
- FY GAAP gross margin was 55.8% versus prior year FY of 55.8%; and
- FY non-GAAP gross margin was 55.4% versus prior year FY of 49.2%.

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

Fourth Quarter and Full Year Business Highlights

- The Company strengthened its balance sheet by successfully raising $287.5 million in gross proceeds through a follow-on offering completed in Q1. Quanterix had $399.0 million in cash, cash equivalents and restricted cash on the balance sheet as of December 31, 2021.

- Quanterix' Simoa phospho-Tau 181 (pTau-181) blood test was granted Breakthrough Device designation by the U.S. Food and Drug Administration (FDA) as an aid in diagnostic evaluation of Alzheimer's disease.
- The FDA expanded the Emergency Use Authorization (EUA) label for Quanterix' Simoa SARS-CoV-2 N Protein Antigen Test to include testing with nasal swab and saliva samples, and for asymptomatic serial testing with nasal swab samples. The expanded label established this test as the first antigen test authorized for use with saliva samples.
- Quanterix' Simoa HD-X technology and assays were used to measure pTau217 using antibodies developed by Eli Lilly and Company for its Phase 2 TRAILBLAZER-ALZ study, which was presented by Lilly at the Alzheimer's Association International Conference (AAIC) 2021.
- Following the FDA approval of ADUHELM™, Biogen conducted biomarker studies on Phase 3 EMERGE and ENGAGE trial samples, utilizing Quanterix' Simoa HD-X to measure plasma pTau-181. Dr. Oskar Hansson from University of Lund reported preliminary data showing a dose-dependent reduction in plasma pTau-181 levels following treatment with ADUHELM, which correlated with decreases in brain amyloid as measured by PET scan and a slowing of cognitive decline across four independent assessment tools.
- Instrument installations increased by 32% in 2021 to 708 at year-end, with many HD-X instruments being used for neuro-related applications.
- Quanterix' Simoa technology powered the largest and most diverse global investigation in the role of plasma neurofilament light (NfL) for dementia diagnosis, published in Nature Communications. The research marks the most robust effort to date to assess the use of NfL in blood to screen for neurodegeneration as a cause of cognitive symptoms, to differentiate among neurodegenerative disorders and distinguish psychiatric disorders, and to derive age-related concentration cutoffs that may help to maximize plasma NfL's usefulness in a clinical setting.
- Data presented at the 2021 Clinical Trials on Alzheimer's Disease (CTAD) conference described a prototype Simoa plasma pTau-231 assay and its potential role in detecting Alzheimer's disease pathology. This emerging biomarker allows for detection even earlier in the disease continuum, when patients are asymptomatic and not yet exhibiting brain pathology in PET imaging studies.
- The Company welcomed Masoud Toloue, with a high growth track record from PerkinElmer, to the position of President of Quanterix and Diagnostics. The Company subsequently accounced its executive transition plan as noted above. The Company also appointed Michael Doyle, a strong financial executive with deep public company experience, to the position of Chief Financial Officer and Treasurer. Laurie Olson, a seasoned industry executive who brings more than three decades of experience in commercial and corporate strategy from Pfizer, Inc., joined Quanterix' Board of Directors.
- Quanterix was named a finalist for the Deloitte Fast 500 list, which ranks the fastest-growing technology, media, telecommunications and life sciences companies based in North America. The annual ranking is based on percentage revenue growth over the Company's last three fiscal years.
- Academic publication pull-through performance continued to be strong. Quanterix' Simoa technology was highlighted in a record 465 new publications in 2021, bringing total Simoa-specific inclusions to over 1,585.

Conference Call

In conjunction with this announcement, Quanterix Corporation will host a conference call on March 1, 2022 at 8:30 a.m. EST. Individuals interested in listening to the conference call may do so by dialing (833) 686-9351 for domestic callers, or (612) 979-9890 for international callers. Please reference the following Conference ID: 5230769.

A live webcast will also be available at: https://edge.media-server.com/mmc/p/udpgv5ou. You may also access the live webcast by visiting the News & Events page within the Investors section of the Quanterix website at www.quanterix.com. The webcast will be available on the Company's website for one year following completion of the call.

