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Qualigen Therapeutics, Inc. (QLGN-NASDAQ)

QLGN: On Track to File IND for QN-165 as COVID-19 Treatment in 2H21…

Based on our probability adjusted DCF model that takes into account potential future revenues from QN-165, QN-247, and RAS-F, QLGN is valued at $10.00 per share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (07/07/21)	$1.91
Valuation	**$10.00**

OUTLOOK

Qualigen Therapeutics, Inc. (QLGN) is developing therapies for the treatment of cancer and viral disease. The therapeutics pipeline includes QN-165 (formerly AS1411), which is expected to enter the clinic in the second half of 2021 as a potential treatment for COVID-19. In addition, the company is conducting IND-enabling studies for QN-247 (formerly ALAN), which will initially be targeted as a treatment for acute myeloid leukemia, and RAS-F, a family of protein-protein interaction inhibitors that could be effective in cancers with RAS mutations such as pancreatic, colon, and lung. An IND for QN-247 is anticipated in the second half of 2022.

SUMMARY DATA

52-Week High	**$6.42**
52-Week Low	**$1.53**
One-Year Return (%)	**-52.72**
Beta	**-0.83**
Average Daily Volume (sh)	**239,490**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$55**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	1.5 A	0.9 A	0.8 A	1.1 A	3.3 A
2021	1.9 A	1.4 E	1.5 E	1.5 E	6.3 E
2022					5.7 E
2023					5.8 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.16 A	-$2.12 A	-$0.41 A	$0.31 A	-$1.28 A
2021	-$0.13 A	-$0.16 E	-$0.17 E	-$0.19 E	-$0.65 E
2022					-$0.62 E
2023					-$0.59 E

WHAT'S NEW

Financial Update

On May 14, 2021, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the first quarter of 2021. The company reported $1.9 million in revenues for the first quarter of 2021, compared to $1.5 million for the three months ending March 31, 2020. The increase was primarily due to the recognition of license revenue from Yi Xin under the Technology Transfer Agreement. The cost of product sales in the first quarter of 2021 were $1.2 million, or 85% of net product sales, compared to $1.0 million, or 68% of net product sales, for the three months ending March 31, 2020. The increase was primarily due to higher manufacturing labor costs and higher manufacturing-support costs of R&D personnel.

G&A expenses were $2.9 million in the first quarter of 2021, compared to $0.9 million for the three months ending March 31, 2020. The increase was primarily due to increased stock-based compensation, insurance expense, payroll expense, and overhead costs. R&D expenses were $3.5 million for the first quarter of 2021 compared to $0.2 million for the three months ending March 31, 2020. The increase is due to the company shifting its focus from diagnostic to therapeutic research. During the first quarter of 2021, the company recorded $2.1 million in non-cash other income due to the change in the fair value of warrant liabilities. This is determined quarterly on a "mark-to-market" basis and could result in significant variability in future quarterly statements.

As of March 31, 2021, Qualigen had approximately $21.9 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into mid-2022. As of May 7, 2021, Qualigen had approximately 28.8 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 42.7 million.

Business Update

IND Filing for QN-165 (formerly AS1411) for Treatment of COVID-19 in 2H21

Qualigen is developing QN-165 (formerly AS1411) as a treatment for COVID-19. In October 2020, the company completed a positive pre-IND meeting with the U.S. FDA regarding QN-165's development pathway. QN-165 is a DNA aptamer that has exhibited antiviral activity in multiple *in vitro* assays against different viruses. The following manuscripts show that QN-165 is active against a number of different RNA viruses, including dengue virus, human immunodeficiency virus (HIV), and respiratory syncytial virus (RSV). We believe that the following studies provide proof-of-concept for QN-165 as an anti-viral agent, nucleolin as an antiviral target, and justify testing QN-165 as a treatment for SARS-CoV-2 infection.

- Balinsky *et al*., 2013: The dengue virus capsid protein is a structural component of the infectious virion, and it interacts with and colocalizes with nucleolin. Both knockdown of nucleolin expression with siRNA and treatment with AS1411 caused a significant reduction in viral titers following dengue virus infection. There was no change in viral RNA or protein levels at early time points post-infection, thus nucleolin is likely involved in viral morphogenesis.

