Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

October 11, 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: Initiating Coverage of Celsion Corporation; Novel DNA-Based Cancer Immunotherapy Technology…

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 (10/11/21)	$0.91
Valuation	**$3.50**

OUTLOOK

We are initiating coverage of Celsion Corporation (CLSN) with a $3.50 valuation. Celsion's lead development candidates are based on the company's TheraPlas technology, which involves the non-viral delivery of nucleic acid therapeutics. The lead development candidate, GEN-1, is an interleukin (IL)-12 encoding DNA plasmid that is currently being tested as a treatment for advanced ovarian cancer. The Phase 2 trial, OVATION 2, is currently enrolling patients and the open label trial may allow for periodic updates of results. Celsion has also initiated a proof of concept development program for a SARS-CoV-2 vaccine utilizing a DNA plasmid that encodes for multiple viral antigens. An IND submission may occur in the first half of 2022 with a Phase 1 trial likely in the second half of 2022.

SUMMARY DATA

52-Week High	**$2.81**
52-Week Low	**$0.47**
One-Year Return (%)	**32.53**
Beta	**1.96**
Average Daily Volume (sh)	**959,254**
Shares Outstanding (mil)	**87**
Market Capitalization ($mil)	**$79**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**4**
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	**-3.0**
P/E using 2022 Estimate	**-2.9**

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 E	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 E	-$0.06 E	-$0.27 E
2022					-$0.26 E
2023					-$0.29 E

WHAT'S NEW

Initiating Coverage

Source: Celsion Corporation

We are initiating coverage of Celsion Corporation (CLSN) with a valuation of $3.50. Celsion is a biopharmaceutical company developing DNA-based immunotherapies and proof-of-concept for next-generation vaccines. The company has two platform technologies, TheraPlas and PLACCINE, each of which is based on non-viral delivery of non-integrating nucleic acid molecules for therapeutic and prophylactic treatment. The delivery system of TheraPlas is based on polyethyleneimine (PEI) coupled to polyethylene glycol (PEG) and cholesterol to form PEG-PEI-Cholesterol (PPC). The lead TheraPlas product, GEN-1, is in clinical development for the first-line treatment of advanced ovarian cancer. It consists of an interleukin (IL)-12 encoding DNA plasmid that is infused intraperitoneally to increase the concentration of IL-12 at the tumor site. Celsion's lead vaccine development candidate is based on the PLACCINE technology and consists of a multi-cistronic DNA plasmid vector that encodes for multiple antigens of the SARS-CoV-2 virus. In its earliest form IL-12 is included as an adjuvant.

IL-12 is a Powerful Immune Modulator
IL-12 is a pleiotropic cytokine that connects the innate and adaptive immune system. It is primarily produced in antigen-presenting cells, such as dendritic cells. As opposed to directly inhibiting cancer growth, IL-12 instead controls a number of physiologic processes including: increasing production of interferon gamma (IFN-γ), stimulating growth of CD8 T cells and shifting differentiation of CD4 T cells to a Th1 phenotype; and remodeling of myeloid derived suppressor cells (MDSCs).

Limited Treatment Options for Advanced Ovarian Cancer
Standard first-line therapy for ovarian cancer is tumor resection and platinum-based chemotherapy. Recurrence occurs in approximately 75% of patients, with 25% of those being resistant to platinum therapy. These patients have few treatment options and a median overall survival of approximately 12 months, thus highlighting the need for additional treatment options.