Financial Highlights *(in thousands)*

Quanterix Income Statement

in '000 USD	**Q4 2021**	**Q4 2020**	**YTD 2021**	**YTD 2020**
Product Revenue	23,476	15,732	81,062	44,017
Service and Other Revenue	5,674	5,498	23,629	24,129
Collaboration and License Revenue	162	408	648	11,809
Development Revenue	975	4,493	5,217	6,422
Total Revenue	**30,287**	**26,131**	**110,556**	**86,377**

Cost of Product Revenue	9,916	7,961	34,149	25,950
Cost of Services Revenue	4,110	3,120	14,679	11,245
Cost of collaboration and license revenue	0	0	0	1,000
Gross Profit	**16,261**	**15,050**	**61,728**	**48,182**
Gross Margin %	53.7%	57.6%	55.8%	55.8%
Research and Development	7,734	6,217	27,978	20,174
Selling, General and Administrative	28,423	18,766	92,336	59,592
Total Operating Expenses	**36,157**	**24,983**	**120,314**	**79,766**
Loss From Operations	**-19,896**	**-9,933**	**-58,586**	**-31,584**
Interest Income (Expense), net	15	-166	-403	-273
Other (Expense) Income, net	-213	155	1,265	-49
Tax	68	123	36	376
Net Loss	**-20,026**	**-9,821**	**-57,688**	**-31,530**

Weighted average shares outstanding was 36.7 million for Q4 2021 and 36.0 million for YTD 2021.

Quanterix Balance Sheet

in '000 USD	**At 12/31/21**	**At 12/31/20**
Cash and Cash Equivalents	396,465	181,584
Accounts Receivable	23,786	17,184
Inventory	22,190	14,856
Prepaid Expenses and Other	6,514	5,981
Total Current Assets	**448,955**	**219,605**
Restricted Cash	2,577	1,000
Property and Equipment, Net	17,960	13,912
Intangible Assets, Net	10,534	13,716
Goodwill	9,632	10,460
Right-of-Use Assets	11,491	11,995
Other Non-Current Assets	378	357

Total Assets	**501,527**	**271,045**
Accounts Payable & Accrued Expenses	28,947	22,421
Deferred Revenue	6,361	5,421
Current Portion of Long Term Debt	0	7,673
Lease Liabilities	1,428	1,234
Other Current Liabilities	241	3,054
Total Current Liabilities	**36,977**	**39,803**
Deferred Revenue, Net of Current Portion	1,099	577
Lease Liabilities, Net of Current Portion	20,464	21,891
Other Non-Current Liabilities	2,035	2,649
Total Liabilities	**60,575**	**64,920**
Total Stockholders' Equity	**440,952**	**206,125**
Total Liabilities and Stockholders' Equity	**501,527**	**271,045**

Use of Non-GAAP Financial Measures

To supplement the Company's financial statements presented on a GAAP basis, the Company has provided certain non-GAAP financial measures, including non-GAAP revenue and non-GAAP gross margin. Management uses these non-GAAP measures to evaluate the Company's operating performance in a manner that allows for meaningful period-to-period comparison and analysis of trends in its business. Management believes that such measures are important in comparing current results with prior period results and are useful to investors and financial analysts in assessing the Company's operating performance. The non-GAAP financial information presented here should be considered in conjunction with, and not as a substitute for, the financial information presented in accordance with GAAP. Investors are encouraged to review the reconciliation of these non-GAAP measures to their most directly comparable GAAP financial measures set forth below.

Reconciliation of non-GAAP Financials

(In thousands)

	2021	**2020**	**2021**	**2020**
	Three months ended December 31		**Twelve months ended December 31**	
Total revenue	$ 30,287	$ 26,131	$ 110,556	$ 86,377
Grant revenue (Note 1)	$ (975)	$ (4,493)	$ (5,217)	$ (6,422)
License agreement revenue (Note 2)	$ -	$ -	$ -	$ (11,200)
Non-GAAP revenue	$ 29,312	$ 21,638	$ 105,339	$ 68,755

