Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

November 17, 2021
David Bautz, PhD
(312) 265-9471
dbautz@zacks.com

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

Celsion Corporation

(CLSN-NASDAQ)

CLSN: OVATION 2 Trial Nears 70% of Target Enrollment…

Based on our probability adjusted DCF model that takes into account potential future revenues of GEN-1 and the PLACCINE technology, CLSN is valued at $3.50/share. This model is highly dependent upon continued clinical success of the development candidates and will be adjusted accordingly based on future clinical results.

Current Price (11/17/21)	$0.81
Valuation	**$3.50**

OUTLOOK

On November 15, 2021, Celsion Corporation (CLSN) announced financial results for the third quarter of 2021 and provided a business update. The company is currently conducting the Phase II OVATION 2 Trial of GEN-1 in patients with advanced-stage ovarian cancer (Stage III/IV). Interim data from the trial shows that 16/20 (80%) of patients treated with GEN-1 achieved R0 resections compared to 9/16 (56%) treated with placebo. We anticipate another update from the OVATION 2 trial in the next few weeks. In addition to GEN-1, the company is also developing a SARS-CoV-2 vaccine based on its PLACCINE technology that allows for multiple antigen expression. Preclinical results show immunization of mice produced antibodies that prevented infection of cultured cells in a viral neutralization assay. The company is currently focusing proof-of-concept efforts on a dual-antigen vaccine targeting multiple strains of SARS-CoV-2.

SUMMARY DATA

52-Week High	**$2.81**
52-Week Low	**$0.50**
One-Year Return (%)	**59.03**
Beta	**1.88**
Average Daily Volume (sh)	**782,924**
Shares Outstanding (mil)	**87**
Market Capitalization ($mil)	**$70**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**20**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-0.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2021 Estimate	**-2.9**
P/E using 2022 Estimate	**-2.8**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0.1 A	0.1 A	0.1 A	0.1 A	0.5 A
2021	0.1 A	0.1 A	0.1 A	0.1 E	0.5 E
2022					0.5 E
2023					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.20 A	-$0.18 A	-$0.24 A	-$0.05 A	-$0.67 A
2021	-$0.09 A	-$0.06 A	-$0.06 A	-$0.06 E	-$0.27 E
2022					-$0.26 E
2023					-$0.29 E

© Copyright 2021, Zacks Investment Research. All Rights Reserved.

Business Update

Ovation 2 Study Near 70% of Target Enrollment

Celsion Corporation (CLSN) is currently conducting the OVATION 2 clinical trial of GEN-1 in patients with advanced ovarian cancer (Stage III/IV). It is a Phase 1/2 randomized, open label, multicenter trial to evaluate the safety, efficacy, and biological activity of intraperitoneal GEN-1 plus neoadjuvant chemotherapy (NACT), compared to NACT alone. Up to 110 patients are anticipated to be enrolled in the trial. The Phase 1 run-in portion of the study began with 14 patients receiving 100 mg/m^2 of GEN-1, as the highest amount of GEN-1 studied prior to this trial was 79 mg/m^2. The primary endpoint is progression free survival (PFS), which will be evaluated following 80 PFS events or 16 months, whichever is longer. Secondary endpoints include clinical response (ORR), pathological response, surgical resection scores, biological response, and safety. The trial is designed with an 80% confidence interval for an observed PFS hazard ratio (HR) of 0.75, which would correspond to an approximately 33% improvement in risk for cancer progression when comparing GEN-1+NACT to NACT alone.

Thus far, over 70% of the projected 110 patients have been enrolled in the OVATION 2 trial. Interim clinical data from the first 36 patients who have undergone interval debulking surgery show that:

- 16/20 (80%) patients treated with GEN-1 (100 mg/m^2) + NACT had a complete tumor resection (R0) following interval debulking surgery, compared to only 9/16 (56%) of patients receiving NACT only
- Both cohorts of patients had similar ORR of approximately 80%

When combining the results seen thus far in the OVATION 2 trial with the results from the OVATION 1 trial (that included patients with identical inclusion criteria to the OVATION 2 trial), the data show that there appears to be a dose-dependent effect of adding GEN-1 to NACT.

		% Patients with R0 Resections
0, 36, 47 mg/m^2 of GEN-1 plus NACT	n=22	50 %
61, 79, 100 mg/m^2 of GEN-1 plus NACT	n=28	82 %

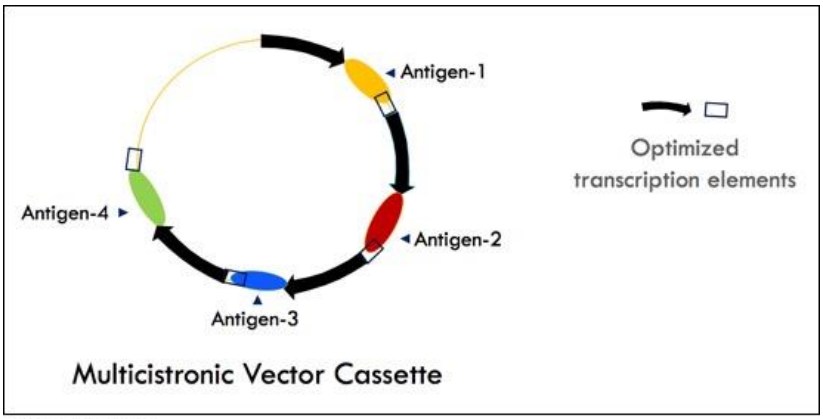
Source: Celsion Corp.

