November 13, 2020

Qualigen Therapeutics Issues CEO Letter to Stockholders, Reports on Significant Progress and Fiscal Second Quarter Financial Results

CARLSBAD, Calif., Nov. 13, 2020 /PRNewswire/ --**Qualigen Therapeutics, Inc.** (Nasdaq: QLGN) announces that Michael Poirier, President, Chief Executive Officer and Chairman, has issued a letter to Qualigen's stockholders. The full text is as follows:

To My Fellow Stockholders,

Since our last business update in August, Qualigen Therapeutics has made significant progress in advancing our strategic plan, including the following highlights:

AS1411. We are excited to be moving forward with our lead compound AS1411, a nucleolin-targeting DNA aptamer drug candidate for the treatment of COVID-19 and other viruses. Preclinical research conducted at the University of Louisville (UofL) has demonstrated that AS1411 has potent antiviral activity against SARS-CoV-2, the coronavirus responsible for COVID-19. Importantly, we believe AS1411 holds potential as a broad antiviral therapeutic agent, which could significantly expand its applications and commercial potential.

In October 2020, we received a positive response to our Pre-Investigational New Drug (Pre-IND) application meeting request from the U.S. Food and Drug Administration (FDA) that is in general agreement with our planned clinical development of AS1411 for the treatment of COVID-19. We are pleased with the FDA's response and plan to move forward with filing the IND application in order to initiate a Phase 2a clinical trial in the first half of calendar year 2021.

Like everyone else, we are heartened by news of recent advancements with COVID-19 vaccines; however, we believe there will still be a long-term and significant market opportunity for innovative therapies such as AS1411 to treat COVID-19 and other viral-based respiratory diseases. Furthermore, we believe that the urgency placed on regulators to advance potential therapies for COVID-19, in addition to vaccines, may provide us an accelerated path to potential approval of our first drug candidate. The data and infrastructure resulting from this may, in turn, serve to streamline subsequent clinical trials for additional indications for AS1411 to combat other viruses, both currently known and those that might affect us in the future.

In this regard, we entered into manufacturing agreements with STA Pharmaceutical Co., Ltd., a subsidiary of WuXi AppTec, and with IRISYS LLC in order to ensure adequate supply of AS1411 for our anticipated clinical trials. We believe that if AS1411 is approved by the FDA for commercial usage, these manufacturing agreements will help assure an efficient

and large-scale rollout of this product.

Finally, to further enhance our AS1411 intellectual property portfolio, we jointly filed a U.S. provisional patent application entitled "Methods of inhibiting or treating coronavirus infection, and methods for delivering an anti-nucleolin agent" with UofL. If AS1411 can successfully serve as a protective defense (or prophylaxis) against, as well as treat, COVID-19 or other viral-based diseases, such as seasonal influenza, this would be a very exciting usage for our technology. We believe that for use as a prophylaxis, AS1411 could be administered by means of inhalers, nose spray or eye drops to individuals who have recently come in contact with SARS-CoV-2, or are at high risk of contracting the virus.

ALAN, RAS-F and STARS™. The balance of our therapeutic pipeline primarily focuses on fighting cancer, and we continue to make progress with each of our drug and device candidates.

- **Expanded research agreement with UofL for ALAN cancer drug candidate.** In October 2020, we announced an amended sponsored research agreement with UofL to advance ALAN (the AS1411 aptamer attached to a gold nanoparticle). UofL will perform preclinical studies on acute myeloid leukemia and we aim to file an IND and initiate a Phase 1 clinical trial later in calendar year 2021. Additionally, UofL will perform studies on other indications including glioblastoma, a malignant brain cancer that is difficult to treat because most drugs cannot pass the blood-brain membrane, and non-small cell lung cancer, which comprises approximately 85% of the 1.6 million global lung cancer cases each year.

- **Signed exclusive license agreement with UofL for RAS interaction inhibitor drug candidates.** In July 2020, we signed an exclusive worldwide license agreement with UofL for the intellectual property covering the RAS-F family of RAS oncogene protein-protein interaction inhibitor small molecule drug candidates. We continue to work with UofL to evaluate these compounds and identify a lead drug candidate to stop tumor growth, especially in pancreatic, colorectal and lung cancers. Although drugs that target downstream signaling of RAS are available, they have shown limited clinical activity, most likely because RAS acts like a hub that activates multiple effectors. As such, blocking any single pathway, or even two, typically provides disappointing clinical effect. By contrast, the intended mechanism of action for the RAS-F small molecules is to inhibit or block the binding of mutated RAS to their effector proteins, thereby leaving the proteins from mutated RAS unable to cause further harm.

