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August 31, 2021
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Qualigen Therapeutics, Inc.

(QLGN-NASDAQ)

QLGN: Focusing on Advancement of QN-247 and RAS-F…

Based on our probability adjusted DCF model that takes into account potential future revenues from QN-247, and RAS-F, QLGN is valued at $9.00 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 (08/31/21)	$1.33
Valuation	**$9.00**

OUTLOOK

Qualigen Therapeutics, Inc. (QLGN) is focused on oncology to develop therapies for rare adult and pediatric cancers. The company is currently conducting IND-enabling studies for QN-247 (formerly ALAN), which will be targeted to treat acute myeloid leukemia, pancreatic cancer or glioblastoma. Additionally, the company has the RAS-F program, a family of protein-protein interaction inhibitors that could be effective in cancers with RAS mutations such as pancreatic, colon, brain, and lung. An IND for QN-247 is anticipated in the second half of 2022. A clinical program for QN-165 as a treatment for COVID-19 was deprioritized by the company after feedback from the FDA indicated additional preclinical data would be required before initiating a clinical trial.

SUMMARY DATA

52-Week High	**$5.31**
52-Week Low	**$1.18**
One-Year Return (%)	**-73.39**
Beta	**-0.83**
Average Daily Volume (sh)	**412,007**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$37**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
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	1.1 A	1.5 E	1.5 E	6.0 E
2022					6.2 E
2023					6.4 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	-$0.18 A	-$0.21 E	-$0.23 E	-$0.76 E
2022					-$0.72 E
2023					-$0.69 E

WHAT'S NEW

Financial Update

On August 17, 2021, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the second quarter of 2021. The company reported $1.1 million in revenues for the second quarter of 2021, compared to $0.9 million for the three months ending June 30, 2020. The increase was primarily due to a recovery from the effects of the COVID-19 pandemic. The cost of product sales in the second quarter of 2021 were $0.9 million, or 82% of net product sales, compared to $0.8 million, or 89% of net product sales, for the three months ending June 30, 2020. The increase was primarily due to higher manufacturing labor costs and higher manufacturing-support costs of R&D personnel.

G&A expenses were $3.0 million in the second quarter of 2021, compared to $2.0 million for the three months ending June 30, 2020. The increase was primarily due to increased stock-based compensation, insurance expense, and payroll expense. R&D expenses were $4.5 million for the second quarter of 2021 compared to $0.6 million for the three months ending June 30, 2020. The increase is due to the company shifting its focus from diagnostic to therapeutic research. During the second 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 June 30, 2021, Qualigen had approximately $15.2 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into mid-2022. As of August 12, 2021, Qualigen had approximately 29.0 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 42.9 million.

Business Update

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. The company will also be pursuing Orphan Drug designation from the FDA for QN-247, which confers a number of advantages including increased market protection and a potentially faster review.

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.

QN-165 (formerly AS1411) for Treatment of COVID-19 Deprioritized

Qualigen submitted an IND to the FDA for QN-165 (formerly AS1411) as a treatment for COVID-19. However, the FDA requested additional preclinical toxicity and safety pharmacology data before allowing clinical trials to commence. Given the very crowded COVID-19 vaccine and therapeutic landscape, coupled with the time that would be required to complete the necessary studies, the company has deprioritized this program in favor of focusing on QN-247 and RAS-F.