During the third quarter conference call, management indicated that another update from the trial could be available within the next few weeks. We anticipate enrollment being completed in the OVATION 2 trial in the first half of 2022, which could lead to the data readout for the primary endpoint in the first half of 2023.

PLACCINE Technology Presented at International Vaccine Congress

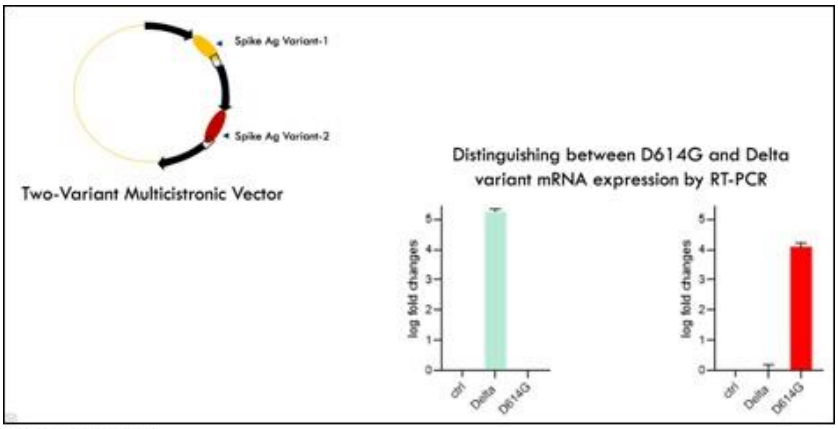
In October 2021, Celsion's Executive Vice President and Chief Scientific Officer, Khursheed Anwer, PhD, presented at the International Vaccines Congress (presentation can be found here) on the company's PLACCINE technology, which is characterized by a single multi-cistronic DNA plasmid vector that can encode for multiple antigens, an immune modifier, and is administered with a synthetic delivery system. Additional potential advantages of the PLACCINE technology include the durability of immune response, storage stability ≥4ºC, and a decreased cost of manufacturing.

The following figure gives an overview of the multicistronic vector cassette that can be utilized for expression of up to four gene sequences. It contains optimized transcription elements and the cloning sites allows for rapid gene insertion and/or removal.



Source: Celsion Corp.

The company is currently investigating the possibility of expressing two or more SARS-CoV-2 antigens as a potential COVID-19 vaccine. The following image shows the construction of the vector cassette that expresses two different variants of the SARS-CoV-2 Spike protein and RT-PCR data showing the expression of the two spike protein variants.



Source: Celsion Corp.

Celsion's immediate goal with the COVID-19 vaccine is to validate the PLACCINE technology in preclinical trials using mRNA vaccines as competitors. Once positive data is obtained, the company will look for a development partner for COVID-19 clinical trials. In addition, should positive data be seen with the COVID-19 vaccine, the company expects to begin development of DNA plasmid vaccines against a range of infectious viral diseases.

Financial Update

On November 15, 2021, Celsion announced financial results for the third quarter of 2021. The company reported licensing revenue of $125,000 for the third quarters of 2021 and 2020. The revenue is derived from a technology development contract entered into in January 2013 with Hisun to support the development of ThermoDox in China. Hisun paid a non-refundable technology transfer fee of $5.0 million in the first quarter of 2013 and it has been recorded to deferred revenue and amortized over the ten-year term of the agreement.

R&D expenses for the third quarters of 2021 and 2020 were $2.5 million. G&A expenses in the third quarter of 2021 were $2.7 million, compared to $1.8 million for the third quarter of 2020. The increase was primarily due to higher non-cash stock-based compensation, increased legal and professional fees, and an increase in insurance premiums.

As of September 30, 2021, Celsion had approximately $60.6 million in cash, cash equivalents, and short-term investments. The company recently announced that the New Jersey Economic Development Authority has approved the sale of $1.5 million of its unused New Jersey net operating losses (NOLs) for tax year 2020. We estimate the company has sufficient capital to fund operations through 2024. As of November 12, 2021, the company had approximately 86.6 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 95.8 million.

Conclusion

We look forward to an update from the OVATION 2 trial and are confident that the trends seen in the initial data will continue in regards to the percentage of patients that achieve R0 on resection. In addition, we look forward to additional updates on the PLACCINE technology and particularly data on the company's SARS-CoV-2 vaccine as a means of validating the technology. With no changes to our model our valuation remains at $3.50 per share.