- Perrone *et al*., 2016: Cell-surface nucleolin is co-receptor for HIV on target cells, thus since AS1411 binds to nucleolin it was tested as a potential anti-HIV therapy. AS1411 inhibited HIV attachment and entry into target cells along with antiviral activity without displaying cytotoxicity.

- Mastrangelo *et al*., 2017: Following administration of AS1411 to RSV-infected mice and rats there was a reduction in lung viral titers, decreased airway inflammation, and decreased IL-4/IFN-g ratios compared to untreated, infected animals.

The company will be performing a small (n=6+) Phase 1b study to confirm the dose level before proceeding directly into a Phase 2a trial with a targeted enrollment of approximately 100 patients. Patients who are admitted to the hospital with COVID-19 but have not yet progressed to respiratory failure will be randomized 1:1 to receive standard of care therapy (e.g., remdesivir, corticosteroids, etc.) along with QN-165 or placebo. The primary endpoint will examine time to release from the hospital, along with multiple secondary endpoints (e.g., viral load, disease progression, etc.). Interim analyses will occur at 20%, 40%, 60%, and 80% of the total enrollment of the Phase 2a efficacy evaluation. If the Phase 2a trial is successful, it may lead the company to seek emergency use authorization (EUA). An interim analysis will be performed after 100 patients are treated and if the trials are successful, it may lead the company to seek emergency use authorization (EUA).

Update on QN-247 (formerly ALAN)

QN-247 (formerly ALAN or AS1411-GNP) is an aptamer-based anticancer formulation composed of QN-165 conjugated to gold nanoparticles (GNPs). Previous preclinical studies showed that QN-247 was stable in aqueous and serum-containing solutions, had superior cellular uptake, and increased antiproliferative effects compared to unconjugated QN-165.

In March 2021, Qualigen entered into a Material Evaluation and Option Agreement with the University College London (UCL) to evaluate the use of QN-247 with G-quadruplex binders (GQBs) developed by Professor Stephen Neidle and colleagues at UCL. Previously published research showed a GQB exhibited potent activity in human gemcitabine-resistant pancreatic cancer cells (Ahmed *et al*., 2020). The use of a GQB along with QN-247 may potentiate its activity against pancreatic cancer and represents another significant potential indication for QN-247.

The company is planning to target acute myeloid leukemia (AML) as a first indication for QN-247. IND-enabling studies are currently ongoing and we anticipate an IND being filed in the second half of 2022.

Update on RAS-F

In July 2020, Qualigen announced an agreement with the University of Louisville for intellectual property covering the “RAS-F” family of RAS protein-protein interaction inhibitor small molecule drug candidates. The company is currently identifying a lead candidate with a strong safety profile and efficacy against a range of solid tumors.

There are three human RAS genes (*HRAS*, *KRAS*, and *NRAS*) that encode four similar RAS proteins that function as transducers to connect cell surface receptors with intracellular signaling pathways (Pylayeva-Gupta *et al*., 2011).

RAS mutations are found at varying rates across many different types of cancers, with *KRAS* mutations found most frequently (86%) followed by *NRAS* (11%) and *HRAS* (3%), with the overall range of any RAS mutation occurring in approximately 9-30% of all tumor samples sequenced (Cox *et al*., 2014).

In an effort to develop a treatment for RAS-driven cancers, researchers at the University of Louisville screened a library of two million compounds to identify small molecules that would inhibit the protein-protein interaction between RAS and effector proteins. Qualigen expects to have a portfolio of lead and backup drug candidates by the end of 2021 at which time the company is likely to provide an update on clinical timelines.

Update on FastPack System

The company’s FastPack diagnostic system is a proprietary platform that provides rapid and accurate immunoassay testing results. It consists of the FastPack Analyzer and FastPack test pouches that includes a single-use, disposable foil packet containing the FastPack reagent chemistry. The company

currently markets 10 assays, including tests for prostate cancer, thyroid function, metabolic disorders, and research applications. FastPack products are now available in approximately 1,000 physician offices worldwide. Since launching in 2001, cumulative sales of FastPack products has exceeded $100 million.

