August 14, 2020

Qualigen Therapeutics Announces Business Highlights and First Quarter Fiscal Year 2021 Financial Results; Has $16 Million in Cash on Hand as of Today

CARLSBAD, Calif., Aug. 14, 2020 /PRNewswire/ -- **Qualigen Therapeutics, Inc.** (NASDAQ: QLGN) (Qualigen or the Company) today announced business highlights and financial results for the fiscal year 2021 first quarter, ended June 30, 2020.

Business highlights for the fiscal first quarter and recent weeks include the following:

- **Raised a total of $18 million in new equity financing.**Under separate purchase agreements in July and August 2020, the Company raised a total of $18 million in cash (before expenses) from registered-direct placements of common stock and warrants with a single institutional investor. As of today, the Company has $16 million in cash and cash equivalents. The Company believes its cash and cash equivalents are sufficient to fund its operations into calendar 2022.

- **Signed exclusive license agreement with the University of Louisville for RAS interaction inhibitor drug candidates.** In July 2020, Qualigen signed an exclusive worldwide license agreement with the University of Louisville (UofL) for the intellectual property covering the RAS-F family of RAS oncogene protein-protein interaction inhibitor small molecule drug candidates. The Company will evaluate these patent-pending compounds in order to identify a lead drug candidate for further development against one or more cancers.

- **Signed exclusive license agreement with the University of Louisville, with plans to develop AS1411 for the treatment of COVID-19.** In June 2020, the Company signed an exclusive license agreement with the UofL to facilitate development of Qualigen's AS1411 DNA aptamer as a drug candidate for the treatment of COVID-19, the disease caused by the novel coronavirus SARS-CoV-2.

- **Engaged NFL Hall of Famer Mike Haynes as advisor to the Company and spokesperson for the FastPack® rapid diagnostic system.** In July 2020, the Company engaged Pro Football Hall of Fame and College Football Hall of Fame inductee Mike Haynes as an advisor to the Company and as spokesperson for Qualigen's FastPack rapid diagnostic system. Since receiving an elevated PSA test result using a FastPack immunoassay test at a 2008 Hall of Fame event sponsored by Qualigen and the American Urological Association, Mr. Haynes has been a prominent advocate for prostate cancer testing.

- **Commenced commercial shipments of its FastPack COVID-19 antibody test.** In

July 2020, Qualigen announced it began commercial shipments of its FastPack SARS-CoV-2 IgG diagnostic test for COVID-19 antibodies. This test has been submitted to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA), and previously the Company submitted an official notification to the FDA of its plans to exercise its right to commence sales while the EUA is pending.

- **Received U.S. patent Notice of Allowance for its STARS™ technology.** In June 2020, the United States Patent and Trademark Office issued Qualigen a Notice of Allowance for a U.S. patent titled "Devices and Methods for On-Line Whole Blood Treatment" regarding the Company's Selective Target Antigen Removal System (STARS) technology. STARS is a DNA/RNA-based treatment product candidate for the removal of viral and tumor-produced compounds from a patient's blood.

Management Commentary

"I am pleased with the significant progress Qualigen has made since our May 2020 reverse recapitalization transaction to expand and advance our development programs," stated Michael Poirier, President and Chief Executive Officer of Qualigen. "We recently raised $18 million in capital, which we will use to advance our therapeutic pipeline of promising cancer and infectious disease drug candidates, including AS1411, ALAN and RAS-F, as well as to further our FastPack diagnostics platform."

First Quarter Financial Results

Total revenues for the three months ended June 30, 2020 were $0.9 million compared with $1.5 million for the same period in 2019. The decrease was primarily due to the COVID-19 pandemic resulting in a decrease in patient visits to physician offices, clinics and small hospitals, which reduced the number of FastPack tests performed. All revenues in both periods were derived from diagnostic products.

General and administrative expense was $2.0 million for the three months ended June 30, 2020 compared with $0.3 million for the prior-year period. The increase is largely attributable to one-time expenses related to the reverse recapitalization transaction and other public company expenses not incurred in the prior-year period.