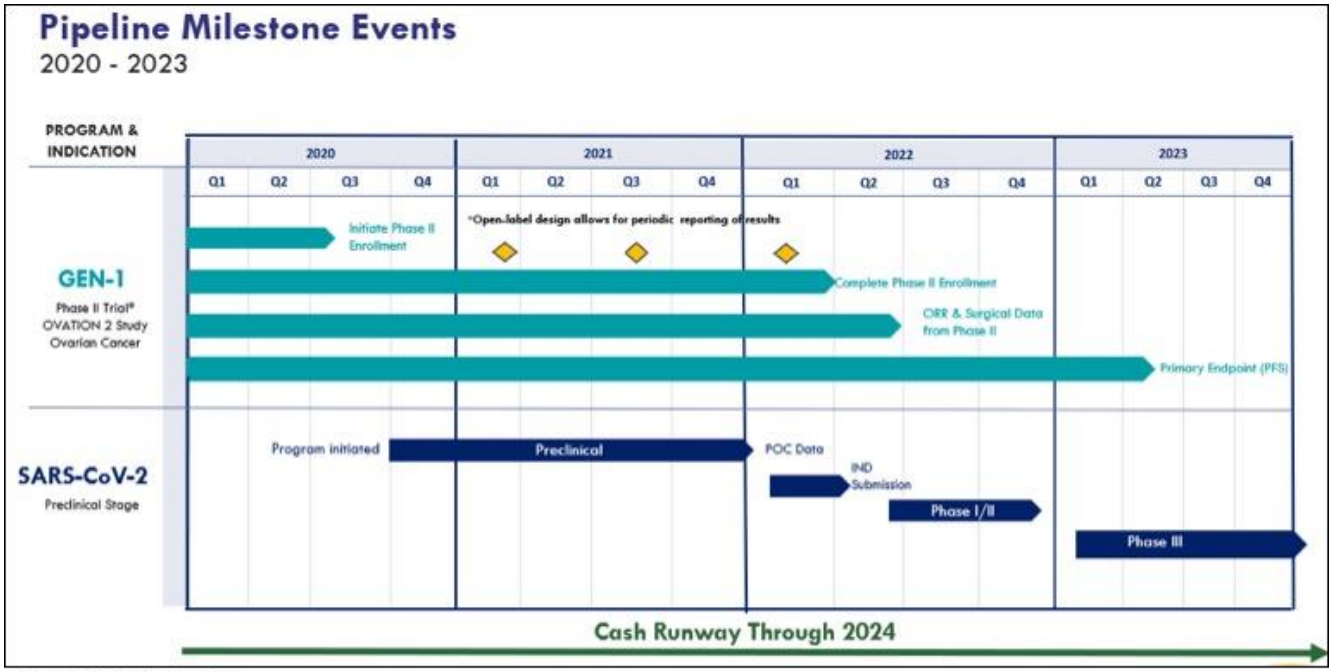
Positive Results for OVATION I Study
Celsion evaluated GEN-1 in combination with standard of care neoadjuvant chemotherapy (NACT) in 18 patients with newly diagnosed Stage IIIC or IV ovarian cancer. Results showed a correlation between high dose GEN-1 and objective tumor response and debulking status. In addition, treatment with GEN-1 resulted in favorable changes in immunosuppressive biomarkers and CD8/CD4 T cell ratio.

Only Multimeric SARS-CoV-2 Vaccine in Development
The company's PLACCINE technology is a DNA-based vaccine technology that allows for the expression of multiple antigens. It is based on the same technology behind GEN-1 and will also include expression of IL-12 to enhance the humoral and cell-mediated immune response to the vaccine. Celsion is planning to establish its capability using SARS-CoV-2 vaccines as benchmarks. The company's thesis suggests that multiple antigens, which may act more like a whole virus vaccine and not be as susceptible to breakthrough infections from viral variants, will provide superior vaccine dependent immunity with greater durability than the current generation of mRNA vaccines.

Cash Runway Through 2024
Celsion had approximately $64.5 million in cash, cash equivalents, and short-term investments as of June 30, 2021. We estimate this is sufficient to fund operations through 2024, which will carry the company through multiple key inflection points for both GEN-1 and the SARS-CoV-2 vaccine.

INVESTMENT THESIS

Celsion Corporation (CLSN) is a biopharmaceutical company developing DNA-based immunotherapies and vaccines. The company's lead development candidate, GEN-1, is a DNA-based immunotherapy for the treatment of ovarian cancer. It consists of an Interleukin (IL)-12 encoding DNA plasmid that is formulated with the company's TheraPlas delivery system. It is delivered intraperitoneally to cause a localized increase in IL-12, with the localized production helping to avoid toxicities caused by the systemic administration of recombinant IL-12. The company is also developing a next-generation vaccine targeting the SARS-CoV-2 virus, which causes COVID-19. It consists of a DNA plasmid encoding multiple antigens of the SARS-CoV-2 virus, and is the only multimeric COVID vaccine we are aware of in development.



Source: Celsion Corporation

Ovarian Cancer

Ovarian cancer represents the seventh most commonly diagnosed cancer in the world, with approximately 230,000 females diagnosed each year and 150,000 dying from the disease (Ferlay *et al*., 2015). The five-year survival rate is only 46% (Doherty *et al*., 2017), which is mostly due to the late stage at which most ovarian cancers are diagnosed; patients with a late-stage diagnosis only have a 29% five-year survival rate, while those diagnosed with early-stage disease have a 92% five-year survival rate (Reid *et al*., 2017). Unfortunately, due to few specific symptoms of the disease at an early stage, approximately 75% of patients are diagnosed at an advanced stage. Even with advances in treatments, the five-year survival rate has risen only approximately 2-4% since 1995 (Allemani *et al*., 2015).