In January 2021, Qualigen announced the achievement of a milestone event that triggered a payment obligation from Yi Xin Duan Jishu (Suzhou) Ltd. related to the initiation of technology transfer of the FastPack system. In October 2020, the company announced that Yi Xin will develop, manufacture, and sell new generations of diagnostic test systems and has the rights to manufacture and sell FastPack diagnostic products in China.

While Qualigen will continue to sell FastPack products, the main focus of the company will be on developing therapeutic candidates that address high unmet medical needs in cancer and infectious diseases.

Update on STARS™

The same core technologies that were developed for the FastPack system are the basis for the company's expansion into a therapeutic application for removing disease associated agents from a patient's blood, the Selective Target Antigen Removal System (STARS). STARS consists of a membrane targeted with a capture reagent inside of a cartridge and is expected to be used with conventional dialysis and hemofiltration machines. Examples of agents that could potentially be removed with STARS include immune checkpoints, metastatic cells, and inflammatory factors. STARS could also potentially be used to treat infectious diseases by removing circulating viruses. In August 2020, the company increased its IP protection for STARS as it was issued U.S. Patent 10,744,257. Qualigen is beginning development of STARS, which includes an analysis of whether to advance it along or through a partnership.

Addition to the Management Team

On May 19, 2021, Qualigen announced the appointment of Dr. Tariq Arshad to the newly-created position of Senior Vice President, Chief Medical Officer. Dr. Arshad is an oncologist with over 20 years of experience in the biotech and pharmaceutical industry, which included leadership roles at Beckton Dickinson, Sanofi Genzyme, Humanigen, XOMA, Merck, Genentech, and Pfizer. He was most recently Global Head of Medical Affairs and Clinical Research for Beckton Dickinson. We believe Dr. Arshad's broad experience in drug development will be a valuable addition for the company as they advance their clinical pipeline.

