August 17, 2021

Qualigen Therapeutics, Inc. Provides Update on Product Development Priorities and Reports Second Quarter and Six Month 2021 Financial Results

CARLSBAD, Calif.,, Aug. 17, 2021 (GLOBE NEWSWIRE) -- Qualigen Therapeutics, Inc. (Nasdaq: QLGN) today announces its intention to prioritize its focus to its oncology pipeline that includes QN-247 and RAS-F. These plans follow feedback the Company received from the United States Food and Drug Administration regarding Qualigen's investigational new drug (IND) application for one of its other compounds, QN-165, for the treatment of COVID-19 in hospitalized patients.

"Although the FDA requested that we perform additional pre-clinical toxicity and safety pharmacology studies before proceeding with clinical trials in COVID-19 patients, we believe that, given the time horizon which these suggested studies would require, coupled with the already very crowded COVID-19 vaccine and therapeutic landscape, the best and most prudent strategy for us at this time is to pivot to focusing primarily on our oncology pipeline that includes QN-247 and RAS-F assets for which we have already seen encouraging preclinical data," commented Michael Poirier, Qualigen's Chairman and Chief Executive Officer. "We appreciate the FDA's guidance regarding our approach to QN-165, which helps us to solidify our priority to address unmet medical needs in treating cancer patients. We look forward to sharing ongoing progress with our shareholders."

Qualigen also today announces its second quarter and six-months 2021 financial results and provides a recap of the highlights of the 2021 second quarter.

Highlights from the Quarter Ended June 30, 2021:

- Q2 revenues increased 24 percent to $1.1 million, compared to $0.9 million in the same quarter of the previous year
- First-half revenues increased 28 percent to $3.0 million, compared to $2.4 million in the same six month period of the previous year
- Cash equivalents of approximately $15.2 million at June 30, 2021
- Continued our license and sponsored research agreements with the University of Louisville to evaluate the use of QN-247 with G-quadruplex binders.
    - Qualigen plans to seek to obtain Orphan Drug status for QN-247 (with or without such binders) for one or more indications, such as pancreatic cancer, acute myeloid leukemia and pediatric neuroblastoma. Orphan Drug status, if obtained, would be expected to confer several advantages including faster review and

increased market protection.

- In May 2021, Qualigen announced that it had named Tariq Arshad, MD, MBA, to the newly-created position of Senior Vice President, Chief Medical Officer. Dr. Arshad brings more than 20 years of biotech and pharmaceutical experience to Qualigen.

- In June 2021, Qualigen announced that it was added to the Russell Microcap® Index. Membership in the Russell Microcap Index means automatic inclusion in certain growth and value indexes. FTSE Russell determines membership for its indexes primarily by objective, market-capitalization rankings as well as style attributes.

Second Quarter and Six Month Financial Highlights and Analysis

Revenues for the three months ended June 30, 2021 were $1.1 million compared to approximately $0.9 million in the same quarter of the previous year. Our 2021 second quarter revenues were all generated from sales of diagnostic tests. This product sales improvement was due to a recovery from the effects of the COVID-19 pandemic.

Revenues for the six month period ended June 30, 2021 were $3.0 million compared to $2.4 million in the same six month period of the previous year. This increase primarily resulted from the recognition during the first quarter of license revenue from Yi Xin Zhen Duan Jishu (Suzhou) Ltd. under a Technology Transfer Agreement, an item which had no counterpart during the prior year, as well as an increase in diagnostic product sales reflecting recovery from the effects of the COVID-19 pandemic.

For the three months ended June 30, 2021, we reported a net loss of $5.3 million, or $0.18 per share, compared to a net loss of $18.6 million, or $2.12 per share, for the corresponding period in 2020. Net loss for the three month 2020 period included non-cash charges of $16.2 million related to a change in fair value of warrant liabilities, compared to a non-cash gain of $2.1 million from change in fair value of warrant liabilities in the current three month period.

For the six months ended June 30, 2021, the Company reported a net loss of $9.0 million, or $0.31 per share, compared to a net loss of $19.5 million, or $2.71 per share, in the corresponding six month period in 2020. Net loss for the six month 2020 period included non-cash charges of $16.2 million related to a change in fair value of warrant liabilities, compared to a non-cash gain of $4.2 million from change in fair value of warrant liabilities in the current six month period.

License revenue during the six months ended June 30, 2021 was approximately $0.5 million, because of the recognition of license revenue from the Yi Xin transaction.

Research and development expenses increased to $4.5 million for the three months ended June 30, 2021, from $0.6 million for the three months ended June 30, 2020. This increase was primarily attributable to $3.4 million in expenses related to the potential application of QN-165 to treatment of COVID-19 during the quarter. Research and development expenses increased to $8.0 million for the six months ended June 30, 2021 from $0.8 million for the six months ended June 30, 2020. This increase was primarily due to $5.9 million in expenses related to the potential application of QN-165 to treatment of COVID-19, in addition to increased pre-clinical research and development costs for QN-247 and RAS as well as wind-down costs related to the withdrawn COVID-19 antibody diagnostic test and stock-based

compensation expense related to our public-company status.

