Zacks Small-Cap Research
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June 13, 2022
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 Study 85% Enrolled…

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 $20/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 (06/13/22)	$2.18
Valuation	**$20.00**

OUTLOOK

On May 16, 2022, Celsion Corporation (CLSN) announced financial results for the first quarter of 2022 and provided a business update. The company recently announced that the Phase 1/2 OVATION 2 study of GEN-1 in advanced stage (Stage III/IV) ovarian cancer is now 85% enrolled, with full enrollment anticipated by the third quarter of 2022.

The company also recently presented results from preclinical studies showing that the PLACCINE DNA vaccine can be generate neutralizing antibodies and T cell responses to two different viral antigens simultaneously. A non-human primate challenge study is currently underway and initial proof-of-concept data should be available in mid-2022.

SUMMARY DATA

52-Week High	**$23.09**
52-Week Low	**$2.16**
One-Year Return (%)	**-90.56**
Beta	**2.29**
Average Daily Volume (sh)	**45,632**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$15**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**20**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-0.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2021 Estimate	**-0.5**
P/E using 2022 Estimate	**-0.5**

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)
2021	0.1 A	0.1 A	0.1 A	0.1 A	0.5 A
2022	0.1 A	0.1 E	0.1 E	0.1 E	0.5 E
2023					0.0 E
2024					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$1.29 A	-$0.95 A	-$0.94 A	-$0.97 A	-$3.83 A
2022	-$1.82 A	-$0.96 E	-$1.00 E	-$1.00 E	-$3.66 E
2023					-$3.76 E
2024					-$3.92 E

WHAT'S NEW

Business Update

OVATION 2 Study 85% Enrolled

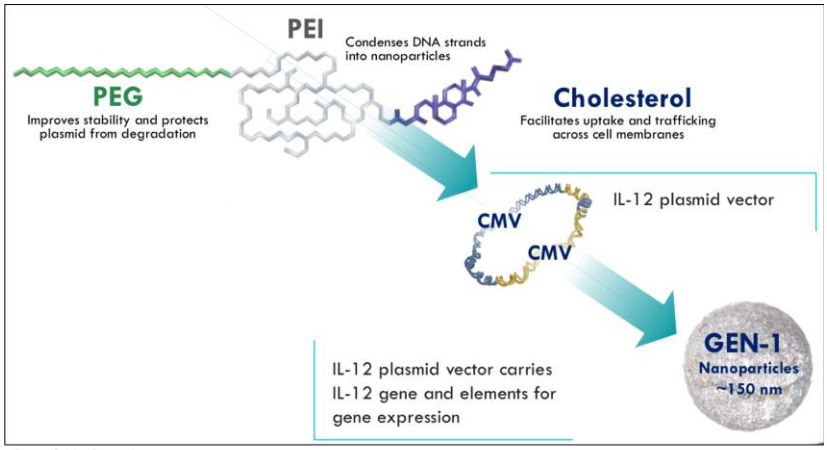
Celsion Corporation (CLSN) is currently conducting the Phase 1/2 OVATION 2 study of GEN-1 (the company's lead immunotherapy development product) in advanced stage (Stage III/IV) ovarian cancer. The company recently announced that the trial is 85% enrolled, with a maximum of 130 patients being enrolled if time allows. The company has indicated that enrollment will conclude by the end of August 2022. The primary endpoint of progression-free survival (PFS) will be reported after 80 PFS events occur, or 16 months median time on study, whichever comes first. We anticipate topline data in the third quarter of 2023.

Celsion previously reported that Interim clinical data from the open-label study shows that for the first 39 patients who have undergone interval debulking surgery, treatment with GEN-1 resulted in a 27% improvement in R0 surgical resection rate over the control arm. R0 refers to a complete tumor resection in which there is no evidence of macroscopic or microscopic tumor in the tumor bed. Long-term survival of ovarian cancer patients is correlated with R0 resection (Viral *et al*., 2021).

In April 2022, Celsion reported findings on the use of synthetic control arm (SCA) in a completed OVATION 1 Phase 1b study of GEN-1. The SCA was created by applying key OVATION 1 inclusion criteria to the Medidata Enterprise Data Store to identify candidate historical clinical trial patients for comparison. A total of 41 patients were included in the SCA. Fifteen OVATION 1 patients (15/18, 83%) were matched to 15 SCA patients (15/41, 37%), with the median progression free survival (PFS) time not being reached by the OVATION 1 patients, compared to 15.8 months for the SCA patients (H.R. 0.53, 95% CI 0.16, 1.73). The comparison of the SCA and the OVATION 1 patients yielded estimates of efficacy endpoints that led to a decrease in the number of planned patients for the OVATION 2 trial.