- **Issuance of STARS technology U.S. patent.** In August 2020, the United States Patent and Trademark Office issued patent No. 10,744,258 entitled "Devices and Methods for On-Line Whole Blood Treatment" regarding our Selective Target Antigen Removal System (STARS) technology. STARS is a DNA/RNA-based treatment for the removal of viral and tumor-produced compounds from a patient's blood. While still early in development, this technology is based on the core, commercialized science behind our FastPack® products, and could have widespread application.

FastPack® diagnostic products. As of the date of this letter, communications with the FDA concerning the requested Emergency Use Authorization for our FastPack COVID-19 antibody test indicate that our regulatory review is still in queue. We are confident that the

data we have provided to the FDA show that our test meets or exceeds the efficacy guidelines for approval of an EUA, and we are frustrated by the unusually long delay. We still believe that a rapid, accurate, point-of-care testing system like FastPack would be beneficial as vaccines for COVID-19 – which generate antibodies for limited periods of time – begin release in 2021.

Furthermore, we have made important strategic moves recently to advance distribution and next-generation versions of our core FastPack "laboratory in a pouch" technology. In October 2020, we entered into a commercialization agreement with China's Yi Xin Zhen Duan Jishu (Suzhou) Ltd. for them to develop, manufacture and sell new generations of diagnostic test systems based on FastPack. In addition, Yi Xin Zhen Duan Jishu will have rights to manufacture and sell our current generations of FastPack products in China. We were pleased to enter this agreement as it provides non-dilutive upfront funding plus potential future royalties, and China is a region we would not otherwise have entered with FastPack.

Corporate updates. In August 2020, we welcomed Amy Broidrick to our Board of Directors. Ms. Broidrick's background includes key roles in the successful worldwide launches and marketing of such notable drugs as VYTORIN®, Zetia® and Celebrex®. It is already evident she will be a valuable asset to Qualigen given her expertise in corporate development, marketing and business innovation with global organizations, as well as with small-cap companies.

Lastly, to fund the continued development of our pipeline, we raised $18 million in two registered-direct offerings under separate purchase agreements in July and August 2020. With a cash balance of $14.5 million as of September 30, 2020, we believe Qualigen has the necessary capital to fund our clinical trial for AS1411 and to advance our pipeline through calendar year 2021. Additionally, we continue to be opportunistic and evaluate strategic relationships that provide potential to enhance our pipeline in oncology and build long-term shareholder value.

As I mentioned, we are delighted with our progress to date and are very excited about our momentum and Qualigen's future prospects. I would like to thank our employees for their outstanding efforts and commitment, and our investors for their continued support.

Sincerely,

Michael Poirier
President, Chief Executive Officer and Chairman

Financial Results for the Fiscal Second Quarter Ended September 30, 2020

Total revenues for the three months ended September 30, 2020 were $0.8 million compared with $1.2 million for the same period in 2019, with all revenues in both periods derived from the sale of diagnostic products. The decrease was primarily due to fewer tests performed as the COVID-19 pandemic resulted in a decrease in patient non-emergency visits to physician offices, clinics and small hospitals.

General and administrative expense was $2.7 million for the three months ended September 30, 2020 compared with $0.2 million for the prior-year period. The difference is largely

attributable to the addition of expenses associated with operating as a publicly traded company in the current period.

Research and development expense was $0.9 million for the three months ended September 30, 2020 compared with $0.2 million for the prior-year period. The increase is related to advancing Qualigen's therapeutic pipeline and work on its COVID-19 antibody diagnostic test and FastPack PRO instrument.

Loss from operations for the three months ended September 30, 2020 increased to $3.7 million from $0.3 million for the prior-year period. Net loss for the three months ended September 30, 2020 was $8.1 million, or $0.41 per share, compared with a net loss of $0.4 million, or $0.06 per share, for the same period of 2019. Net loss for the 2020 period included non-cash charges of $4.4 million related to the change in fair value of warrant liabilities, as well as additional non-cash charges totaling $1.2 million for stock-based compensation expense.

Financial Results for the Six Months Ended September 30, 2020

Total revenues for the six months ended September 30, 2020 were $1.7 million compared with $2.7 million for the same period in 2019, with all revenues in both periods derived from the sale of diagnostic products. The decrease was primarily due to fewer tests performed as the COVID-19 pandemic resulted in a decrease in patient non-emergency visits to physician offices, clinics and small hospitals.

General and administrative expense was $4.6 million for the six months ended September 30, 2020 compared with $0.5 million for the prior-year period. The increase is largely attributable to the addition of expenses associated with operating as a publicly traded company in the current period.

