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Qualigen Therapeutics, Inc. (QLGN-NASDAQ)

QLGN: Testing AS1411 as COVID-19 Treatment…

Based on our probability adjusted DCF model that takes into account potential future revenues from ALAN, AS1411, 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 (11/30/20)	$3.55
Valuation	**$10.00**

OUTLOOK

On November 13, 2020, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the second quarter of fiscal year 2021 ending September 30, 2020 and provided a business update. The company recently completed a pre-IND meeting with the U.S. FDA at which time the agency generally agreed with the planned clinical development of AS1411 as a treatment for COVID-19. We anticipate a Phase 2a trial initiating by mid-2021. Qualigen also recently expanded its research agreement with the University of Louisville for cancer drug candidate ALAN and we anticipate an IND being filed and a Phase 1 clinical trial initiating for ALAN in the second half of 2021.

SUMMARY DATA

52-Week High	**$18.05**
52-Week Low	**$3.30**
One-Year Return (%)	**-20.45**
Beta	**-0.63**
Average Daily Volume (sh)	**621,420**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$82**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**15**
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	**High**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	1.5 A	1.2 A	1.4 A	1.5 A	5.6 A
2021	0.9 A	0.8 A	1.2 E	1.3 E	4.2 E
2022					5.5 E
2023					7.8 E

Earnings Per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	-$0.11 A	-$0.06 A	$0.01 A	-$0.16 A	-$0.32 A
2021	-$2.12 A	-$0.41 A	$0.12 E	$0.13 E	-$1.74 E
2022					-$0.63 E
2023					-$0.69 E

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WHAT'S NEW

Business Update

AS1411 Clinical Trial in COVID-19 to Initiate 1H21

On October 28, 2020, Qualigen Therapeutics, Inc. (QLGN) announced a positive pre-IND meeting with the U.S. FDA regarding the development of AS1411 as a treatment for COVID-19. AS1411 is a DNA aptamer that has exhibited antiviral activity in a number of different *in vitro* assays against different viruses. The following manuscripts show that AS1411 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 AS1411 as an anti-viral agent, nucleolin as an antiviral target, and justify testing AS1411 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 a low-affinity 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 FDA recommended a Phase 2a proof-of-concept study to evaluate safety and initial efficacy at Day 28 of AS1411 in COVID-19 patients along with determining an appropriate dose to move into a Phase 2b trial. We anticipate the company initiating the Phase 2a trial in the first half of 2021.

In June 2020, Qualigen entered into an exclusive license agreement with the University of Louisville to develop AS1411 as a treatment for COVID-19. The company is working with the University to complete pre-IND studies such that an IND can be filed in early 2021. In September 2020, Qualigen and the University filed a provisional patent application entitled "Methods of inhibiting or treating coronavirus infection, and methods for delivering an anti-nucleolin agent."

Qualigen also recently announced a manufacturing agreement with STA Pharmaceutical Co., a subsidiary of WuXi AppTec, for cGMP production of AS1411 to ensure adequate supply for anticipated clinical trials in COVID-19 patients.

Expands Research Agreement for ALAN

On October 1, 2020, Qualigen announced it entered into an amended Sponsored Research Agreement with the University of Louisville regarding the company's anti-cancer drug candidate ALAN. The original agreement encompassed animal studies to assess the safety and efficacy of ALAN compositions designed to treat pediatric and adult acute myeloid leukemia (AML). The amended agreement includes testing ALAN for additional indications including glioblastoma and non-small cell lung cancer.

ALAN (Aptatmer-Linked Anti-Nucleolin) is an aptamer-based anticancer compound composed of AS1411 attached to gold nanoparticles. Previous preclinical studies showed that ALAN was stable in aqueous and serum-containing solutions, had superior cellular uptake, and increased antiproliferative effects compared to unconjugated AS1411.