GEN-1

IL-12 is a broad-acting immune stimulatory molecule that showed remarkable promise in preclinical studies in the 1990's. However, this activity was never recapitulated in the clinical following the systemic administration of IL-12 due to severe side effects and the molecules short half-life. In an effort to develop an alternative approach to IL-12 delivery, a gene-based IL-12 therapeutic was formulated that produced locally increased concentrations of IL-12 and IFN-γ but did not produce systemic toxicity in a mouse model of ovarian cancer (Fewell *et al*., 2005; Fewell *et al*., 2009). These experiments provided proof-of-concept for Celsion's TheraPlas technology, which consists of a plasmid DNA payload encoding a therapeutic protein and a delivery system. GEN-1 (formerly EGEN-001), the company's lead development product based on the TheraPlas technology, comprises a plasmid encoding human IL-12 coupled to a non-viral DNA delivery system, polyethyleneglycol-polyethyleneimine-cholesterol (PPC). The compound forms nanoparticles that are approximately 150 nm in diameter, protect the plasmid from degradation after administration, and aid in getting the plasmid across the cell membrane. The composition of GEN-1 is shown in the following figure.



Source: Celsion Corporation

Multiple preclinical studies of GEN-1 showed that it could be utilized in combination with different ovarian cancer treatments to increase their efficacy, leading to significant reductions in tumor burden. Previous clinical trials of GEN-1 showed that the drug was well tolerated and potentiated the activity of various chemotherapy agents, including the OVATION 1 study, in which a total of 18 patients received increasing doses of GEN-1 (36, 47, 61, 79 mg/m^2). Tumor response was associated with higher doses of GEN-1, and in the highest dose cohort 100% of patients had a complete or partial response and 88% achieved R0 resection.

Non-Human Primate Study of SARS-CoV-2 Vaccine Candidate Initiated

Celsion recently announced that a non-human primate challenge study was initiated with the company's DNA-based approach for a SARS-CoV-2 vaccine. The NHP study is a five-arm study that has three objectives: 1) confirm that the same positive response that was seen in mice is seen in NHPs; 2) determine how the DNA vaccine compares to the mRNA vaccine; and 3) determine the durability of response with the DNA vaccine. The study consists of a control group, a group receiving an mRNA SARS-CoV-2 vaccine, two cohorts each receiving a different dose of Celsion's DNA vaccine candidate, and a fifth cohort that will be challenged with SARS-CoV-2 after six months. Comparisons regarding antibody titer will be made between the mRNA vaccine and DNA vaccine cohorts, with those animals being challenged with SARS-CoV-2 after antibody levels been built up. At the six-month mark, the fifth cohort that received the DNA vaccine will be challenged with SARS-CoV-2 to determine durability of response.

In April 2022, Dr. Khursheed Anwer, Celsion's Chief Scientific Officer, presented the company's PLACCINE platform vaccine technology at the World Vaccine Congress. A copy of the presentation can be found here. Dr. Anwer's presentation included data showing that in mice, the multivalent vaccine targeting two different variants of SARS-CoV-2 induced a potent immune response as exhibited by IgG levels, neutralizing antibody levels, and T cell responses.

Financial Update

On May 16, 2022, Celsion announced financial results for the first quarter of 2022. The company reported licensing revenue of $125,000 for the first quarters of 2022 and 2021. 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 first quarters of 2022 and 2021 were $3.1 million and $2.6 million, respectively. The increase was primarily due to increased costs for the OVATION 2 study and development of the PLACCINE DNA vaccine technology. G&A expenses in the first quarters of 2022 and 2021 were $2.9 million. Lower non-cash stock-based compensation was offset by higher salaries and benefits.

As of March 31, 2022, Celsion had approximately $47.3 million in cash, cash equivalents, and short-term investments. In addition, on April 8, 2022 the company completed a registered direct offering that resulted in net proceeds of $6.5 million and has $3.5 million in future planned sales of the company's State of New Jersey

net operating losses (NOLs). Thus, we estimate Celsion has sufficient capital to fund operations into the second quarter of 2025. As of May 13, 2022, the company had approximately 7.1 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 95.8 million.