Gross profit	$ 16,261	$ 15,050	$ 61,728	$ 48,182
Grant revenue (Note 1)	$ (975)	$ (4,493)	$ (5,217)	$ (6,422)
License agreement revenue (Note 2)	$ -	$ -	$ -	$ (11,200)
Acquisition-related purchase accounting charges (Note 3)	$ 382	$ 433	$ 1,804	$ 2,251
Cost of license revenue (Note 4)	$ -	$ -	$ -	$ 1,000
Non-GAAP gross profit	$ 15,668	$ 10,990	$ 58,315	$ 33,811
GAAP gross margin %	53.7 %	57.6 %	55.8 %	55.8 %
Non-GAAP gross margin %	53.5 %	50.8 %	55.4 %	49.2 %
GAAP total operating expenses	$ 36,157	$ 24,983	$ 120,314	$ 79,766
Grant research and development expenses (Note 5)	$ -	$ (2,322)	$ (3,355)	$ (3,625)
Acquisition-related purchase accounting charges (Note 6)	$ (20)	$ (20)	$ (80)	$ (81)
Non-GAAP total operating expenses	$ 36,137	$ 22,641	$ 116,879	$ 76,060
GAAP loss from operations	$ (19,896)	$ (9,933)	$ (58,586)	$ (31,584)
Non-GAAP loss from operations	$ (20,469)	$ (11,651)	$ (58,564)	$ (42,249)

Note 1: During the three months ended December 31, 2021, we recognized $1.0 million in revenue in connection with our workplan 2 award under the National Institute of Health Rapid Acceleration of Diagnostics Program. During the twelve months ended December 31, 2021, we recognized $5.2 million in revenue in connection with our workplan 2 award under the National Institute of Health Rapid Acceleration of Diagnostics Program. During the three months ended December 31, 2020, we recognized $4.5 million in revenue in connection with our workplan 1 and workplan 2 awards under the National Institute of Health Rapid Acceleration of Diagnostics Program. During the twelve months ended December 31, 2020, we recognized $6.4 million in revenue in connection with our workplan 1 and workplan 2 awards under the National Institute of Health Rapid Acceleration of Diagnostics Program.

Note 2: During the twelve months ended December 31, 2020, we recognized $10.0 million in license revenue in connection with a non-exclusive license agreement with Abbott Laboratories. Also, during the twelve months ended December 31, 2020, we recognized $1.2 million of previously deferred license revenue as a result of entering into the license agreement with Abbott Laboratories.

Note 3: During the three months ended December 31, 2021, we incurred $382 thousand of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics. During the twelve months ended December 30, 2021, we incurred $274 thousand of acquisition-related amortization of inventory valuation and $1,530 thousand of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics. During the three months ended December 31, 2020, we incurred $51 thousand of acquisition-related amortization of inventory valuation and $382 thousand of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics. During the twelve months ended December 31, 2020, we incurred $722 thousand of acquisition-related amortization of inventory valuation and $1,529 thousand of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics.

Note 4: During the twelve months ended December 31, 2020, we incurred $1.0 million in license fees in connection with our non-exclusive license agreement with Abbott Laboratories.

Note 5: During the twelve months ended December 31, 2021, we incurred $3.4 million in research and development expenses in connection with our workplan 2 award under the National Institute of Health Rapid Acceleration of Diagnostics Program. During the three months ended December 31, 2020, we incurred $2.3 million in research and development expenses in connection with our workplan 1 and workplan 2 awards under the National Institute of Health Rapid Acceleration of Diagnostics Program. During the twelve months ended December 31, 2020, we incurred $3.6 million in research and development expenses in connection with our workplan 1 and workplan 2 awards under the National Institute of Health Rapid Acceleration of Diagnostics Program.

Note 6: During the three and twelve months ended December 31, 2021, we incurred $20 thousand and $80 thousand, respectively, of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics. During three and twelve months ended December 31, 2020, we incurred $20 thousand and $81 thousand, respectively, of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics.

About Quanterix

Quanterix is a company that's digitizing biomarker analysis with the goal of advancing the science of precision health. The company's digital health solution, Simoa, has the potential to change the way in which healthcare is provided today by giving researchers the ability to closely examine the continuum from health to disease. Quanterix' technology is designed to enable much earlier disease detection, better prognoses and enhanced treatment methods to improve the quality of life and longevity of the population for generations to come. The technology is currently being used for research applications in several therapeutic areas, including oncology, neurology, cardiology, inflammation and infectious disease. The company was established in 2007 and is located in Billerica, Massachusetts. For additional information, please visit https://www.quanterix.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this news release are based on Quanterix' expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause Quanterix' actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Quanterix' filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Quanterix assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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