Quanterix Corporation Releases Operating Results for Third Quarter of 2021

November 4, 2021

Third quarter revenue driven by unprecedented growth in consumables (+98% vs PY) and instruments (+44% vs PY)

BILLERICA, Mass.--(BUSINESS WIRE)--Nov. 4, 2021-- 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 three months ending September 30, 2021.

"We are making critical advances across neurology and infectious disease with recent breakthrough device designation for an Alzheimer's blood test and expanded EUA label for a COVID-19 test by the U.S. FDA," said Kevin Hrusovsky, Chairman and Chief Executive Officer, Quanterix. "Our Simoa phospho-Tau 181 (pTau-181) blood test is a critical potential aid in the diagnostic evaluation of Alzheimer's disease, in particular by unlocking the possibility for earlier, more accessible, higher-throughput, non-invasive diagnosis to enable advances in neuro-diagnostic therapies. Furthermore, our label expansion for our Simoa SARS-CoV-2 N Protein Antigen Test demonstrates yet another example of Simoa's potential for achieving asymptomatic and low-invasive clinical testing."

Third Quarter 2021 Financial Highlights

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

- Q3 GAAP total revenue, which includes grant revenue of $1.0M, was $27.7M versus prior year Q3 of $31.4M; prior year Q3 included one-time license revenue of $11.2M and grant revenue of $1.9M;
- Q3 non-GAAP total revenue was $26.7M versus prior year Q3 non-GAAP total revenue of $18.3M, an increase of 46%;
- Q3 GAAP product revenue was $20.7M versus prior year Q3 of $11.7M, an increase of 77%;
- Q3 GAAP service and other revenue was $5.9M versus prior year Q3 of $6.6M, a decrease of 10% over a strong 2020 driven by one time COVID-related services; our two year CAGR (Q319 - Q321) for services is 18%; and
- Q3 GAAP gross margin was 55.1% versus prior year Q3 GAAP gross margin of 67.2%; Q3 non-GAAP gross margin was 54.8% versus prior year Q3 non-GAAP gross margin of 51.5%.

YTD 2021 Financial Highlights

Key financial results for YTD 2021 are shown below:

- YTD GAAP total revenue, which includes grant revenue of $4.2M, was $80.3M versus prior year YTD of $60.2M; prior year YTD included one-time license revenue of $11.2M and grant revenue of $1.9M;
- YTD non-GAAP total revenue was $76.0M versus prior year YTD non-GAAP total revenue of $47.1M, an increase of 61%;
- YTD GAAP product revenue was $57.6M versus prior year YTD of $28.3M, an increase of 104%;
- YTD GAAP service and other revenue was $18.0M, versus prior year YTD of $18.6M, a decrease of 4% over a strong 2020 driven by one time COVID-related services; our two year CAGR (YTD19 - YTD21) for services is 24%; and
- YTD GAAP gross margin was 56.6% versus prior year YTD GAAP gross margin of 55.0%; YTD non-GAAP gross margin was 56.1% versus prior year YTD non-GAAP gross margin of 48.4%.

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

Third Quarter 2021 Business Highlights

- 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 pTau-217 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;
- Hosted the webinar: COVID-19 Testing in a Residential University Setting with leading pathologist Dr. John Roback, M.D., Ph.D., Professor of Pathology and Laboratory Medicine, Executive Vice-Chair for Clinical Operations, and Medical Director for Emory Medical Laboratories, that discussed implementation of a broad SARS-CoV-2 screening program for Emory students, faculty and staff, enabling a safe return to campus-based learning. To date, Emory has run over 120,000 tests

using the Simoa SARS-CoV-2 N Protein Antigen Test;

