Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

August 30, 2023
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Qualigen Therapeutics, Inc. (QLGN-NASDAQ)

QLGN: Receives U.S. FDA IND Clearance; Phase 1 Trial to Initiate 2H23…

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 (08/30/23)	$1.01
Valuation	**$5.00**

OUTLOOK

On August 15, 2023, Qualigen Therapeutics, Inc. (QLGN) announced financial results for the second quarter of 2023 and provided a business update. The company recently received U.S. FDA IND clearance for QN-302 and a Phase 1 clinical trial is ready to initiate in the second half of 2023. The trial will be a multicenter, open label, dose escalation, safety, pharmacokinetic, and pharmacodynamic study that will evaluate the safety, tolerability, and antitumor activity of QN-302 in approximately 24 patients with advanced solid tumors.

Qualigen also recently divested its FastPack diagnostic business to Chembio Diagnostics, Inc., an American subsidiary of French diagnostics provider BIOSYNEX Group, for $5.1 million in cash. The proceeds from the sale will be used to help fund the Phase 1 trial of QN-302 and will help focus the company's resources on cancer therapeutic development.

SUMMARY DATA

52-Week High	**$3.98**
52-Week Low	**$0.87**
One-Year Return (%)	**-73.97**
Beta	**-0.38**
Average Daily Volume (sh)	**13,885**
Shares Outstanding (mil)	**5**
Market Capitalization ($mil)	**$5**
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	0.5 E	0.0 E	3.7 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 E	-$0.97 E	-$2.31 A	-$4.85 A
2023	-$0.78 A	-$0.69 A	-$0.92 E	-$0.90 E	-$3.29 E
2024					-$1.73 E
2025					-$1.30 E

© Copyright 2023, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

IND for QN-302 Cleared; Phase 1 Trial to Initiate in 2H23

On August 1, 2023, Qualigen Therapeutics, Inc. (QLGN) announced that the U.S. Food and Drug Administration (FDA) had cleared the Investigation New Drug (IND) application for QN-302, the company's lead cancer therapeutic development compound. We anticipate a Phase 1 clinical trial for QN-302 initiating in the second half of 2023. This is an important milestone for the company as it marks its transition from a preclinical to a clinical-stage entity.

The Phase 1 clinical trial will be a multicenter, open label, dose escalation study that will evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of QN-302 in patients with advanced solid tumors. We anticipate approximately 24 patients will be enrolled and the study should be completed by the end of 2024. Qualigen has partnered with Translational Drug Development (TD2) as the contract research organization (CRO) to conduct the Phase 1 trial.

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.

FastPack Business Divested

On July 24, 2023, Qualigen announced it had sold its FastPack diagnostics business to Chembio Diagnostics, Inc., an American subsidiary of the French diagnostics provider BIOSYNEX Group. AT the closing, Qualigen received $5.2 million in cash, which will be used to partially fund the Phase 1 clinical trial of QN-302. The sale of the FastPack business also helps to align the company's resources more closely with its new mission of developing cancer therapeutics.

Financial Update

On August 15, 2023, Qualigen announced financial results for the second quarter of 2023. The company reported $1.6 million in revenues for the second quarter of 2023, compared to $1.4 million for the three months ending June 30, 2022. This represented a 14% year-over-year increase. The increase was primarily due to growth in sales volumes and higher average unit selling prices. Cost of product sales increased during the current quarter to $1.0 million, or 62% of net product sales, compared to approximately $1.1 million, or 77% of net product sales, for the three months ending June 30, 2022. The decrease was due to a reduction in force implemented in January 2023.

R&D expenses were $1.5 million for the second quarter of 2023 compared to $1.5 million for the three months ending June 30, 2022. Of the $1.5 million in R&D costs in the current quarter, $1.2 million (89%) was due to therapeutics and $0.2 million (11%) was due to diagnostics. Of the $1.5 million in R&D costs in the second quarter of 2022, $1.1 million (73%) was due to therapeutics and $0.4 million (27%) was due to diagnostics. The decrease in diagnostics R&D costs in the current quarter was primarily due to a decrease in stock-based compensation and payroll expenses partially offset by an increase in R&D expenses for NanoSynex. The increase in therapeutics R&D costs was primarily due to increased preclinical research costs for QN-302 partially offset by a decrease in preclinical research costs for QN-247. G&A expenses in the second quarters of 2023 and 2022 were both $2.7 million.

As of June 30, 2023, Qualigen had approximately $1.3 million in cash and cash equivalents. On July 25, 2023, the company received $4.7 million in cash from Chembio for the sale of the FastPack business, with another $450,000 being held in escrow to satisfy certain indemnification obligations. We estimate the company has sufficient capital to fund operations into the first quarter of 2024. As of August 10, 2023, Qualigen had approximately 5.1 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 9.6 million.

Conclusion

We're excited to see that the FDA has cleared the IND for QN-302 and we look forward to the initiation of the Phase 1 trial in the second half of 2023. We believe the divestiture of the FastPack business is a smart strategic move by the company as its priorities and resources can now be better aligned with the therapeutics business. The non-dilutive cash from the sale will also help to fund the Phase 1 clinical trial, which is advantageous given the current difficult funding environment. We have removed the FastPack business from our model and added in the cash received for its sale. Our valuation remains at $5.00 per share.

