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Qualigen Therapeutics, Inc. (QLGN-NASDAQ)

QLGN: Dosing Begins in Phase 1 Trial of QN-302…

Based on our probability adjusted DCF model that takes into account potential future revenues from QN-302 and the pan-RAS platform, QLGN is valued at $5.00 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

Current Price (11/27/23)	$0.68
Valuation	**$5.00**

OUTLOOK

On November 14, 2023, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the third quarter of 2023 and provided a business update. The company recently initiated dosing of three patients in the first cohort of the Phase 1 clinical trial of QN-302 for the treatment of advanced or metastatic solid tumors. We anticipate initial data on safety and preliminary efficacy in the second quarter of 2024. In addition, the company recently presented data on QN-302 at AACR Special Conference: Pancreatic Cancer. For the Pan-RAS platform, a poster was recently presented on the company's lead RAS inhibitor compounds suppressing the interaction of RAS with different signaling pathways in Luminal B breast cancer model systems. We anticipate the company selecting a lead pan-RAS inhibitor candidate for IND enabling studies in the first quarter of 2024.

SUMMARY DATA

52-Week High	**$1.85**
52-Week Low	**$0.67**
One-Year Return (%)	**-63.37**
Beta	**-0.50**
Average Daily Volume (sh)	**14,450**
Shares Outstanding (mil)	**5**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
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	**N/A**
P/E using 2023 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0.7 A	1.4 A	1.4 A	1.4 A	5.0 A
2023	1.6 A	1.6 A	0.0 A	0.0 E	3.2 E
2024					0.0 E
2025					0.0 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$1.22 A	-$1.14 A	-$0.97 A	-$2.31 A	-$4.85 A
2023	-$0.78 A	-$0.69 A	-$0.72 A	-$0.52 E	-$2.70 E
2024					-$1.00 E
2025					-$0.71 E

WHAT'S NEW

Business Update

Dosing Begins in Phase 1 Trial of QN-302

On November 7, 2023, Qualigen Therapeutics, Inc. (QLGN) announced that the first three patients have begun dosing in the Phase 1a clinical trial of QN-302. This is a multicenter, open label, dose escalation, and dose expansion trial evaluating the safety, pharmacodynamics, and pharmacokinetics of intravenous QN-302 in patients with advanced or metastatic solid tumors. A total of up to 36 patients will be enrolled in the dose escalation portion of the trial, with the exact number to be enrolled dependent upon the observed safety profile. The dose expansion (Phase 1b) portion of the study may enroll up to an additional 20 patients with advanced, metastatic solid tumors. The primary objectives of the study are to determine the maximum tolerated dose (MTD) and the dose-limiting toxicities (DLTs) of QN-302 monotherapy and to establish the Recommended Phase 2 Dose (RP2D). Secondary objectives of the trial include determination of the pharmacokinetics of QN-302, to explore the pharmacodynamic effects of QN-302 on selected tumor biomarkers, and to monitor for evidence of antitumor activity by objective radiographic assessment. We anticipate initial safety and preliminary efficacy data in the second quarter of 2024.

QN-302 is a G-quadruplex (G4)-selective transcription inhibitor that the company licensed from the laboratory of Professor Stephen Neidle at University College London (UCL). Stretches of nucleic acids with repetitive guanine (G)-rich sequences can form higher order quadruplex arrangements (G4s). G4s can occur in genomic DNA and are widely distributed in a non-random manner in the human genome (Huppert *et al*., 2005). These complexes are over-represented in numerous cancer-related genes (Siddiqui-Jain *et al*., 2002). In addition, G4s contribute to the genomic instability of cancer cells and may be involved in the regulation of transcription and replication (Wang *et al*., 2019; Varshney *et al*., 2020). Their enhancement in cancer cells is exemplified by one study showing approximately 10,000 G4 structures in an immortalized cell line in contrast to a noncancer cell line that exhibited only approximately 1,500 G4 structures (Hänsel-Hertsch *et al*., 2016).