Conclusion

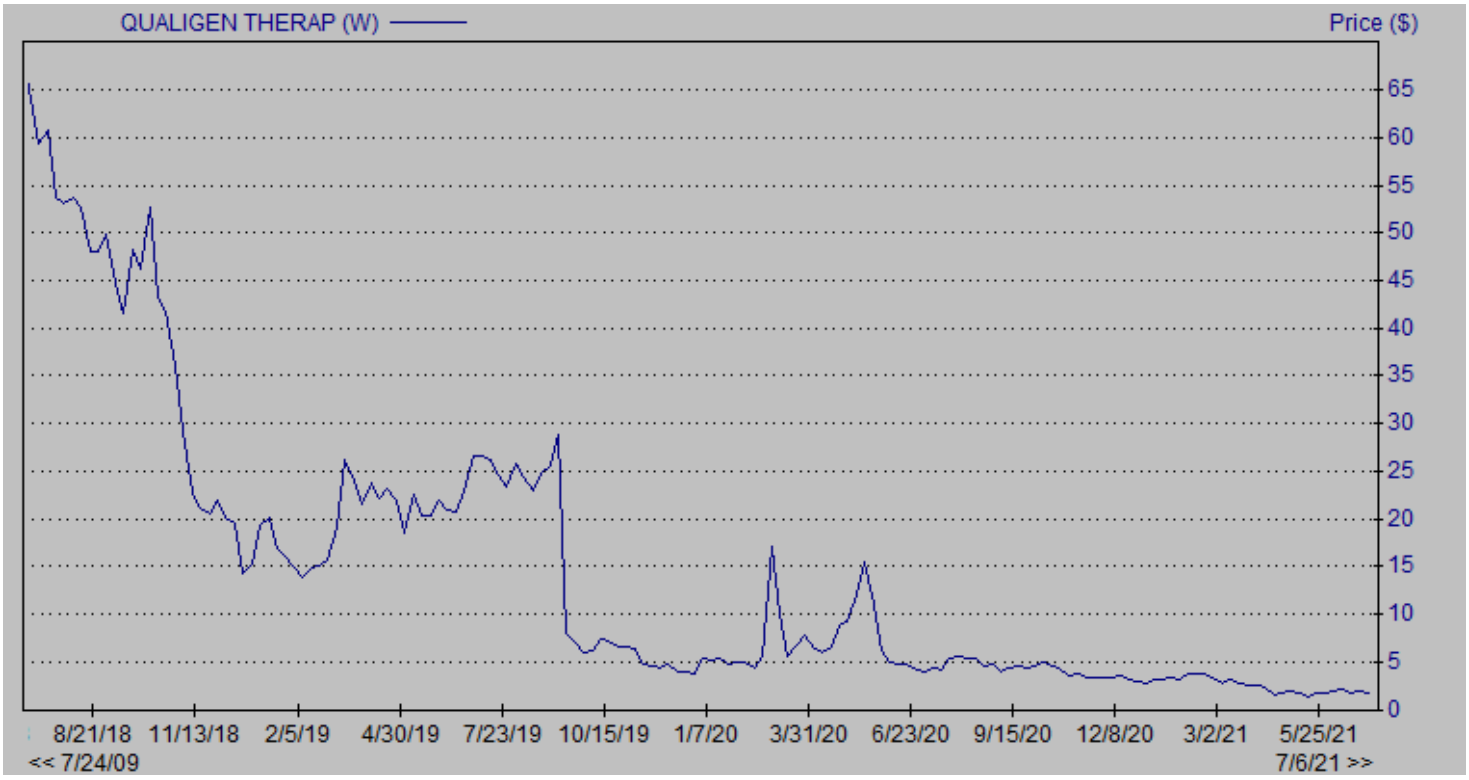
We look forward to additional updates regarding the upcoming clinical trial of QN-165 in COVID-19 patients, which we believe the company will provide upon filing of the IND in the second half of 2021. In addition, we anticipate significant preclinical updates for the QN-247 and the RAS-F programs later in the year. With no changes to our model our valuation remains at $10 per share.

PROJECTED FINANCIALS

Qualigen Therapeutics, Inc.	Nine Months Ending Dec-20	Q1 A	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
QN-247	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
QN-165	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
RAS-F3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
STARS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
FastPack	$2.8	$1.4	$1.4	$1.5	$1.5	$5.8	$5.7	$5.8
Other Income	$0.0	$0.5	$0.0	$0.0	$0.0	$0.5	$0.0	$0.0
Total Revenues	**$2.8**	**$1.9**	**$1.4**	**$1.5**	**$1.5**	**$6.3**	**$5.7**	**$5.8**
Cost of Sales	$2.6	$1.2	$0.8	$0.8	$0.8	$3.6	$4.1	$4.5
Product Gross Margin	*7%*	*37%*	*43%*	*47%*	*47%*	*43%*	*28%*	*22%*
Research & Development	$3.3	$3.5	$2.2	$2.5	$3.0	$11.2	$12.0	$14.0
Selling and Marketing	$0.3	$0.1	$0.2	$0.2	$0.2	$0.7	$0.8	$0.8
General & Administrative	$7.1	$2.9	$2.7	$2.9	$3.1	$11.6	$12.0	$12.5
Other (Income) Expense	$1.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($11.9)	($5.8)	($4.5)	($4.9)	($5.6)	($20.8)	($23.2)	($26.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$7.7	($2.1)	$0.1	$0.1	$0.1	($1.8)	$0.4	$0.4
Pre-Tax Income	($19.5)	($3.7)	($4.6)	($5.0)	($5.7)	($19.0)	($23.6)	($26.4)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($19.5)**	**($3.7)**	**($4.6)**	**($5.0)**	**($5.7)**	**($19.0)**	**($23.6)**	**($26.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.12)**	**($0.13)**	**($0.16)**	**($0.17)**	**($0.19)**	**($0.65)**	**($0.62)**	**($0.59)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	17.4	28.2	29.0	29.5	30.0	29.2	38.0	45.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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