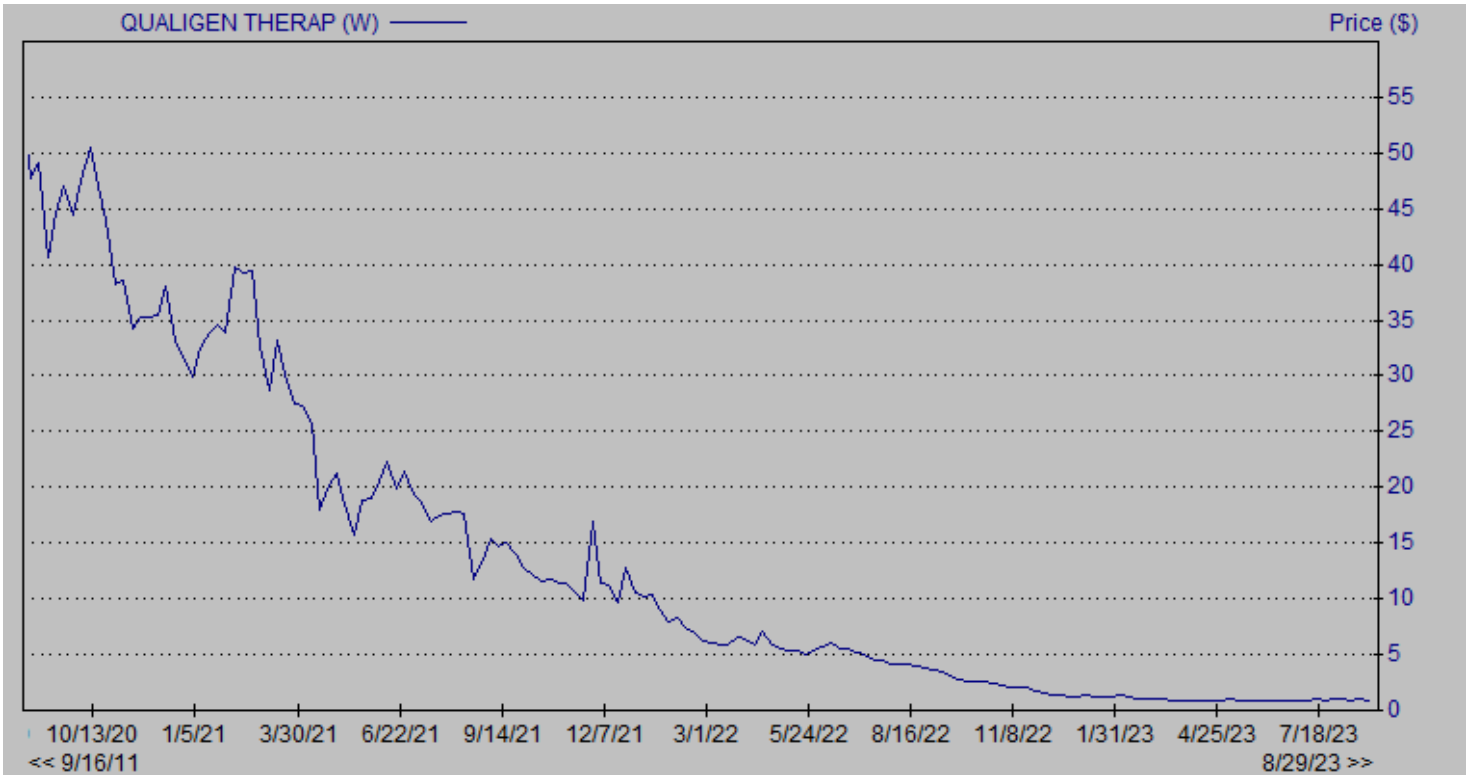
PROJECTED FINANCIALS

Qualigen Therapeutics, Inc.	2022 E	Q1 A	Q2 A	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
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	$0.5	$0.0	$3.7	$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**	**$0.5**	**$0.0**	**$3.7**	**$0.0**	**$0.0**
Cost of Sales	$4.3	$1.3	$1.0	$0.3	$0.0	$2.6	$0.0	$0.0
Product Gross Margin	*14%*	*21%*	*38%*	*40%*	*#DIV/0!*	*31%*	*#DIV/0!*	*#DIV/0!*
Research & Development	$6.8	$2.1	$1.3	$2.1	$2.1	$7.6	$9.0	$10.0
Selling and Marketing	$1.0	$0.2	$0.2	$0.2	$0.0	$0.6	$0.0	$0.0
General & Administrative	$10.8	$1.7	$2.7	$2.8	$2.8	$10.0	$11.0	$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)	($3.7)	($3.6)	($4.9)	($4.9)	($17.0)	($20.0)	($21.8)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.9)	$0.6	($0.0)	$0.0	$0.0	$0.6	$0.0	$0.0
Pre-Tax Income	($21.3)	($4.3)	($3.5)	($4.9)	($4.9)	($17.6)	($20.0)	($21.8)
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)**	**($4.9)**	**($4.9)**	**($17.6)**	**($20.0)**	**($21.8)**
Net Margin	-	-	-	-	-	-	-	-
Net loss attributable to noncontrolling interest	($2.4)	($0.3)	($0.0)	($0.2)	($0.2)	($0.7)	($1.0)	($1.0)
Net loss attributable to Qualigen Therapeutics, Inc.	($18.6)	($3.8)	($3.5)	($4.7)	($4.7)	($16.7)	($19.0)	($20.8)
Reported EPS	**($4.85)**	**($0.78)**	**($0.69)**	**($0.92)**	**($0.90)**	**($3.29)**	**($1.73)**	**($1.30)**
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*

© Copyright 2023, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

© Copyright 2023, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.