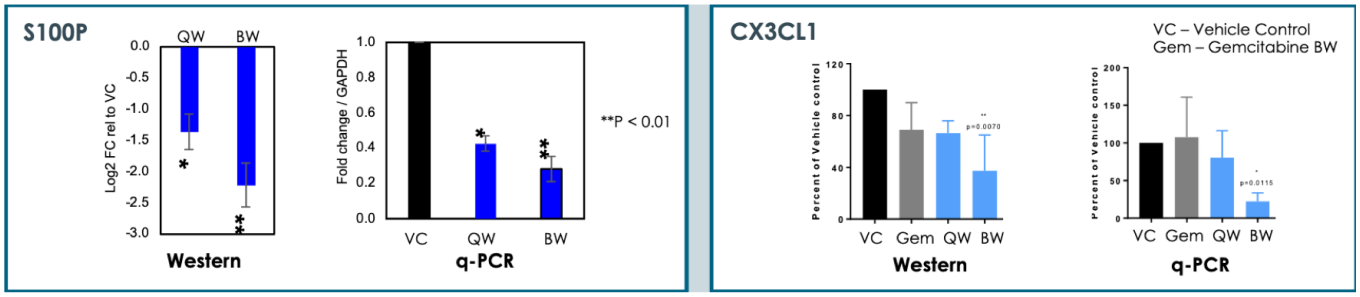
G4s can be exploited by cancer therapeutics that stabilize the structures and inhibit various cellular processes. These types of compounds are particularly attractive when targeting "undruggable" proteins such as MYC, which is upregulated in approximately 70% of all cancers and controls the expression of a wide variety of genes associated with proliferation, differentiation, apoptosis, and oncogenesis (Dang, 2012).

QN-302 is a tetra-substituted naphthalene diimide (ND) derivative that exhibits low nM anti-proliferative activity against a panel of human cancer cell lines (Ahmed *et al*., 2020). In addition, it was shown to down-regulate a large number of genes including those in the TNF, NK-kappa B, and Wnt signaling pathways. Lastly, protein levels of MAPK11 (which is overexpressed in multiple human cancers) were reduced to undetectable levels following 2x-weekly dosing of QN-302 for 4 weeks in a PDAC xenograft model.

The company recently presented two posters on QN-302 at the AACR Special Conference on Pancreatic Cancer, which took place in Boston, MA in September 2023:

The Pan G-Quadruplex experimental drug QN-302 in PDAC: identification of potential biomarkers for clinical studies (Ahmed *et al*., 2023). This poster included results showing that treatment of mice bearing MIA-PACA2 xenografts resulted in decreased expression of the genes S100P and CX3CL1. Increased expression of both of those genes has previously been correlated with PDAC disease progression. As the following graphs show, both genes are highly down-regulated at the mRNA and

protein levels following 28-day dosing with dosing of 1 mg/kg BW (twice weekly) or QW (once weekly). The authors of the poster propose that since S100P and CX3CL1 both contain many potential G4 sequences, they may be direct targets of the drug and could serve as biomarkers of response to QN-302 in PDAC patients.



Source: Ahmed *et al.*, 2023

Target genes in pancreatic cancer cells of the Pan G-Quadruplex clinical candidate compound QN-302 revealed by comparative transcriptome profiling (Ahmed *et al.*, 2023). This poster included data showing that administration of QN-302 to PDAC cells *in vitro* resulted in significant changes in the pattern of down-regulated G-quadruplex (G4) genes. In addition, the following table shows that QN-302, I relation to the similar compounds CM03 and SOP1247, showed nanomolar potency against various cell lines, including gemcitabine-resistant MIA-PACA2 and PANC-1 cell lines. In addition, significant G4 stability is evidenced by low nanomolar binding affinity [ΔTm (º)] to G4s.

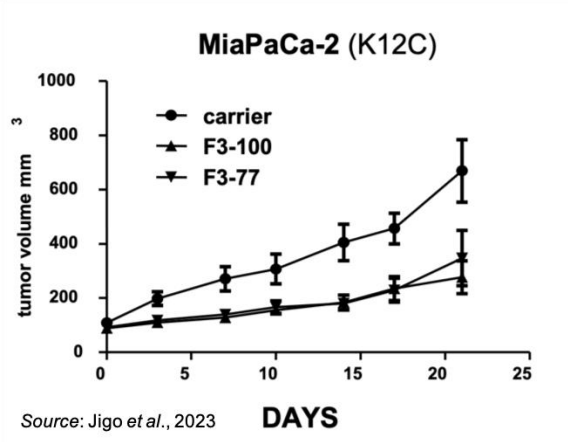
	QN-302	CM03	SOP1247
IC_{50} 96 hr (nM)			
MIA-PACA2	**1.3**	9.0	13.8
PANC-1	**1.4**	15.6	15.7
CAPAN-1	**5.9**	26.5	38.8
Bx-PC3	**2.6**	15.5	20.5
MIA-PACA2-GemR	**3.8**	14.9	N/A
ΔT_m (°)	**23.1**	17.6	18.4