- Co-hosted the webinar, Cytokine Profiles and Personalized Therapeutics in COVID-19 Patients with Guy Gorochov, M.D., Ph.D., Professor of Medicine, Head of the Dept. of Immunology and Co-Director CIMI Research Centre, Sorbonne University/INSERM and Laurel Provencher, Ph.D., Sr. Director of Strategic Collaborations, Quanterix, who discussed recently published observations that describe distinct cytokine profiles and COVID-19 severity and mortality;
- Kevin Hrusovsky delivered a presentation at the Second Annual Biomarkers for Alzheimer's Disease Conference on Aug. 26 with Nicholas Ashton, Ph.D., Assistant Professor, Department of Psychiatry & Neurochemistry, University of Gothenburg. The presentation discussed key features of assay development of plasma pTau-181 and pTau-231 on the Simoa platform, provided an overview of plasma pTau across the AD continuum and featured head-to-head comparisons of pTau plasma biomarkers;
- Delivered a presentation at the Precision Medicine Leaders' Summit on transforming cancer detection with biomarker technology; and
- Quanterix Simoa technology was highlighted in 125 new publications, bringing total Simoa-specific inclusions to more than 1,480 publications.

Conference Call

In conjunction with this announcement, Quanterix Corporation will host a conference call on November 4, 2021 at 4:30 p.m. EDT. 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: 3488875.

A live webcast will also be available at: https://edge.media-server.com/mmc/p/bpkzrdsj. The webcast will be available on the Company's website, http://www.quanterix.com, for one year following completion of the call.

Financial Highlights *(in thousands)*

Quanterix Income Statement

in '000 USD	**Q3 2021**	**Q3 2020**	**YTD 2021**	**YTD 2020**
Product Revenue	20,662	11,662	57,586	28,285
Service and Other Revenue	5,898	6,552	17,955	18,631
Collaboration and License Revenue	120	11,246	486	11,401
Development Revenue	1,009	1,929	4,242	1,929
Total Revenue	**27,689**	**31,389**	**80,269**	**60,246**
Cost of Product Revenue	8,639	6,387	24,233	17,989
Cost of Services Revenue	3,806	2,896	10,569	8,125
Cost of collaboration and license revenue	0	1,000	0	1,000
Gross Profit	**15,244**	**21,106**	**45,467**	**33,132**
Gross Margin %	55.1%	67.2%	56.6%	55.0%
Research and Development	6,807	5,377	20,244	13,957

Selling, General and Administrative	23,670	13,451	63,913	40,826
Total Operating Expenses	**30,477**	**18,828**	**84,157**	**54,783**
(Loss) Income From Operations	**-15,233**	**2,278**	**-38,690**	**-21,651**
Interest Expense, net	-90	-160	-418	-107
Other (Expense) Income, net	-305	-26	1,478	-204
Tax	-33	111	-32	253
Net (Loss) Income	**-15,661**	**2,203**	**-37,662**	**-21,709**

Weighted average shares outstanding was 36.5 million for Q3 2021 and 35.8 million for YTD 2021.

Quanterix Balance Sheet

in '000 USD	**At 9/30/21**	**At 12/31/20**
Cash and Cash Equivalents	410,747	181,584
Accounts Receivable	18,434	17,184
Inventory	22,794	14,856
Prepaid Expenses and Other	7,454	5,981
Total Current Assets	**459,429**	**219,605**
Restricted Cash	1,658	1,000
Property and Equipment, Net	16,466	13,912
Intangible Assets, Net	11,374	13,716
Goodwill	9,903	10,460
Right-of-Use Assets	11,626	11,995
Other Non-Current Assets	384	357
Total Assets	**510,840**	**271,045**
Accounts Payable & Accrued Expenses	20,875	22,421
Deferred Revenue	5,743	5,421