General and administrative expenses increased to $3.0 million during the three months ended June 30, 2021, from $2.0 million during the three months ended June 30, 2020. General and administrative expenses increased to $5.8 million for the six months ended June 30, 2021, compared to $2.9 million during the six months ended June 30, 2020. The increases for both periods were primarily a result of overhead expenses related to our public-company status in contrast to our private-company status during most of the 2020 periods.

As of June 30, 2021, we had $15.2 million of cash and cash equivalents.

About Qualigen Therapeutics, Inc.

Qualigen Therapeutics, Inc.’s cancer therapeutics pipeline includes QN-247, RAS-F, and STARS. QN-247 (formerly referred to as ALAN) is a DNA coated gold nanoparticle cancer drug candidate that has the potential to target various types of cancer with minimal side effects; the nanoparticle coating technology is similar to the core nanoparticle coating technology used in our blood-testing diagnostic products. The foundational aptamer of QN-247, QN-165, is also a drug candidate for viral-based infectious diseases. (QN-165 was formerly referred to as AS1411.) 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.

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 the Company's prospects and strategy for the development of therapeutic drug candidates. Actual events or results may differ from the Company's expectations. For example, there can be no assurance that preclinical or clinical development of the Company's drugs (including QN-247 and RAS-F, and deprioritized infectious-disease programs such as QN-165) or therapeutic devices will be completed on any projected timeline or will be successful; that the FDA will approve any of the Company’s IND applications; that any 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 (including QN-247 and RAS-F) or therapeutic devices; 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 (including Orphan Drug status) 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 inlicensed 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 (including QN-247 and RAS-F, and any repositioning of QN-165); or that the Company will be able to maintain or expand market demand and/or market share for the Company's diagnostic products. 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 can be found in the Company's prior filings with the Securities and Exchange Commission, including its most recent Form 10-K, all of which 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.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
REVENUES				
Net product sales	$ 1,117,935	$ 904,067	$ 2,538,776	$ 2,315,823
License revenue	—	—	478,654	—
Collaborative research revenue	—	—	—	45,000
Total revenues	1,117,935	904,067	3,017,430	2,360,823
EXPENSES				
Cost of product sales	916,624	807,922	2,119,103	1,799,574
General and administrative	2,952,100	1,979,614	5,826,038	2,897,993
Research and development	4,508,466	597,345	8,007,840	835,403
Sales and marketing	135,543	88,844	272,129	181,106
Total expenses	8,512,733	3,473,725	16,225,110	5,714,076
LOSS FROM OPERATIONS	(7,394,798)	(2,569,658)	(13,207,680)	(3,353,253)
OTHER (INCOME) EXPENSE, NET				

Loss (gain) on change in fair value of warrant liabilities	(2,075,100)	16,201,400	(4,198,000)	16,201,400
Interest (income) expense, net	(12,718)	57,364	(30,061)	148,121
Other (income), net	(2,352)	(250,114)	(2,894)	(251,272)
Total other (income) expense, net	(2,090,170)	16,008,650	(4,230,955)	16,098,249
LOSS BEFORE PROVISION FOR INCOME TAXES	(5,304,628)	(18,578,308)	(8,976,725)	(19,451,502)
PROVISION (BENEFIT) FOR INCOME TAXES	605	597	1,135	(22)
NET LOSS	$ (5,305,233)	$ (18,578,905)	$ (8,977,860)	$ (19,451,480)
Net loss per common share, basic and diluted	$ (0.18)	$ (2.12)	$ (0.31)	$ (2.71)
Weighted—average number of shares outstanding, basic and diluted	28,850,451	8,746,250	28,510,014	7,174,233

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 15,232,402	$ 23,976,570
Accounts receivable, net	766,911	615,757
Inventory, net	1,073,335	953,458
Prepaid expenses and other current assets	2,033,857	2,678,894
Total current assets	19,106,505	28,224,679
Right-of-use assets	321,076	430,795
Property and equipment, net	253,261	247,323
Equipment held for lease, net	5,821	17,947
Intangible assets, net	183,933	187,694
Other assets	18,334	18,334
Total Assets	**$ 19,888,930**	**$ 29,126,772**
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities		
Accounts payable	$ 784,474	$ 500,768
Accrued expenses and other current liabilities	1,923,708	746,738
Notes payable, current portion	—	131,766
Deferred revenue, current portion	325,988	486,031
Operating lease liability, current portion	270,640	254,739
Warrant liabilities	4,112,100	8,310,100
Total current liabilities	7,416,910	10,430,142
Notes payable, net of current portion	—	6,973
Operating lease liability, net of current portion	98,145	236,826
Deferred revenue, net of current portion	112,057	158,271
Total liabilities	7,627,112	10,832,212
Stockholders' equity		
Series Alpha convertible preferred stock, $0.001 par value; 7,000 shares authorized; 180 shares issued and outstanding as of June 30, 2021 and December 31, 2020	1	1
Common stock, $0.001 par value; 225,000,000 shares authorized; 28,902,188 and 27,296,061 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	28,902	27,296
Additional paid-in capital	88,058,267	85,114,755
Accumulated deficit	(75,825,352)	(66,847,492)
Total stockholders' equity	12,261,818	18,294,560
Total Liabilities and Stockholders' Equity	**$ 19,888,930**	**$ 29,126,772**

Source: Qualigen Therapeutics, Inc.