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Qualigen Therapeutics, Inc. (QLGN-NASDAQ)

QLGN: IND for QN-302 to be Submitted in Mid-2023…

Based on our probability adjusted DCF model that takes into account potential future revenues from QN-302, Pan-RAS platform, and QN-247, 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 (05/12/23)	$1.04
Valuation	**$5.00**

OUTLOOK

On May 2, 2023, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the fourth quarter and full year for 2022 and provided a business update. Qualigen is diligently working toward the submission of an Investigational New Drug (IND) application for its lead development candidate, QN-302. We anticipate the IND being filed in mid-2023 such that a Phase 1 clinical trial can initiate in the second half of 2023. Qualigen recently presented four posters on QN-302 at the 2023 AACR Annual Meeting, including data showing its activity in multiple pancreatic cancer cell lines and in vivo models. The company is continuing work on its other lead program targeting RAS and will present two abstracts, one of which will be a poster, on work related to that program at the 2023 ASCO Annual Meeting. We expect a lead development compound to be selected for the Pan-RAS platform by the end of 2023.

SUMMARY DATA

52-Week High	**$6.10**
52-Week Low	**$0.87**
One-Year Return (%)	**-79.39**
Beta	**-0.42**
Average Daily Volume (sh)	**53,792**
Shares Outstanding (mil)	**5**
Market Capitalization ($mil)	**$5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**60**
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	**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)
2022	0.7 A	1.4 A	1.4 A	1.4 A	5.0 A
2023	1.4 E	1.5 E	1.5 E	1.6 E	6.0 E
2024					6.3 E
2025					6.6 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$1.22 A	-$1.14 E	-$0.97 E	-$2.31 A	-$4.85 A
2023	-$0.85 E	-$0.54 E	-$0.46 E	-$0.46 E	-$2.16 E
2024					-$1.39 E
2025					-$1.29 E

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WHAT'S NEW

Business Update

IND to be Filed for QN-302 in Mid-2023

Qualigen Therapeutics, Inc. (QLGN) is continuing work toward the submission of an Investigational New Drug (IND) application for its lead therapeutic program, QN-302. We anticipate an IND being filed for QN-302 in mid-2023.

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.

Qualigen recently presented four posters on QN-302 at the 2023 American Association for Cancer Research (AACR) Annual Meeting.

A comparison of the activity of the quadruplex-targeting experimental drugs QN-302 and CX-5461 (Pidnarulex) in wild-type and gemcitabine-resistant pancreatic cancer cells (Ahmed *et al*., 2023). This poster described *in vitro* cell growth inhibition data for QN-302, CM03 (a precursor to QN-302), CX-5461 (a structurally unrelated G4-binding agent), and gemcitabine in parental and gemcitabine-resistant pancreatic cancer cell lines. The data showed that QN-302 retained potency against gemcitabine-resistant cell lines as judged by cell growth inhibition as well as expression changes in G4 genes targeted by QN-302. This suggests that QN-302 may offer advantages over gemcitabine-based therapies. Gemcitabine resistance is common and a major contributor to poor outcomes for most pancreatic cancer patients.

The potent quadruplex-binding compound QN-302 down-regulates the S100P gene in in vitro and in vivo models of pancreatic cancer: a potential therapeutic target and biomarker for PDAC (Ahmed *et al*., 2023). This poster presented data showing that QN-302 downregulated expression of S100P, a small calcium-binding protein in the PI3K/AKT signaling pathway that is over-expressed in