Research and development expense was $1.5 million for the six months ended September 30, 2020 compared with $0.9 million for the prior-year period. The difference is primarily related to increased spending for the therapeutic pipeline.

Loss from operations for the six months ended September 30, 2020 increased to $6.3 million from $0.8 million for the prior-year period. Net loss for the six months ended September 30, 2020 was $26.7 million, or $1.87 per share, compared with a net loss of $1.0 million, or $0.17 per share, for the same period of 2019. Net loss for the 2020 period included non-cash charges of $20.6 million related to the change in fair value of warrant liabilities, as well as additional non-cash charges totaling $1.6 million for stock-based compensation expense.

Qualigen had cash and cash equivalents of $14.5 million as of September 30, 2020, as a result of the $18 million in gross proceeds raised during the second quarter of fiscal year 2021. The Company believes its cash and cash equivalents are sufficient to fund its anticipated operations through calendar year 2021.

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 nucleolin-targeting DNA aptamer of ALAN, AS1411, is also being studied as a drug candidate for use in treating COVID-19 and other viral-based infectious diseases. 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 potential future development, testing, efficacy, approval, manufacturing and commercialization of product candidates, including the possible effectiveness of AS1411 against COVID-19 or other viral infections. Actual events or results may differ from the Company's expectations. For example, there can be no assurance that clinical trials will be approved to begin by or will proceed as contemplated by any projected timeline; 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 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 owned and 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 Emergency Use Authorization 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)

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
REVENUES				
Net product sales	$ 361,218	$ 526,865	$ 845,641	$ 1,087,516
Net product sales—related party	476,496	634,262	896,140	1,584,446
Collaborative research revenue	—	40,000	—	40,000
Total revenues	837,714	1,201,127	1,741,781	2,711,962
EXPENSES				
Cost of product sales	318,460	408,203	673,887	724,716
Cost of product sales—related party	603,015	603,890	1,055,510	1,265,157
General and administrative	2,664,658	202,679	4,644,272	471,696
Research and development	870,876	200,217	1,468,221	347,858
Research and development—related party	—	1,193	—	540,618
Sales and marketing	98,045	74,518	186,889	176,912
Total expenses	4,555,054	1,490,700	8,028,779	3,526,957
LOSS FROM OPERATIONS	(3,717,340)	(289,573)	(6,286,998)	(814,995)
OTHER EXPENSE (INCOME), NET				
Change in fair value of warrant liabilities	4,395,300	—	20,596,700	—
Interest expense, net	715	65,480	58,079	135,465
Other income, net	(2,447)	(248)	(252,561)	(1,240)
Total other expense (income), net	4,393,568	65,232	20,402,218	134,225
LOSS BEFORE PROVISION FOR INCOME TAXES	(8,110,908)	(354,805)	(26,689,216)	(949,220)

PROVISION FOR INCOME TAXES	2,305	1,420	2,902	1,570
NET LOSS	(8,113,213)	(356,225)	(26,692,118)	(950,790)
Net loss per common share, basic and diluted	$ (0.41)	$ (0.06)	$ (1.87)	$ (0.17)
Weighted—average number of shares outstanding, basic and diluted	19,799,468	5,602,214	14,303,058	5,602,214

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

	September 30, 2020	March 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 14,465,541	$ 153,121
Accounts receivable, net	179,870	417,122
Accounts receivable — related party, net	189,474	290,180
Inventory, net	805,383	660,138
Prepaid expenses and other current assets	1,925,446	98,385
Total current assets	17,565,714	1,618,946
Right-of-use asset	483,643	—
Property and equipment, net	1,565,275	1,447,514
Equipment held for lease, net	32,726	64,005
Intangible assets, net	1,009,453	571,270
Other assets	18,334	18,279
Total Assets	$ 20,675,145	$ 3,720,014
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 408,254	$ 879,264
Accrued expenses and other current liabilities	726,542	1,243,764
Notes payable, current portion	787,478	1,913,255
Deferred revenue, current portion	58,773	105,416
Deferred revenue — related party	95,160	271,206
Due to related party	176,046	926,385
Lease liability	247,050	—
Warrant liabilities	20,596,700	—
Total current liabilities	23,096,003	5,339,290
Notes payable, net of current portion	159,670	305,805
Lease liability, net of current portion	303,894	—
Deferred revenue, net of current portion	4,219	2,689
Total liabilities	23,563,786	5,647,784
Total stockholders' deficit	(2,888,641)	(1,927,770)

Total Liabilities and Stockholders' Deficit	$ 20,675,145	$ 3,720,014

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