

November 15, 2021



Qualigen Therapeutics, Inc. Reports Third Quarter 2021 Financial Results

- **Quarterly revenues increased 38% to approximately \$1.2 million, compared to approximately \$0.8 million in the same quarter of the previous year**
- **Year-to-date revenues increased 30% to \$4.2 million, compared to \$3.2 million in the same nine-month period of the previous year**
- **Cash equivalents of approximately \$12.3 million as of September 30, 2021**

CARLSBAD, Calif., Nov. 15, 2021 (GLOBE NEWSWIRE) -- Qualigen Therapeutics, Inc. (Nasdaq: QLGN), a biotechnology company focused on developing novel therapeutic products for the treatment of adult and pediatric patients with rare cancers, as well as maintaining and expanding its flagship FastPack[®] diagnostic platform, today announced its financial results for the third quarter and nine months ended September 30, 2021.

“We are very encouraged by what we believe to be a strong quarter, with a 38% increase in year-over-year revenue,” commented Michael S. Poirier, Qualigen’s Chairman, CEO, and President. “As the country emerges from the pandemic and visits to medical offices are on the rise, we have experienced a corresponding recovery in our FastPack test kit sales. We continue to be encouraged by this increase.”

“In the meantime, we continue efforts to develop our therapeutics business, which is focused on novel approaches to rare cancers. We look forward to sharing news on those programs soon,” added Mr. Poirier.”

Third Quarter 2021 Financial Highlights

Revenues for the three months ended September 30, 2021 were \$1.2 million compared to approximately \$0.8 million in the same quarter of the previous year. Qualigen’s revenues are primarily generated from sales of diagnostic tests. The increased revenue was primarily due to a continued recovery from the effects of the COVID-19 pandemic versus the same quarter of the prior year.

Revenues for the nine-month period ended September 30, 2021 were \$4.2 million compared to \$3.2 million in the same nine-month period of the previous year. This increase was also

primarily due to an increase in diagnostic product sales, reflecting recovery from the effects of the COVID-19 pandemic, as well as recognition of license revenue from Yi Xin Zhen Duan Jishu (Suzhou) Ltd. under a Technology Transfer Agreement during the first quarter, which had no counterpart during the prior year.

For the three months ended September 30, 2021, Qualigen reported a net loss of \$2.9 million, or \$0.10 per share, compared to a net loss of \$8.1 million, or \$0.41 per share, for the corresponding period in 2020. Net loss for the three-month 2020 period included non-cash charges of \$4.4 million related to the change in fair value of warrant liabilities, compared to a non-cash gain of \$1.9 million related to the change in fair value of warrant liabilities in the current period.

For the nine months ended September 30, 2021, the Company reported a net loss of \$11.8 million, or \$0.41 per share, compared to a net loss of \$27.6 million, or \$2.41 per share, in the corresponding nine-month period in 2020. Net loss for the nine-month 2020 period included non-cash charges of \$20.6 million related to the change in fair value of warrant liabilities, compared to a non-cash gain of \$6.1 million related to the change in fair value of warrant liabilities in the current period.

License revenue during the nine months ended September 30, 2021 was approximately \$0.5 million, due to the recognition of revenue from the Yi Xin transaction.

General and administrative expenses increased slightly to \$2.8 million during the three months ended September 30, 2021, from \$2.7 million during the three months ended September 30, 2020. General and administrative expenses increased to \$8.6 million during the nine months ended September 30, 2021 compared to \$5.6 million during the same nine-month period of the prior year. This increase was primarily due to overhead expenses related to Qualigen's public-company status in contrast to the Company's private-company status during much of the 2020 period.

Research and development expenses increased to \$2.1 million during the three months ended September 30, 2021, from \$0.9 million during the three months ended September 30, 2020. Research and development expenses increased to \$10.1 million during the nine months ended September 30, 2021 compared to \$1.7 million during the same nine-month period of the prior year. These increases were primarily due to increased spending on our pre-clinical therapeutics pipeline programs.

As of September 30, 2021, Qualigen had \$12.3 million in cash and cash equivalents. The Company believes its cash and cash equivalents are sufficient to fund its anticipated operations through late 2022.

About Qualigen Therapeutics, Inc.

Qualigen is a biotechnology company focused on developing novel therapeutic products for the treatment of adult and pediatric patients with rare cancers, as well as maintaining and expanding its flagship FastPack[®] diagnostic platform. Qualigen intends to apply for Orphan Drug Designation for several of its drug candidates. The FastPack[®] line of FDA-cleared and CE-Marked products has been used successfully in diagnostics for 20 years. Our therapeutics pipeline includes cancer drug compounds such as QN-247 (formerly referred to as AS1411-GNP or ALAN) and RAS-F. By combining our demonstrated ability to develop

and commercialize innovative medical products with the advanced capabilities of leading cancer research centers, such as the University of Louisville, we are committed to providing exciting new therapeutic technologies to physicians and patients.

