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Qualigen Therapeutics, Inc. (QLGN-NASDAQ)

QLGN: Encouraging Preclinical Data Presented for QN-302 and RAS Inhibitor…

Based on our probability adjusted DCF model that takes into account potential future revenues from QN-302, QN-247, and RAS, QLGN is valued at $27.00 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 (12/01/22)	$1.50
Valuation	**$27.00**

OUTLOOK

On November 15, 2022, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the third quarter of 2022 and provided a business update. Revenues of FastPack® continued to increase since the company assumed sales and marketing from former partner Sekisui Diagnostics, with sales up approximately 25% year-over-year.

For the therapeutics pipeline, Qualigen recently presented encouraging preclinical data for both QN-302 and the RAS program. For QN-302, the data included information on the compound's safety, tolerability, and efficacy in a pancreatic cancer tumor model. For the RAS program, data was presented on a lead candidate that suppressed malignant peripheral nerve sheath (MPNST) tumors as well as xenograft growth in a pancreatic cancer patient-derived xenograft model.

SUMMARY DATA

52-Week High	**$15.80**
52-Week Low	**$1.50**
One-Year Return (%)	**-89.74**
Beta	**-0.43**
Average Daily Volume (sh)	**21,074**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**15**
Insider Ownership (%)	**6**
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 2022 Estimate	**-0.2**
P/E using 2023 Estimate	**-0.2**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	1.4 A	1.1 A	1.2 A	1.5 A	5.0 A
2022	0.7 A	1.4 A	1.4 A	1.5 E	5.1 E
2023					6.4 E
2024					8.0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$1.30 A	-$1.84 E	-$0.98 E	$1.51 A	-$6.10 A
2022	-$1.22 A	-$1.14 A	-$0.97 A	-$1.40 E	-$5.02 E
2023					-$4.33 E
2024					-$3.14 E

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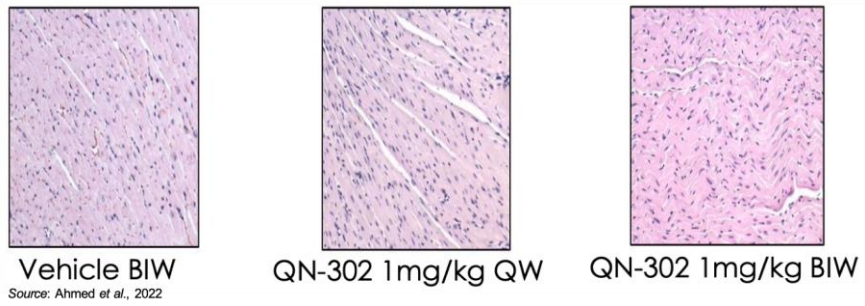
WHAT'S NEW

Business Update

Preclinical Data on QN-302 Presented at AACR Conference on Pancreatic Cancer

In September 2022, Qualigen Therapeutics, Inc. (QLGN) announced the presentation of two posters on QN-302 at the AACR 8th Special Conference on Pancreatic Cancer. The data presented include information on the compound's safety, tolerability, and efficacy in a pancreatic cancer model.

The quadruplex-binding compound QN-302 in the MIA-PaCa2 pancreatic adenocarcinoma model shows no cardiac or neurological liabilities at therapeutic doses (Ahmed *et al.*, 2022). This poster included preclinical toxicology data that showed QN-302 does not produce adverse toxicological reactions in mouse models at therapeutic doses. In *in vitro* tests, QN-302 inhibits acetylcholinesterase (AChE) by 53% and muscarinic receptor (M2) by 70% at 1 μM. However, the IC_{50} for QN-302 in MIA-PACA2 pancreatic ductal adenocarcinoma (PDAC) cells is approximately 1 nM. When mice were treated with 1 mg/kg QN-302 there was no change in AChE or M2 levels, thus there is unlikely to be an issue with binding to these receptors. Histology was performed on mice treated with QN-302 and showed no damage to heart tissue or kidney tissue and there were no abnormal behavioral effects. The following image shows cardiac muscle from mice treated with vehicle and two different doses of QN-302. Animals treated with QN-302 showed normal morphology of the myocardium and normal distribution of cardiomyocytes. Lastly, there were no significant adverse effects seen on heart rate even at dosages that were in excess of the therapeutic dose.