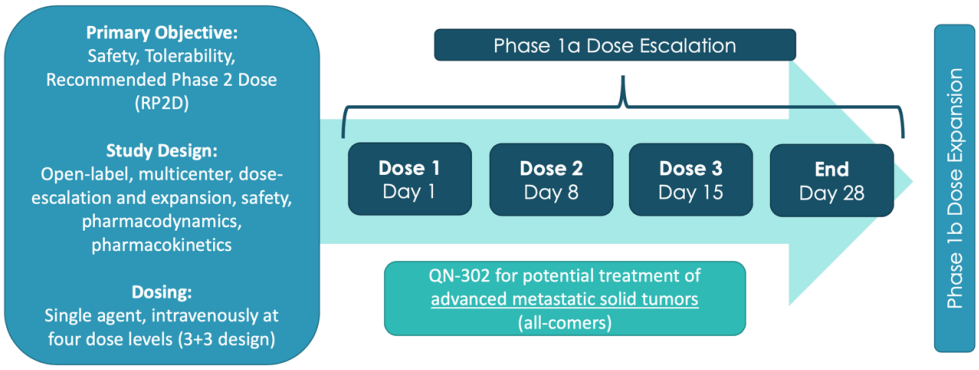
~70% of human pancreatic cancers. S100P may serve as a therapeutic target of QN-302 and may also serve as a biomarker to evaluate response to QN-302 therapy.

The potent quadruplex-binding compound QN-302 shows anti-tumor activity as a monotherapy in an orthotopic in vivo model of pancreatic cancer (Williams *et al*., 2023). This poster presented data showing in vivo activity for QN-302 in a fourth pancreatic cancer model, which further confirms its potential for treating pancreatic cancer patients.

Structure-based design rules for potent quadruplex-binding compounds based on the naphthalene diimide core (Neidle *et al*., 2023). This poster described the factors that contribute to G4 binding and affinity. Molecular modeling was utilized to examine what could increase G4 affinity and enhance cellular uptake, the factors that were used to develop QN-302.

In March 2023, Qualigen announced the publication of a peer-review journal article in *Molecules* that described data showing how QN-302 downregulates the expression of the *S100P* gene and the S100P protein in cells and in vivo (Ahmed *et al*., 2023). The paper also describes how the *S100P* gene contains 60 putative quadruplex-forming sequences, one of which is in the promoter region 48 nucleotides upstream from the transcription start site. Through biophysical and molecular modeling studies, the researchers showed that this sequence forms a highly-stable G-quadruplex in vitro that is further stabilized by QN-302. Transcriptome analysis showed that *S100P* expression is highly upregulated in pancreatic cancer tumor tissue compared to normal pancreatic tissue and the highest level of *S100P* expression is associated with the most differentiated tumor cells. These data support the hypothesis that the S100P promoter G-quadruplex is a potential therapeutic target of QN-302.

The following slide gives an overview of the company's proposed Phase 1a clinical study of QN-302. It will be an open label, multicenter, dose escalation and expansion study with a primary objective of safety, tolerability, and determination of the recommended Phase 2 dose. Patients with advanced metastatic solid tumors will be included in the trial. Intravenous dosing of QN-302 will occur on Day 1, Day 8, Day 15, and Day 28. We expect additional information regarding the trial to be released by the company before initiation.



Source: Qualigen Therapeutics, Inc.

Update on Pan-RAS Platform

In March 2023, Qualigen announced the presentation of two posters at the AACR Special Conference: Targeting RAS. The two posters described preclinical studies for the Pan-RAS platform that showed potential anti-RAS activity in both pancreatic and breast cancer models.

A Novel RAS inhibitor for Pancreatic Cancer (Donninger *et al*., 2023). This poster described the anti-RAS activity of a series of RAS inhibitors with predicted unique interaction regions. The compounds bind to both wild-type KRAS and HRAS, however they exhibit preferential binding to specific mutations of KRAS. Data showed suppression of mutant RAS signaling and inhibition of 3D cell growth of mutant RAS

cell lines. In addition, the compounds enhanced the activity of both MRTX-1133 (against KRAS G12D cell lines) and AMG-510 (against KRAS G12C cell lines).

A Novel RAS inhibitor for Luminal B and Triple Negative Breast Cancers (Jigo *et al*., 2023). This poster describes the novel RAS inhibitor F3860 and its ability to inhibit tumor growth *in vitro* and *in vivo* in model systems of Luminal B and Triple Negative breast cancers. Tumor growth suppression is achieved through suppression of key RAS signaling activities at nanomolar levels in Luminal B cells and at micromolar levels in Triple Negative breast cancer cells.