Current Portion of Long Term Debt	1,993	7,673
Lease Liabilities	1,374	1,234
Other Current Liabilities	1,205	3,054
Total Current Liabilities	**31,190**	**39,803**
Deferred Revenue, Net of Current Portion	929	577
Lease Liabilities, Net of Current Portion	20,845	21,891
Other Non-Current Liabilities	2,362	2,649
Total Liabilities	**55,326**	**64,920**
Total Stockholders' Equity	**455,514**	**206,125**
Total Liabilities and Stockholders' Equity	**510,840**	**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		**Nine months ended**	
	September 30		**September 30**	
Total revenue	$ 27,689	$ 31,389	$ 80,269	$ 60,246
Grant revenue (Note 1)	$ (1,009)	$ (1,929)	$ (4,242)	$ (1,929)
License agreement revenue (Note 2)	$ -	$ (11,200)	$ -	$ (11,200)
Non-GAAP revenue	$ 26,680	$ 18,260	$ 76,027	$ 47,117
Gross profit	$ 15,244	$ 21,106	$ 45,467	$ 33,132
Grant revenue (Note 1)	$ (1,009)	$ (1,929)	$ (4,242)	$ (1,929)

License agreement revenue (Note 2)	$ -	$ (11,200)	$ -	$ (11,200)
Acquisition-related purchase accounting charges (Note 3)	$ 382	$ 422	$ 1,422	$ 1,818
Cost of license revenue (Note 4)	$ -	$ 1,000	$ -	$ 1,000
Non-GAAP gross profit	$ 14,617	$ 9,399	$ 42,647	$ 22,821
GAAP gross margin %	55.1 %	67.2 %	56.6 %	55.0 %
Non-GAAP gross margin %	54.8 %	51.5 %	56.1 %	48.4 %
GAAP total operating expenses	$ 30,477	$ 18,828	$ 84,157	$ 54,783
Grant research and development expenses (Note 5)	$ (461)	$ (1,302)	$ (3,355)	$ (1,302)
Acquisition-related purchase accounting charges (Note 6)	$ (20)	$ (20)	$ (60)	$ (61)
Non-GAAP total operating expenses	$ 29,996	$ 17,505	$ 80,742	$ 53,420
GAAP (loss) income from operations	$ (15,233)	$ 2,278	$ (38,690)	$ (21,651)
Non-GAAP loss from operations	$ (15,379)	$ (8,107)	$ (38,095)	$ (30,599)

Note 1: During the three months ended September 30, 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 nine months ended September 30, 2021, we recognized $4.2 million in revenue in connection with our workplan 2 award under the National Institute of Health Rapid Acceleration of Diagnostics Program. During the three and nine months ended September 30, 2020, we recognized $1.9 million in revenue in connection with our workplan 1 award under the National Institute of Health Rapid Acceleration of Diagnostics Program.

Note 2: During the three and nine months ended September 30, 2020, we recognized $10.0 million in license revenue in connection with a non-exclusive license agreement with Abbott Laboratories. Also, during the three and nine months ended September 30, 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 September 30, 2021, we incurred $382 thousand of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics. During the nine months ended September 30, 2021, we incurred $274 thousand of acquisition-related amortization of inventory valuation and $1,148 thousand of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics. During the three months ended September 30, 2020, we incurred $40 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 nine months ended September 30, 2020, we incurred $671 thousand of acquisition-related amortization of inventory valuation and $1,147 thousand of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics.

Note 4: During the three and nine months ended September 30, 2020, we incurred $1.0 million in license fees in connection with our non-exclusive license agreement with Abbott Laboratories.

Note 5: During the three months ended September 30, 2021, we incurred $461 thousand 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 nine months ended September 30, 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 and nine months ended September 30, 2020, we incurred $1.3 million in research and development expenses in connection with our workplan 1 award under the National Institute of Health Rapid Acceleration of Diagnostics Program.

Note 6: During the three and nine months ended September 30, 2021, we incurred $20 thousand and $60 thousand, respectively, of acquisition-related amortization of intangible assets adjustments in connection with our acquisition of UmanDiagnostics. During three and nine months ended September 30, 2020, we incurred $20 thousand and $61 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20211104006272/en/

Media Contact:
PAN Communications
Paige Romine, 321-652-8370
pan.quanterix@pancomm.com

Investor Relations Contact:
Stephen Hrusovsky
(774) 278-0496
shrusovsky@quanterix.com

Source: Quanterix