May 14, 2021

Qualigen Therapeutics, Inc. Reports First Quarter 2021 Financial Results and Provides Corporate Update

Conference call scheduled for May 18, 2021 at 4:10 p.m. EDT.

- Revenues Increased 30 Percent to $1.9 Million Compared to $1.5 Million in the Same Quarter of the Previous Year
- On Track to File an IND in 2H21 for Treating Hospitalized COVID-19 Patients with QN-165
- Completed the R&D Evaluation and Qualification for QN-247; Expect to Finalize Formulation in 2H21
- Quarter-End Cash and Cash Equivalents Approximately $21.9 Million; Provides Sufficient Runway to Accomplish Key Inflection Points

CARLSBAD, Calif., May 14, 2021 (GLOBE NEWSWIRE) --Qualigen Therapeutics, Inc. (Nasdaq: QLGN), a biotechnology company focused on developing novel therapeutics for the treatment of cancer and viral diseases, today announced its financial results for the quarter ended March 31, 2021, and provided an update on its therapeutics pipeline and other corporate developments.

The Company will present its first quarter 2021 financial results and operational highlights in a conference call on May 18, 2021 at 4:10 p.m. EDT.

Highlights from the Quarter Ended March 31, 2021:

“We were very pleased to see the improvement in our revenue growth during the first quarter from our FastPack® System. Despite the challenges of operating during the pandemic, we managed to safely stay open to manufacture and ship our FastPack immunoassay products to meet the needs of our valued Diagnostics customers," stated Michael Poirier, Chief Executive Officer at Qualigen Therapeutics, Inc. He added: “While we are maintaining our diagnostics business, we are also working diligently to develop our therapeutics pipeline, which includes QN-165, QN-247, RAS-F, and STARS™.”

“We continue to strengthen our team with proven pharmaceutical professionals who leverage their knowledge and experience in order for us to achieve important milestones with each of our pipeline programs,” stated Amy Broidrick, EVP, Chief Strategy Officer.

Pipeline and Corporate Highlights

- Made significant progress with the IND-enabling studies for Qualigen’s lead candidate, QN-165, which is a broad-spectrum antiviral drug candidate for treating COVID-19 and other viral-based infectious diseases.

- Completed the R&D evaluation and qualification for QN-247, 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 Qualigen's blood-testing diagnostic products.

- 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 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.

- Entered into a Material Evaluation and Option Agreement with the University College London (UCL) which will allow Qualigen to study a significant potential indication for QN-247 with improved selectivity for pancreatic cancer cells. In addition to the pancreatic cancer treatment indication, Qualigen will also continue to evaluate QN-247 to treat leukemia and glioblastoma, and as an adjuvant therapy to stop the recurrence of cancer after initial treatment.

- Qualigen’s patent portfolio for therapeutics now has 37 owned or in-licensed patents and patent applications covering the QN-247 and/or QN-165 programs, 26 of which are issued.

First Quarter 2021 Financial Highlights

- Revenues in the three months ended March 31, 2021 were $1.9 million compared to $1.5 million during the three months ended March 31, 2020, an increase of $0.4 million. Our operating revenues are primarily generated from sales of diagnostic tests. This increase was primarily due to recognition of license revenue from Yi Xin Duan Jishu (Suzhou) Ltd. under our agreement with them for FastPack in China.

Net product sales remained level at approximately $1.4 million during the three months ended March 31, 2021 and 2020, but improved compared to the later 2020 quarters which were negatively impacted by the COVID-19 pandemic.

- License revenue during the three months ended March 31, 2021 was approximately $479,000, due to the recognition of revenue from the Yi Xin transaction.

- General and administrative expenses increased to $2.9 million during the three months ended March 31, 2021 from $0.9 million during the three months ended March 31, 2020. This increase was primarily due to overhead expenses related to our public-company status in the three months ended March 31, 2021 in contrast to our private-company status in the three months ended March 31, 2020.

- As of March 31, 2021, Qualigen Therapeutics had $21.9 million of cash and cash equivalents.