Source: Ahmed *et al.*, 2022

The quadruplex-binding compound QN-302 targets the S100P gene in PDAC (Ahmed *et al.*, 2022). QN-302 is hypothesized to exert it anti-cancer activity through high-affinity binding to, and stabilization of, G4-forming sequences. RNA-Seq analysis of QN-302 in MIA-PACA2 cells showed a pattern of susceptible genes involved in cancer-associated pathways. Expression of S100P is among the most highly down-regulated genes, as shown in the following figure. RNA-Seq analysis was also performed on tumor material from human patients and S100P is highly over-expressed (45-fold) in those samples. This data agrees with a published set of 229 genes associated with human PDAC and includes SPARC, CX3CL1, and S100P. The S100P gene has a G4 promoter, which is strongly suggestive of a stable G4 structure and could represent a binding site for QN-302.

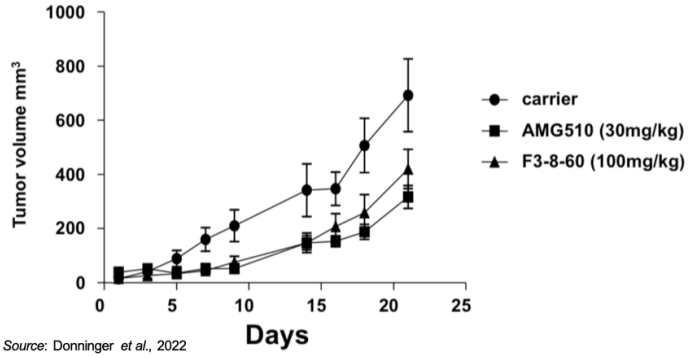
Gene	Down-regulation by QN-302, 24 hr, MIA-PACA2 cells	P	Fold change in expression in poorly-differentiated human tumours relative to normal pancreas tissue	P	No of PG4s	Gene function	PDAC role and occurrence
SPARC	-2.252	0.61	2.685	0.07	10	Secreted protein acidic and cysteine rich	Promotes pancreatic cancer cell proliferation and migration
S100P	**-3.230**	**0.08**	**45.27**	**0.05**	**3**	Calcium binding protein involved in signal transduction	Sensitive and specific marker for the detection of PDAC, promotes PDAC growth and survival, upregulated in PDAC
CX3CL1	-2.912	0.04	2.87	0.02	5	Chemokine	Modulates the development of PDAC via JAK/STAT signalling pathway; upregulated in PDAC

Source: Ahmed *et al.*, 2022

Encouraging Preclinical Data Presented for RAS Program

In October 2022, Qualigen announced the presentation of two posters at the Fourth RAS Initiative Symposium on the company's RAS-targeted platform. The program aims to identify small molecule inhibitors of RAS-RAS protein interaction. A summary of the posters is presented below.

A Novel RAS Inhibitor for Pancreatic Cancer (Donninger *et al*., 2022). An *in silico* screening approach was utilized to identify compounds that had the potential to bind to a groove in the surface of RAS to block the interaction with its effector RALGDS. A lead compound was identified (F3-8-60) that blocks RAS signaling, binds to K-RAS 12D and promotes changes in effector domain structure, is active against a pancreatic cancer xenograft model, and enhances the activity of an immune checkpoint inhibitor. The following image shows that F3-8-60 is just as effective as AMG510 (sotorasib), which is approved for the treatment of non-small-cell lung cancer that is driven by the G12C mutation in K-Ras. In addition, F3-8-60 showed synergism with a checkpoint inhibitor and exhibited no overt toxicity.