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 the Company will successfully develop any drugs (including QN-247 and RAS-F); that preclinical or clinical development of the Company's drugs (including QN-247 and RAS-F) will be completed on any projected timeline or will be successful; that any clinical trials will be approved to begin by or will proceed as contemplated by any projected timeline; that any 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 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 currently 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 (including QN-247 and RAS-F); 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 September 30, | | For the Nine Months Ended September 30, | |
|--|--|--------------------|--|--------------------|
| | 2021 | 2020 | 2021 | 2020 |
| | <u>2021</u> | <u>2020</u> | <u>2021</u> | <u>2020</u> |
| REVENUES | | | | |
| Net product sales | \$ 1,155,065 | \$ 837,714 | \$ 3,693,842 | \$ 3,153,536 |
| License revenue | — | — | 478,654 | — |
| Collaborative research revenue | — | — | — | 45,000 |
| Total revenues | <u>1,155,065</u> | <u>837,714</u> | <u>4,172,496</u> | <u>3,198,536</u> |
| EXPENSES | | | | |
| Cost of product sales | 993,120 | 921,475 | 3,112,224 | 2,721,049 |
| General and administrative | 2,756,323 | 2,664,658 | 8,582,362 | 5,562,650 |
| Research and development | 2,083,315 | 870,876 | 10,091,155 | 1,706,280 |
| Sales and marketing | 130,217 | 98,045 | 402,347 | 279,151 |
| Total expenses | <u>5,962,976</u> | <u>4,555,054</u> | <u>22,188,087</u> | <u>10,269,130</u> |
| LOSS FROM OPERATIONS | <u>(4,807,910)</u> | <u>(3,717,340)</u> | <u>(18,015,591)</u> | <u>(7,070,594)</u> |
| OTHER (INCOME) EXPENSE, NET | | | | |
| Loss (gain) on change in fair value of warrant liabilities | (1,942,900) | 4,395,300 | (6,140,900) | 20,596,700 |
| Interest (income) expense, net | (6,801) | 715 | (36,862) | 148,836 |
| Other (income) expense, net | (702) | (2,447) | (3,596) | (253,719) |
| Total other (income) expense, net | <u>(1,950,403)</u> | <u>4,393,568</u> | <u>(6,181,358)</u> | <u>20,491,817</u> |
| LOSS BEFORE PROVISION FOR INCOME TAXES | (2,857,507) | (8,110,908) | (11,834,233) | (27,562,411) |
| PROVISION (BENEFIT) FOR INCOME TAXES | <u>1,011</u> | <u>2,305</u> | <u>2,146</u> | <u>2,283</u> |
| NET LOSS | \$ (2,858,518) | \$ (8,113,213) | \$ (11,836,378) | \$ (27,564,694) |
| Net loss per common share, basic and diluted | \$ (0.10) | \$ (0.41) | \$ (0.41) | \$ (2.41) |

| | | | | |
|--|------------|------------|------------|------------|
| Weighted-average number of shares outstanding, basic and diluted | 29,026,211 | 19,799,468 | 28,683,972 | 11,434,649 |
|--|------------|------------|------------|------------|

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

| | September 30, 2021 | December 31, 2020 |
|---|-----------------------------------|----------------------------------|
| ASSETS | | |
| Current Assets | | |
| Cash and cash equivalents | \$ 12,319,809 | 23,976,570 |
| Accounts receivable, net | 633,550 | 615,757 |
| Inventory, net | 1,178,007 | 953,458 |
| Prepaid expenses and other current assets | 1,601,512 | 2,678,894 |
| Total current assets | 15,732,878 | 28,224,679 |
| Right-of-use asset | 264,140 | 430,795 |
| Property and equipment, net | 208,958 | 247,323 |
| Equipment held for lease, net | 2,693 | 17,947 |
| Intangible assets, net | 177,562 | 187,694 |
| Other assets | 18,334 | 18,334 |
| Total Assets | \$ 16,404,564 | \$ 29,126,772 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ 908,703 | \$ 500,768 |
| Accrued expenses and other current liabilities | 1,799,431 | 746,738 |
| Notes payable, current portion | — | 131,766 |
| Deferred revenue, current portion | 270,761 | 486,031 |
| Operating lease liability, current portion | 278,901 | 254,739 |
| Warrant liabilities | 2,169,200 | 8,310,100 |
| Total current liabilities | 5,426,996 | 10,430,142 |
| Notes payable, net of current portion | — | 6,973 |
| Operating lease liability, net of current portion | 24,993 | 236,826 |
| Deferred revenue, net of current portion | 106,493 | 158,271 |
| Total liabilities | 5,558,482 | 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 September 30, 2021 and December 31, 2020 | 1 | 1 |
| Common stock, \$0.001 par value; 225,000,000 shares authorized; 29,082,069 and 27,296,061 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively | 29,082 | 27,296 |
| Additional paid-in capital | 89,500,869 | 85,114,755 |
| Accumulated deficit | <u>(78,683,870)</u> | <u>(66,847,492)</u> |
| Total Stockholders' Equity | 10,846,082 | 18,294,560 |
| Total Liabilities & Stockholders' Equity | \$ 16,404,564 | \$ 29,126,772 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.



Source: Qualigen Therapeutics, Inc.