Conference Call Information

Qualigen will host a conference call for analysts and investors to present its first quarter

2021 financial results and operational highlights on May 18, 2021 at 4:10 p.m. EDT. Management will answer questions at the end of the call. Please submit questions for management no later than 10:00 a.m. EDT on Monday, May 17, 2021 to ir@qualigeninc.com.

Speakers on the call from Qualigen will be Michael Poirier, Chairman, Chief Executive Officer and Christopher Lotz, Vice President and Chief Financial Officer.

We encourage participants to pre-register for the conference call using the following link:
https://dpregister.com/sreg/10154044/e5f384fc7c

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 live webcast of the call will be available at the following link:
https://services.choruscall.com/mediaframe/webcast.html?webcastid=sljQb3Cl

Those without internet access or unable to register may dial in by calling:
Participant Dial In (Toll Free): 1-866-777-2509
Participant International Dial In: 1-412-317-5413

A recording and a transcript of the call will be available on the Investors page of the Company's website at https://www.qualigeninc.com.

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 20 years. Our cancer therapeutics pipeline includes QN-247 (formerly referred to as ALAN or AS1411-GNP), RAS-F and STARS ™. QN-247 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 (formerly referred to as AS1411), is also a drug candidate for treating COVID-19 and other viral-based infectious diseases; we currently plan that our first clinical trial would be a trial of QN-165 against 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, and vitamin D status. 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 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 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; or 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. 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.

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

	For the Three Months Ended March 31,	
	2021	2020
REVENUES		
Net product sales	$ 1,420,842	$ 1,411,755
License revenue	478,654	—
Collaborative research revenue	—	45,000
Total revenues	1,899,496	1,456,755
EXPENSES		
Cost of product sales	1,202,479	991,651
General and administrative	2,873,939	918,379
Research and development	3,499,373	238,059
Sales and marketing	136,587	92,262
Total expenses	7,712,378	2,240,351
LOSS FROM OPERATIONS	(5,812,882)	(783,596)
OTHER (INCOME) EXPENSE, NET		
Gain on change in fair value of warrant liabilities	(2,122,900)	—
Interest (income) expense, net	(17,343)	90,757
Other income, net	(542)	(1,158)
Total other (income) expense, net	(2,140,785)	89,599
LOSS BEFORE PROVISION FOR INCOME TAXES	(3,672,097)	(873,195)
PROVISION FOR INCOME TAXES	530	(619)
NET LOSS	(3,672,627)	(872,576)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.16)
Weighted—average number of shares outstanding, basic and diluted	28,165,796	5,602,214

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 21,947,912	$ 23,976,570

Accounts receivable, net	862,235	615,757
Inventory, net	885,855	953,458
Prepaid expenses and other current assets	1,219,759	2,678,894
Total current assets	24,915,761	28,224,679
Right-of-use assets	376,616	430,795
Property and equipment, net	224,932	247,323
Equipment held for lease, net	10,687	17,947
Intangible assets, net	189,294	187,694
Other assets	18,334	18,334
Total Assets	**$ 25,735,624**	**$ 29,126,772**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 485,551	$ 500,768
Accrued expenses and other current liabilities	1,869,424	746,738
Notes payable, current portion	10,683	131,766
Deferred revenue, current portion	381,366	486,031
Lease liability, current portion	262,601	254,739
Warrant liabilities	6,187,200	8,310,100
Total current liabilities	9,196,825	10,430,142
Notes payable, net of current portion	4,923	6,973
Lease liability, net of current portion	168,254	236,826
Deferred revenue, net of current portion	135,235	158,271
Total liabilities	9,505,237	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 March 31, 2021 and December 31, 2020	1	1
Common stock, $0.001 par value; 225,000,000 shares authorized; 28,833,059 shares and 27,296,061 shares issued and outstanding as of March 31, 2021 and December 31, 2020	28,833	27,296
Additional paid-in capital	86,721,672	85,114,755
Accumulated deficit	(70,520,119)	(66,847,492)
Total stockholders' equity	16,230,387	18,294,560
Total Liabilities and Stockholders' Equity	**$ 25,735,624**	**$ 29,126,772**

Source: Qualigen Therapeutics, Inc.