Source: Donninger *et al*., 2022

A Novel Pan-RAS Inhibitor for Malignant Peripheral Nerve Sheath Tumors (Donninger *et al*., 2022). This study examined the effect of F3-8-60 against malignant peripheral nerve sheath tumors, which exhibit a low overall five year survival rate of 40% and for which there is no effective treatment or cure. The data showed that F3-8-60 suppressed tumor growth of an MPNST cell line and in a MPNST primary tumor graft model. The compound again showed no overt *in vivo* toxicity.

These data are very encouraging as RAS mutations are found in approximately one-fourth of all cancers, including K-RAS mutations in 98% of pancreatic ductal adenocarcinomas, 52% of colon cancers, and 32% of lung adenocarcinomas.

Financial Update

On November 15, 2022, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the third quarter of 2022. The company reported $1.4 million in revenues for the third quarter of 2022, compared to $1.2 million for the three months ending September 30, 2021. All revenues were generated from product sales of diagnostics. The revenues reported in the current quarter represent a 25% year-over-year increase from the third quarter of 2021.

R&D expenses were $1.7 million for the third quarter of 2022 compared to $2.1 million for the three months ending September 30, 2021. The decrease was primarily due to decreased preclinical costs associated with the potential application of QN-165 for the treatment of COVID-19 and QN-247. G&A expenses were $2.6 million for the third quarter of 2022 compared to $2.8 million for the third quarter of 2021. The decrease was primarily due to a reduction in wages/bonuses and related payroll taxes.

As of September 30, 2022, Qualigen had approximately $6.6 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into the third quarter of 2023. On November 22, 2022, Qualigen announced a 1-for-10 reverse stock split, thus we estimate that the

company currently has approximately 4.2 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 5.9 million.

Conclusion

Qualigen is continuing to advance its development candidates as shown through the preclinical work presented in the past couple of months for QN-302 and the RAS program. We continue to anticipate an IND being filed for QN-302 and the initiation of a Phase 1 clinical trial in the first half of 2023. It's nice to see that FastPack sales are continuing to increase since Qualigen assumed full responsibility for its sales and marketing from former partner Sekisui Diagnostics. After accounting for the reverse split our valuation now stands at $27 per share.