Qualigen will have two abstracts included in the American Society of Clinical Oncology's (ASCO) 2023 Annual Meeting Abstract Book, one of which was also accepted as a poster to be presented during the meeting. In addition, the company is continuing work on identifying a lead pan-RAS drug candidate and we anticipate a lead candidate being selected by the end of 2023.

Financial Update

On May 2, 2023, Qualigen announced financial results for the fourth quarter and full year 2022. The company reported approximately $5.0 million in revenues for 2022, compared to approximately $5.7 million for 2021. All revenues were generated from product sales of diagnostics. The decrease was primarily due to the recognition of approximately $0.6 million in license revenue from Yi Xin under the technology transfer agreement for the year ending December 31, 2021.

R&D expenses were $6.8 million for 2022 compared to $11.7 million for 2021. The decrease was primarily due to a decrease in expenses related to the potential application of QN-165 for the treatment of COVID-19 partially offset by an increase in QN-302 spending. G&A expenses were $10.8 million for 2022 compared to $11.7 million for 2021. The decrease was primarily due to a reduction in professional fees, payroll-related expenses, insurance expenses, and investor relations expenses.

As of December 31, 2022, Qualigen had approximately $7.0 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into the third quarter of 2023. As of April 11, 2023, Qualigen had approximately 5.1 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 9.9 million.

Conclusion

We look forward to Qualigen filing the IND for QN-302 such that a Phase 1 trial can initiate in the second half of 2023. We expect additional details regarding the Phase 1 trial to be released with news of acceptance of the IND along with preliminary timelines for that trial. The Pan-RAS platform is continuing to advance and we are hopeful that a lead development candidate for that program will be selected by the end of 2023. Qualigen will need to raise additional capital later this year, thus we have accounted for that in our model, which has reduced our valuation to $5 per share.