Financial Update

On November 13, 2020, Qualigen announced financial results for the second quarter of fiscal year 2021 that ended on September 30, 2020. Total revenues for the three months ending September 30, 2020 were $0.8 million compared to $1.2 million for the same period in 2019. The decrease was primarily due to the COVID-19 pandemic, which resulted in a decreased number of patient visits to physician offices, clinics, and small hospitals. All revenue was derived from the sale of diagnostic products.

G&A expenses for the second quarter of fiscal year 2021 were $2.7 million compared with $0.2 million for the second quarter of fiscal year 2020. The increase is primarily due to the addition of expenses associated with being a publicly traded company during the current period. R&D expenses for the three months ending September 30, 2020 were $0.9 million compared to $0.2 million for the prior-year period. The increase was primarily due to advancing the development pipeline along with work related to the COVID-19 antibody diagnostic test and FastPack PRO instrument.

Net loss for the second quarter of fiscal year 2021 was $8.1 million, or $0.41 per share, compared with a net loss of $0.4 million, or $0.06 per share, for the second quarter of fiscal year 2020. The net loss in the most recent quarter included a non-cash charge of $4.4 million for the change in fair value of warrant liabilities along with non-cash charges of $1.2 million for stock-based compensation. Loss from operations for the three months ending September 30, 2020 was $3.7 million compared to $0.3 million for the months ending September 30, 2019.

As of September 30, 2020, Qualigen had approximately $14.5 million in cash and cash equivalents. We estimate this is sufficient to fund operations through calendar year 2021. As of November 5, 2020, Qualigen had approximately 23.1 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 37.5 million.

Conclusion

Since we initiated on Qualigen in September 2020 the company continues to execute on its business plan, as evidenced by the positive feedback from the FDA regarding the clinical development plan for AS1411 in COVID-19 patients. We anticipate an IND being filed for AS1411 in COVID-19 in early 2021 such that a Phase 2a trial can initiate by mid-2021. In addition, we are glad to see the expanded agreement with the University of Louisville regarding ALAN and look forward to additional updates as the company advances it toward the clinic later in 2021. With no changes to our model our valuation remains at $10 per share.

PROJECTED FINANCIALS

Qualigen Therapeutics, Inc.	FY2020 A	Q1FY21 A	Q2FY21 A	Q3FY21 E	Q4FY21 E	FY2021 E	FY2022 E	FY2023 E
ALAN	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
AS1411	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.5
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	$5.5	$0.9	$0.8	$1.2	$1.3	$4.2	$5.5	$6.3
Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$5.6**	**$0.9**	**$0.8**	**$1.2**	**$1.3**	**$4.2**	**$5.5**	**$7.8**
Cost of Sales	$4.0	$0.8	$0.9	$0.8	$0.9	$3.4	$4.0	$4.5
Product Gross Margin	*28%*	*11%*	*-10%*	*33%*	*31%*	*19%*	*27%*	*42%*
Research & Development	$1.2	$0.6	$0.9	$0.8	$0.9	$3.2	$7.0	$11.0
Selling and Marketing	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.8
General & Administrative	$1.5	$2.0	$2.7	$2.2	$2.4	$9.2	$10.0	$11.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($1.5)	($2.6)	($3.7)	($2.7)	($3.0)	($12.0)	($16.0)	($19.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.3)	$16.0	$4.4	$0.0	$0.0	$20.4	($0.3)	($0.3)
Pre-Tax Income	($1.8)	($18.6)	($8.1)	($2.7)	($3.0)	($32.4)	($15.7)	($19.2)
Income Taxes	$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	**($1.8)**	**($18.6)**	**($8.1)**	**($2.7)**	**($3.0)**	**($32.4)**	**($15.7)**	**($19.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($2.12)**	**($0.41)**	**($0.12)**	**($0.13)**	**($1.74)**	**($0.63)**	**($0.69)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	5.6	8.7	19.8	23.0	23.1	18.7	25.0	28.0

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

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Source: Zacks Small Cap Research

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