Conclusion

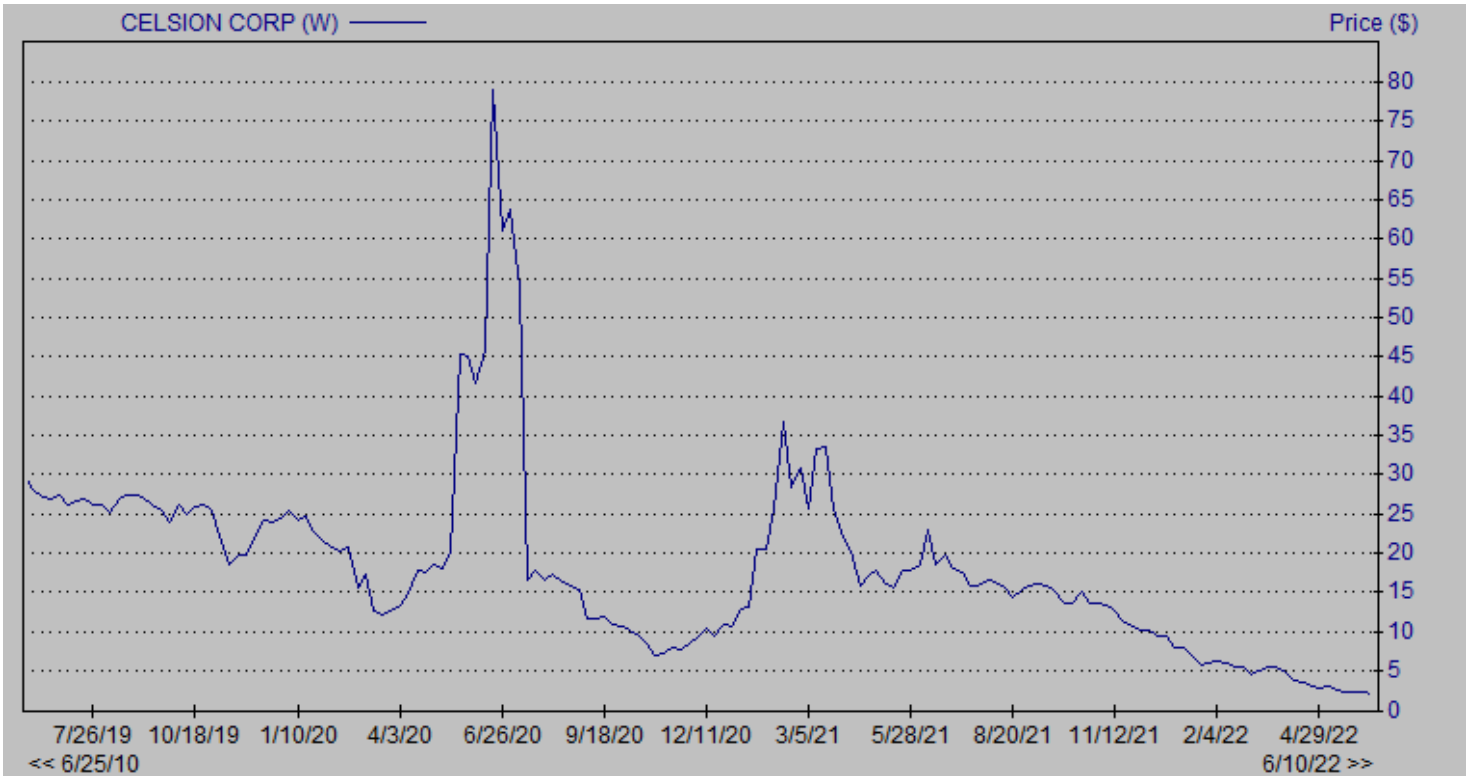
We are glad to see enrollment continuing at a good pace for the OVATION 2 study and we anticipate the trial being fully enrolled in the third quarter of 2022. We look forward to results from the NHP study of the company's SARS-CoV-2 vaccine, which could serve as a nice proof-of-concept for the PLACCINE technology. After accounting for the additional shares from the registered direct offering, and increasing the discount rate utilized in our model to account for the volatility in the overall biotech market, our valuation has decreased to $20.

PROJECTED FINANCIALS

Celsion Corporation	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 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	$0.0	$0.0
Total Revenues	**$0.5**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.5**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
R&D	$10.6	$3.1	$2.8	$3.0	$3.0	$11.9	$12.5	$14.0
SG&A	$10.9	$2.9	$2.9	$3.0	$3.1	$11.9	$12.3	$13.0
Operating Income	($21.0)	($5.8)	($5.6)	($5.9)	($6.0)	($23.3)	($24.8)	($27.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($1.1)	$4.6	$0.1	$0.1	$0.1	($4.9)	($0.4)	($0.4)
Pre-Tax Income	($22.2)	($10.5)	($5.7)	($6.0)	($6.1)	($28.2)	($25.2)	($27.4)
Taxes & Other	($1.4)	$0.0	$0.0	$0.0	$0.0	($1.5)	($1.5)	($1.5)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($20.8)	($10.5)	($5.7)	($6.0)	($6.1)	($26.7)	($23.7)	($25.9)
Reported EPS	**($3.83)**	**($1.82)**	**($0.92)**	**($0.85)**	**($0.86)**	**($4.10)**	**($3.25)**	**($3.45)**
Weighted Shares Outstanding	5.4	5.8	6.2	7.0	7.1	6.5	7.3	7.5

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

HISTORICAL STOCK PRICE



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