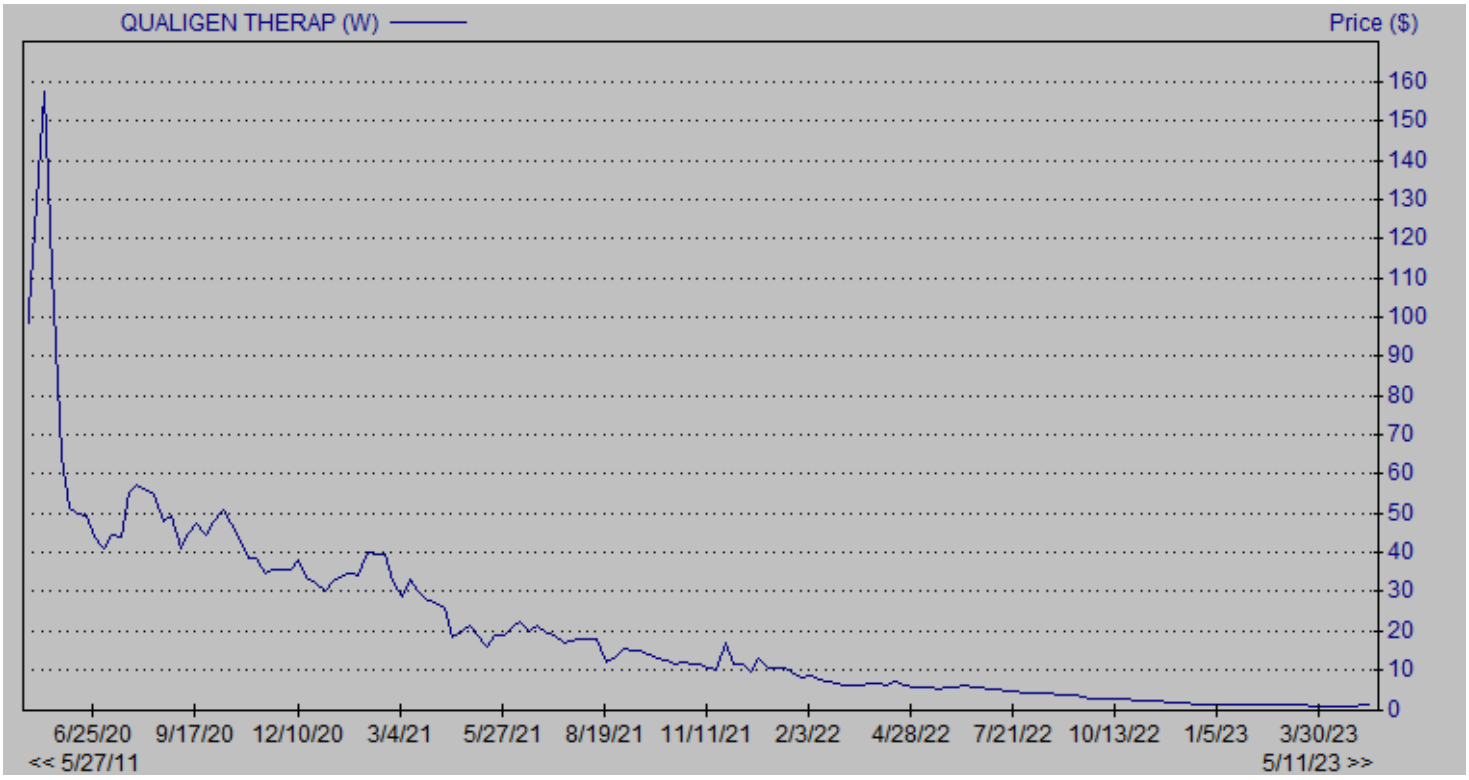
PROJECTED FINANCIALS

Qualigen Therapeutics, Inc.	2022 A	Q1 E	Q2 E	Q3 E	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
RAS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
FastPack	$5.0	$1.4	$1.5	$1.5	$1.6	$6.0	$6.3	$6.6
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$5.0**	**$1.4**	**$1.5**	**$1.5**	**$1.6**	**$6.0**	**$6.3**	**$6.6**
Cost of Sales	$4.3	$1.1	$1.1	$1.2	$1.3	$4.7	$5.4	$5.4
Product Gross Margin	*14%*	*21%*	*25%*	*21%*	*22%*	*22%*	*14%*	*18%*
Research & Development	$6.8	$1.9	$1.9	$2.1	$2.1	$8.0	$9.0	$10.0
Selling and Marketing	$1.0	$0.3	$0.3	$0.3	$0.3	$1.0	$1.1	$1.1
General & Administrative	$10.8	$2.7	$2.7	$2.8	$2.8	$11.0	$11.3	$11.8
Other (Income) Expense	$4.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($22.2)	($4.55)	($4.48)	($4.83)	($4.80)	($18.66)	($20.5)	($21.7)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.9)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($21.3)	($4.6)	($4.5)	($4.8)	($4.8)	($18.7)	($20.5)	($21.7)
Income Taxes	($0.3)	$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	**($21.0)**	**($4.6)**	**($4.5)**	**($4.8)**	**($4.8)**	**($18.7)**	**($20.5)**	**($21.7)**
Net Margin	-	-	-	-	-	-	-	-
Net loss attributable to noncontrolling interest	($2.4)	($0.2)	($0.2)	($0.2)	($0.2)	($0.8)	($1.0)	($1.0)
Net Loss attributable to Qualigen Therapeutics, Inc.	($18.6)	($4.4)	($4.3)	($4.6)	($4.6)	($17.9)	($19.5)	($20.7)
Reported EPS	**($4.85)**	**($0.85)**	**($0.54)**	**($0.46)**	**($0.46)**	**($2.16)**	**($1.39)**	**($1.29)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	3.8	5.1	8.0	10.0	10.0	8.3	14.0	16.0

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

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