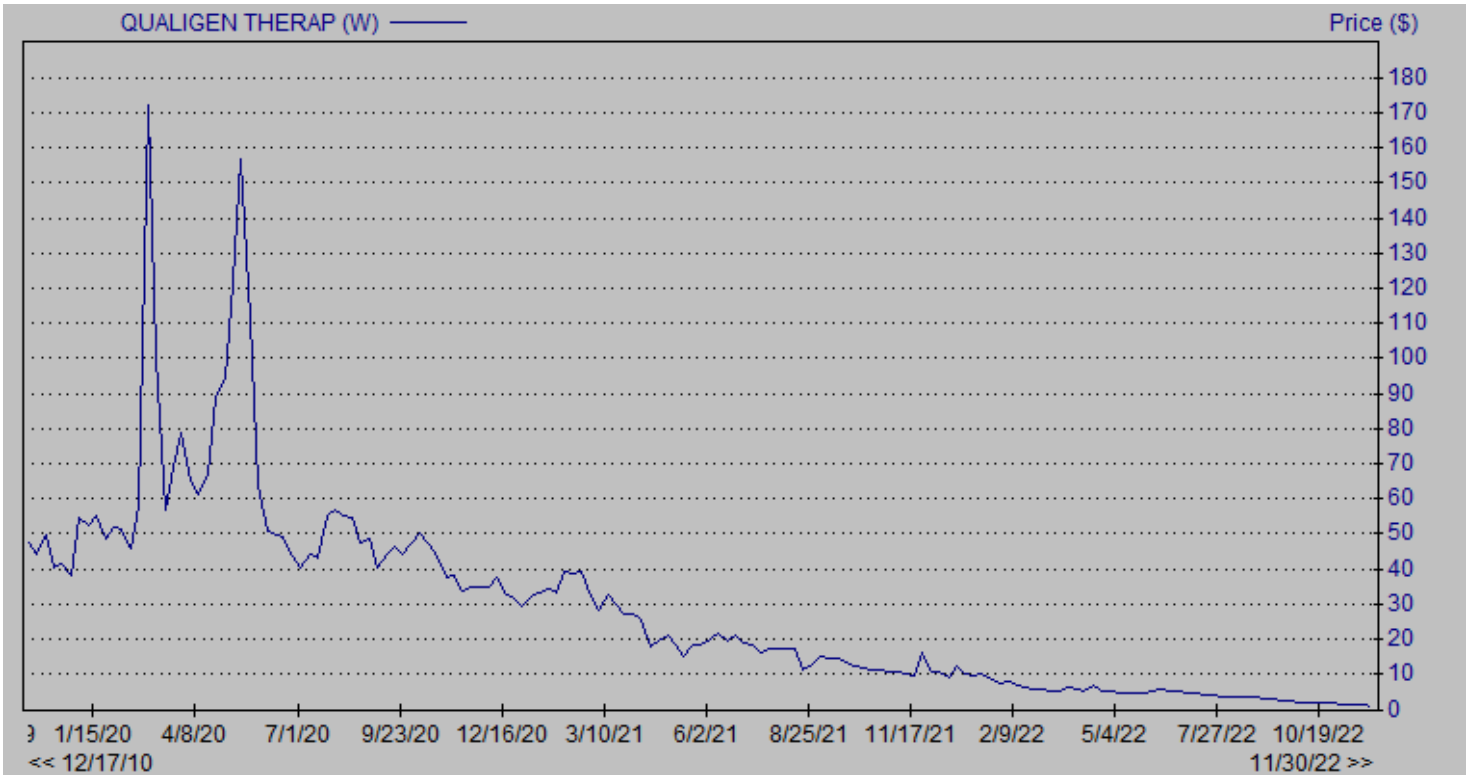
PROJECTED FINANCIALS

Qualigen Therapeutics, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
QN-302	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
QN-247	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
RAS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
FastPack	$5.0	$0.7	$1.4	$1.4	$1.5	$5.1	$6.4	$7.0
Other Income	$0.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$5.7**	**$0.7**	**$1.4**	**$1.4**	**$1.5**	**$5.1**	**$6.4**	**$7.0**
Cost of Sales	$4.3	$0.8	$1.1	$1.3	$1.2	$4.4	$4.9	$5.4
Product Gross Margin	*23%*	*-15%*	*23%*	*11%*	*23%*	*14%*	*23%*	*23%*
Research & Development	$11.7	$1.9	$1.5	$1.7	$3.0	$8.1	$9.0	$11.0
Selling and Marketing	$0.5	$0.1	$0.3	$0.2	$0.2	$0.9	$1.0	$1.1
General & Administrative	$11.7	$2.9	$2.7	$2.6	$2.6	$10.8	$11.0	$11.5
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($22.7)	($5.0)	($4.1)	($4.4)	($5.5)	($19.0)	($19.5)	($22.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($4.8)	($0.7)	$0.0	$0.6	$0.0	($0.1)	$0.0	$0.0
Pre-Tax Income	($17.9)	($4.3)	($4.2)	($3.8)	($5.5)	($18.9)	($19.5)	($22.0)
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	**($17.9)**	**($4.3)**	**($4.2)**	**($3.8)**	**($5.5)**	**($18.9)**	**($19.5)**	**($22.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($6.10)**	**($1.22)**	**($1.14)**	**($0.97)**	**($1.40)**	**($5.02)**	**($4.33)**	**($3.14)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.9	3.5	3.7	3.9	3.9	3.8	4.5	7.0

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

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