Source: Ahmed *et al.*, 2023

Poster on Pan-RAS Inhibitor Platform Presented at AACR Special Conference

On October 23, 2023, Qualigen announced a poster presentation on the company's Pan-RAS platform was presented at the AACR Special Conference in Breast Cancer Research. The company's Pan-RAS platform includes a series of compounds that are believed to suppress or block the interaction of endogenous RAS with c-RAF, thus influencing the KRAS, HRAS, and NRAS effector pathways. While RAS is seldom mutated in breast cancer, it is often hyperactivated by upregulation of positive regulators (e.g., HER2) or downregulation of negative regulators (e.g., NF1, DAB2IP), both of which are common in luminal breast cancers.

Pan-RAS Inhibitors to Treat Luminal B Breast Cancer (Jigo *et al.*, 2023). This poster included results showing that the company's RAS inhibitors suppressed the interaction of RAS with its downstream mitogenic effectors and suppress RAS signaling pathways (MAPK and RAL pathways) in Luminal B breast cancer cell model systems. In addition, the compounds inhibit 3D growth at doses that have little to no effect on normal 2D growth. The compounds are orally available and, as shown in the following graph, can inhibit the growth of *in vivo* xenograft breast tumors.



Financial Update

On November 14, 2023, Qualigen announced financial results for the third quarter of 2023. The company did not report any revenues from continuing operations following the sale of the FastPack business in July 2023.

R&D expenses were $1.4 million for the third quarter of 2023 compared to $0.9 million for the three months ending September 30, 2022. The increase in R&D expenses was primarily due to increased preclinical research costs for QN-302. G&A expenses for the third quarter of 2023 were $1.3 million compared to $2.5 million for the third quarter of 2022. The decrease was primarily due to a decrease in stock-based compensation and professional fees.

As of September 30, 2023, Qualigen had approximately $2.1 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into the first quarter of 2024. As of November 10, 2023, Qualigen had approximately 5.2 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.7 million.