Total R&D expense was $0.6 million for the three months ended June 30, 2020 compared with $0.7 million for the prior-year period. Higher expenses related to sponsored therapeutics research at the University of Louisville and COVID-19 antibody diagnostic test development were offset by the absence in the 2020 period of related-party research and development costs associated with a diagnostics development project with Sekisui Diagnostics, LLC which was terminated in May 2019.

Loss from operations for the three months ended June 30, 2020 increased to $2.6 million from a $0.5 million loss from operations for the prior-year period. Net loss for the three months ended June 30, 2020 was $18.6 million, or $2.12 per share, compared with a net loss of $0.6 million, or $0.11 per share, for the same period of 2019. Net loss for the three months ended June 30, 2020 included a non-cash charge of $16.2 million for the fair value of warrant liabilities.

Qualigen had cash and cash equivalents of $2.3 million as of June 30, 2020. Subsequent to

the close of the quarter, in July and August 2020 the Company raised an additional $18 million in gross proceeds from registered-direct equity offerings.

Conference Call

Qualigen senior management will host a business update conference call and live audio webcast beginning at 4:30 p.m. Eastern time on August 18, 2020. Participants are encouraged to pre-register for the conference call using this link. Callers who pre-register will be given a conference passcode and unique PIN to gain immediate access to the call and bypass the live operator. Participants may register at any time, including up to and after the call start time. A webcast of the call may also be accessed at Qualigen's Investor Relations page at Qualigen Business Update Conference Call. Those without internet access or unable to pre-register may dial in by calling 1-866-777-2509 (U.S.) or 1-412-317-5413 (International).

A replay of the webcast will be available beginning approximately one hour after the completion of the live conference call at Qualigen Business Update Conference Call. A dial-in replay of the call will be available until August 25, 2020 by calling 1-877-344-7529 (U.S.) or 1-412-317-0088 (International) and providing the passcode 10147089.

About Qualigen Therapeutics, Inc.

Qualigen Therapeutics, Inc. is a biotechnology company focused on developing novel therapeutics for the treatment of cancer and infectious diseases, as well as maintaining and expanding its core FDA-approved FastPack System, which has been used successfully in diagnostics for almost 20 years. The Company's cancer therapeutics pipeline includes ALAN (AS1411-GNP), RAS-F and STARS. ALAN (AS1411-GNP) is a DNA coated gold nanoparticle cancer drug candidate that has the potential to target various types of cancer with minimal side effects. The foundational aptamer of ALAN, AS1411, is also being studied for use in treating viral-based infectious diseases, including COVID-19. RAS-F is a family of RAS oncogene protein-protein interaction inhibitor small molecules for preventing mutated RAS genes' proteins from binding to their effector proteins; preventing this binding could stop tumor growth, especially in pancreatic, colorectal and lung cancers. STARS is a DNA/RNA-based treatment device candidate for removal from circulating blood of precisely targeted tumor-produced and viral compounds. Because Qualigen's therapeutic candidates are still in the development stage, Qualigen's only products that are currently commercially available are FastPack System diagnostic instruments and test kits, used in physician offices, clinics and small hospitals around the world. The FastPack System menu includes rapid point-of-care diagnostic tests for cancer, men's health, hormone function, vitamin D status and antibodies against SARS-CoV-2. Qualigen's facility in Carlsbad, California is FDA and ISO Certified and its FastPack product line is sold worldwide by its commercial partner Sekisui Diagnostics, LLC. For more information on Qualigen Therapeutics, Inc., please visit https://www.qualigeninc.com/.

Forward-Looking Statements

This news release contains forward-looking statements by the Company that involve risks and uncertainties and reflect the Company's judgment as of the date of this release. These statements include those related to cash burn estimates and potential future development, testing and launch of product candidates. Actual events or results may differ from the