Conclusion

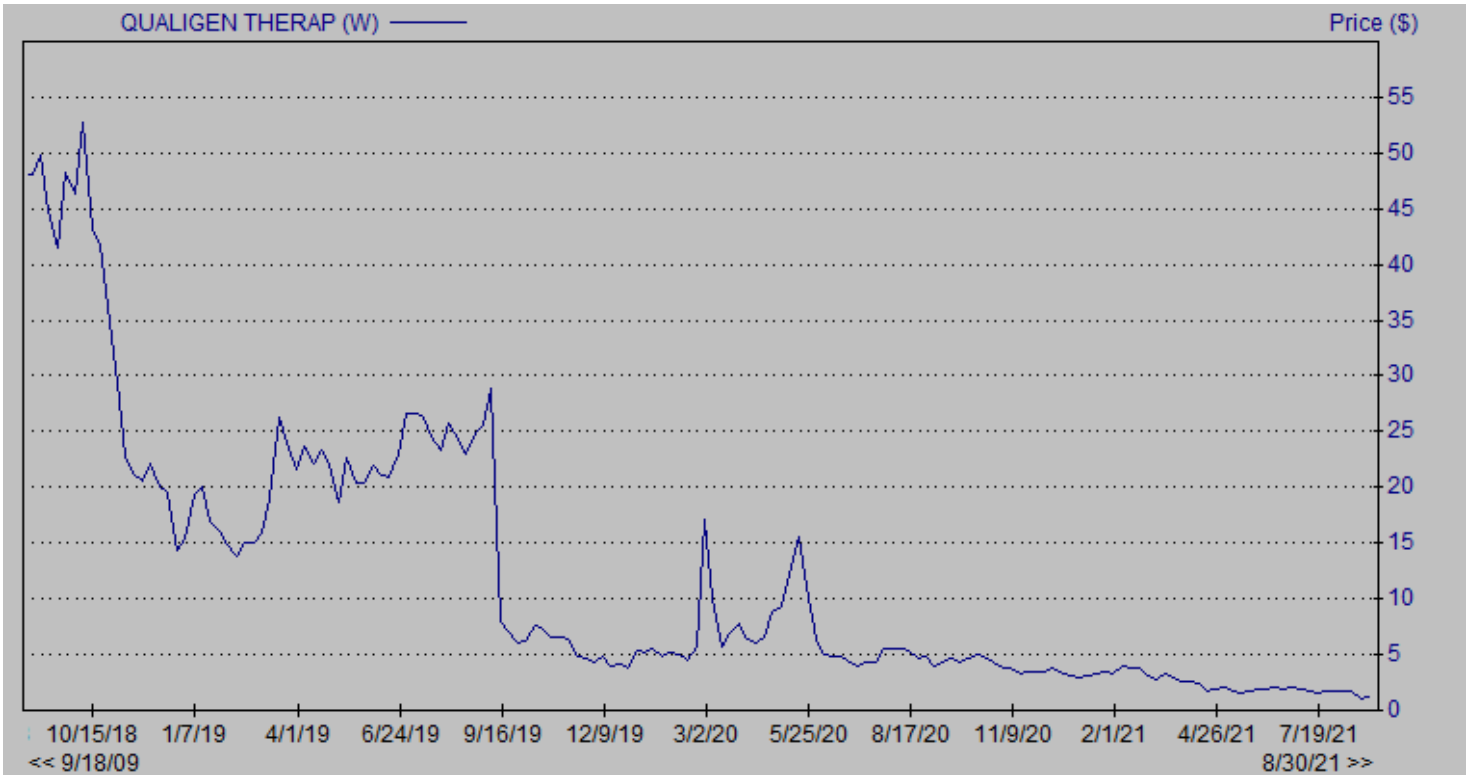
Following feedback from the FDA regarding the IND submission for QN-165 the company deprioritized development of QN-165 as an anti-viral treatment and is now focused on developing their oncology pipeline platform programs QN-247 and RAS-F. We now look forward to additional preclinical updates for QN-247 and the RAS-F programs later this year. We have removed QN-165 from our model, which has resulted in a slight decrease to our valuation to $9.00 per share.

PROJECTED FINANCIALS

Qualigen Therapeutics, Inc.	Nine Months Ending Dec-20	Q1 A	Q2 A	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
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	$1.1	$1.5	$1.5	$5.5	$6.2	$6.4
Other Income	$0.0	$0.5	$0.0	$0.0	$0.0	$0.5	$0.0	$0.0
Total Revenues	**$2.8**	**$1.9**	**$1.1**	**$1.5**	**$1.5**	**$6.0**	**$6.2**	**$6.4**
Cost of Sales	$2.6	$1.2	$0.9	$1.1	$1.1	$4.3	$3.5	$3.6
Product Gross Margin	*7%*	*37%*	*18%*	*27%*	*27%*	*28%*	*44%*	*44%*
Research & Development	$3.3	$3.5	$4.5	$3.5	$4.0	$15.5	$17.0	$20.0
Selling and Marketing	$0.3	$0.1	$0.1	$0.2	$0.2	$0.7	$0.8	$0.8
General & Administrative	$7.1	$2.9	$3.0	$2.9	$3.1	$11.8	$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)	($7.4)	($6.2)	($6.9)	($26.3)	($27.1)	($30.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$7.7	($2.1)	($2.1)	$0.1	$0.1	($4.0)	$0.4	$0.4
Pre-Tax Income	($19.5)	($3.7)	($5.3)	($6.3)	($7.0)	($22.3)	($27.5)	($30.9)
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)**	**($5.3)**	**($6.3)**	**($7.0)**	**($22.3)**	**($27.5)**	**($30.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.12)**	**($0.13)**	**($0.18)**	**($0.21)**	**($0.23)**	**($0.76)**	**($0.72)**	**($0.69)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	17.4	28.2	28.9	29.5	30.0	29.1	38.0	45.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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