Conclusion

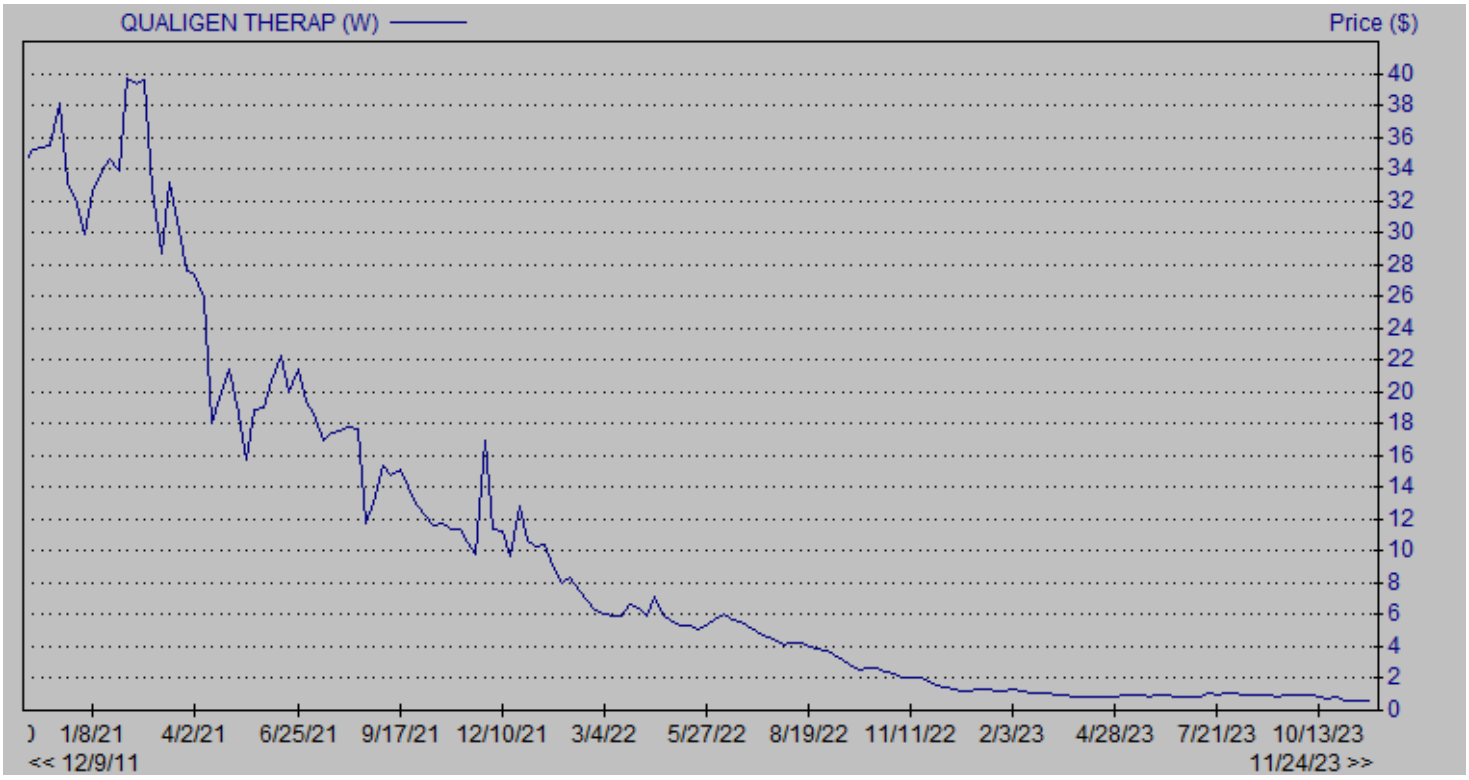
Dosing of the first three patients in the Phase 1 clinical trial of QN-302 is an important milestone for the company and we eagerly await the initial safety and efficacy data, which we hope to see in the second quarter of 2024. We are also expecting the company to choose a lead development candidate from the pan-RAS platform in the first quarter of 2024 to move into IND enabling studies. With no changes to our model our valuation remains at $5.00 per share.

PROJECTED FINANCIALS

Qualigen Therapeutics, Inc.	2022 E	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 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	$1.6	$1.6	$0.0	$0.0	$3.2	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$5.0**	**$1.6**	**$1.6**	**$0.0**	**$0.0**	**$3.2**	**$0.0**	**$0.0**
Cost of Sales	$4.3	$1.3	$1.0	$0.0	$0.0	$2.3	$0.0	$0.0
Product Gross Margin	*14%*	*21%*	*38%*	-	-	*29%*	-	-
Research & Development	$6.8	$2.1	$1.3	$1.4	$1.4	$6.3	$5.7	$5.9
Selling and Marketing	$1.0	$0.2	$0.2	$0.0	$0.0	$0.4	$0.0	$0.0
General & Administrative	$10.8	$1.7	$2.7	$1.3	$1.3	$7.0	$5.3	$5.5
Other (Income) Expense	$4.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($22.2)	($3.7)	($3.6)	($2.8)	($2.7)	($12.7)	($11.0)	($11.4)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.9)	$0.6	($0.0)	$0.5	$0.0	$1.0	$0.0	$0.0
Pre-Tax Income	($21.3)	($4.3)	($3.5)	($3.2)	($2.7)	($13.8)	($11.0)	($11.4)
Income Taxes	($0.3)	($0.2)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($21.0)**	**($4.1)**	**($3.5)**	**($3.2)**	**($2.7)**	**($13.8)**	**($11.0)**	**($11.4)**
Net Margin	-	-	-	-	-	-	-	-
Loss from Discontinued Operations	$0.0	$0.0	$0.0	($0.5)	$0.0	($0.5)		
Net loss attributable to noncontrolling interest	($2.4)	($0.3)	($0.0)	($0.0)	$0.0	($0.3)	$0.0	$0.0
Net loss attributable to Qualigen Therapeutics, Inc.	($18.6)	($3.8)	($3.5)	($3.7)	($2.7)	($13.7)	($11.0)	($11.4)
Reported EPS	**($4.85)**	**($0.78)**	**($0.69)**	**($0.72)**	**($0.52)**	**($2.70)**	**($1.00)**	**($0.71)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	3.8	5.0	5.1	5.1	5.2	5.1	11.0	16.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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