Company's expectations. For example, there can be no assurance that the Company will successfully develop any drugs or therapeutic devices; that preclinical or clinical development of the Company's drugs or therapeutic devices will be successful; that clinical trials will be approved to begin by or will proceed as contemplated by any projected timeline; that future clinical trial data will be favorable or that such trials will confirm any improvements over other products or lack negative impacts; that any drugs or therapeutic devices will receive required regulatory approvals or that they will be commercially successful; that patents will issue on the Company's in-licensed patent applications; that such patents, if any, and the Company's current owned and in-licensed patents would prevent competition; that the Company will be able to procure or earn sufficient working capital to complete the development, testing and launch of the Company's prospective therapeutic products; that the Company will be able to maintain or expand market demand and/or market share for the Company's diagnostic products generally, particularly in view of COVID-19-related deferral of patients' physician-office visits and FastPack reimbursement pricing challenges; that adoption and placement of FastPack PRO System instruments (which are the only FastPack instruments on which the Company's SARS-CoV-2 IgG test kits can be run) will be widespread; that the Company will be able to manufacture the FastPack PRO System instruments and SARS-CoV-2 IgG test kits successfully; that any commercialization of the FastPack PRO System instruments and SARS-CoV-2 IgG test kits will be profitable; or that the FDA will ultimately approve an EUA for the Company's SARS-CoV-2 IgG test. The Company's stock price could be harmed if any of the events or trends contemplated by the forward-looking statements fails to occur or is delayed or if any actual future event otherwise differs from expectations. Additional information concerning these and other risk factors affecting the Company's business (including events beyond the Company's control, such as epidemics and resulting changes) can be found in the Company's prior filings with the Securities and Exchange Commission, available at www.sec.gov. The Company disclaims any intent or obligation to update these forward-looking statements beyond the date of this news release, except as required by law. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

[Tables to Follow]

QUALIGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,	
	2020	**2019**
REVENUES		
Net product sales	$ 484,423	$ 560,651
Net product sales—related party	419,644	950,184
Total revenues	904,067	1,510,835
EXPENSES		
Cost of product sales	355,427	316,513
Cost of product sales—related party	452,495	661,267
General and administrative	1,979,614	269,017
Research and development	597,345	147,641
Research and development—related party	—	539,425
Sales and marketing	88,844	102,394

Total expenses	3,473,725	2,036,257
LOSS FROM OPERATIONS	(2,569,658)	(525,422)
OTHER EXPENSE (INCOME), NET		
Change in fair value of warrant liabilities	16,201,400	—
Interest expense, net	57,364	69,985
Other income, net	(250,114)	(992)
Total other expense (income), net	16,008,650	68,993
LOSS BEFORE PROVISION FOR INCOME TAXES	(18,578,308)	(594,415)
PROVISION FOR INCOME TAXES	597	150
NET LOSS	$ (18,578,905)	$ (594,565)
Net loss per common share, basic and diluted	$ (2.12)	$ (0.11)
Weighted—average number of shares outstanding, basic and diluted	8,746,250	5,602,214

QUALIGEN THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2020	March 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,306,422	$ 153,121
Restricted cash	75,696	—
Accounts receivable, net	282,170	417,122
Accounts receivable — related party, net	55,292	290,180
Inventory, net	640,260	660,138
Prepaid expenses and other current assets	2,318,057	98,385
Total current assets	5,677,897	1,618,946
Right-of-use asset	535,194	—
Property and equipment, net	1,547,380	1,447,514
Equipment held for lease, net	45,411	64,005
Intangible assets, net	855,132	571,270
Other assets	18,279	18,279
Total Assets	$ 8,679,293	$ 3,720,014
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 892,182	$ 879,264
Accrued expenses and other current liabilities	1,315,899	1,243,764
Notes payable, current portion	1,106,518	1,913,255
Deferred revenue, current portion	69,571	105,416

Deferred revenue — related party	271,206	271,206
Due to related party	1,144,513	926,385
Lease liability	239,549	—
Warrant liabilities	16,201,400	—
Total current liabilities	21,240,838	5,339,290
Notes payable, net of current portion	218,832	305,805
Lease liability, net of current portion	368,785	—
Deferred revenue, net of current portion	3,594	2,689
Total liabilities	21,832,049	5,647,784
Total stockholders' deficit	(13,152,756)	(1,927,770)
Total Liabilities and Stockholders' Deficit	$ 8,679,293	$ 3,720,014

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SOURCE Qualigen, Inc.