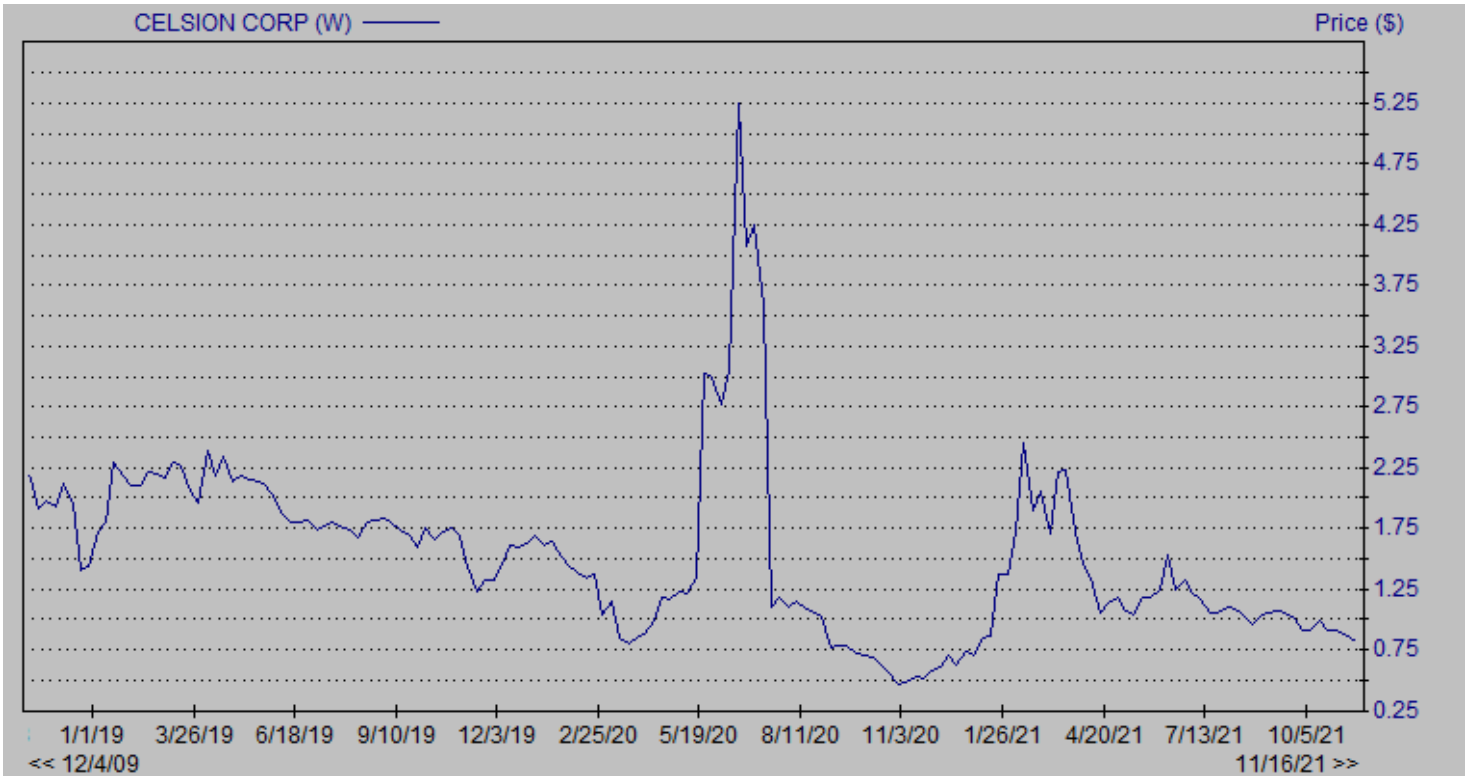
PROJECTED FINANCIALS

Celsion Corporation	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
GEN-1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
SARS-CoV-2 Vaccine	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.5	$0.1	$0.1	$0.1	$0.1	$0.5	$0.5	$0.0
Total Revenues	**$0.5**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.5**	**$0.5**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
R&D	$11.3	$2.6	$2.6	$2.5	$2.8	$10.4	$12.0	$14.0
SG&A	$7.6	$2.9	$2.6	$2.7	$2.9	$11.2	$12.0	$13.0
Operating Income	($18.5)	($5.4)	($5.1)	($5.1)	($5.6)	($21.1)	($23.5)	($27.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($4.8)	$0.3	$0.4	$0.3	$0.0	($1.0)	$0.2	$0.2
Pre-Tax Income	($23.3)	($5.7)	($5.4)	($5.4)	($5.5)	($22.1)	($23.3)	($26.8)
Taxes & Other	($1.8)	$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	($21.5)	($5.7)	($5.4)	($5.4)	($5.5)	($22.1)	($23.3)	($26.8)
Reported EPS	**($0.67)**	**($0.09)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.27)**	**($0.26)**	**($0.29)**
Weighted Shares Outstanding	32.0	66.3	85.9	86.6	87.0	81.4	90.0	93.0

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

© Copyright 2021, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2021, 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.