First-line treatment for ovarian cancer is primary debulking surgery (PDS), followed by chemotherapy, which has become the standard of care for the past three decades following the seminal paper by Thomas Griffiths (Griffiths, 1975). The primary goal of PDS is no residual tumor (R0), which is the most important prognostic factor for survival (du Bois *et al*., 2009). Patients that are too sick for abdominal surgery or whose disease is too extensive to be resected are treated with neoadjuvant chemotherapy (NACT), followed by interval debulking surgery (IDS). Two randomized trials showed similar survival times between PDS and NACT/IDS with lower morbidity for NACT/IDS (Kehoe *et al*., 2015; Vergote *et al*., 2010).

Standard first-line chemotherapy for advanced stage ovarian cancer is intravenous carboplatin (AUC 5-6 mg/mL/min every three weeks) and paclitaxel (80 mg/m^2 weekly). The addition of bevacizumab (Avastin®) was

shown to increase progression-free survival (PFS), but not overall survival, in the GOG218 (Burger *et al*., 2011) and ICON7 (Perren *et al*., 2011) clinical trials. The FDA approved bevacizumab for both newly diagnosed and recurrent ovarian cancer, however given its association with potentially fatal complications its use is not universal.

Ovarian cancer recurs in approximately 75% of patients (Baldwin *et al*., 2012). In 2015, the Gynecologic Cancer Intergroup defined patients as platinum-sensitive or platinum-resistant based on whether the length of time from completion of platinum therapy to recurrence is greater than (platinum-sensitive) or less than (platinum-resistant) six months (Wilson *et al*., 2017). The only options available for platinum-resistant patients (approximately 25% of patients) is pegylated liposomal doxorubicin, topotecan, and bevacizumab. These patients have a median overall survival of approximately 12 months. For patients that remain platinum-sensitive, re-treating with platinum doublet chemotherapy is standard-of-care, which can also include bevacizumab.

Newer treatment modalities include poly(ADP-ribose) polymerase inhibitors (PARPi), which have shown good activity as both single agents and as part of combination therapy. Lynparza® (olaparib), Zejula® (niraparib), and Rubraca® (rucaparib) are all FDA approved for maintenance treatment of advanced ovarian cancer with and without *BRCA* mutations (Lynparza prescribing information, Zejula prescribing information, Rubraca prescribing information). The following chart shows the 2020 revenues for each of those medications, along with projected 2026 sales (EvaluatePharma).

Product	Drug	Company	2020 Revenues ($billions)	Projected 2026 Revenues ($billions)
Lynparza	olaparib	AZN	$1.46	$2.98
Zejula	niraparib	GSK	$0.44	$1.02
Rubraca	rucaparib	CLVS	$0.16	$0.42

Source: EvaluatePharma / Zacks SCR

Other treatments that are currently in development for ovarian cancer include the following:

Mirvetuximab soravtansine – This is an antibody-drug conjugate (ADC) being developed by Immunogen (IMGN). It consists of a monoclonal antibody that targets folate receptor alpha (FRα) coupled with maytansinoid DM4, a potent tubulin-targeting agent. Immunogen is currently conducting two Phase 3 clinical trials to test mirvetuximab as a monotherapy. The SORAYA trial is a single-arm study enrolling patients with FRα-high, platinum-resistant ovarian cancer who have previously been treated with bevacizumab with results expected in the fourth quarter of 2021. The MIRASOL trial is a randomized study in which approximately 430 patients with platinum-resistant ovarian cancer will be randomized 1:1 to treatment with either mirvetuximab or physician's choice chemotherapy. Results from the MIRASOL trial are expected in the third quarter of 2022.

Upifitamab Rilsodotin (UpRi) – This is an ADC targeting the sodium-dependent phosphate transport protein NaPi2b being developed by Mersana Therapeutics (MRSN). It is currently being evaluated in a Phase 1 trial as a therapy for platinum-resistant ovarian cancer and will be evaluated in a Phase 3 trial as a monotherapy maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer.

TC-210 – This is a cell therapy that consists of autologous genetically engineered T cells expressing a single-domain antibody that recognizes mesothelin fused to the CD3-ε subunit that is then incorporated into the endogenous T cell receptor. TCR^2 Therapeutics (TCRR) is conducting a Phase 1/2 clinical trial focused on four indications: non-small cell lung cancer, ovarian cancer, malignant pleural/peritoneal mesothelioma, and cholangiocarcinoma.

IL-12 Treatment for Ovarian Cancer

Immunotherapy has proven to be effective against a number of different cancer types, and there are indications that ovarian cancer would lend itself to being treatable with various immunotherapeutic agents due to the presence of a high mutational load in *BRCA1/2*-mutated tumors, elevated PD-(L)1 in tumor associated

immune cells, and the presence of a high number of T cells in patients that experience longer progression-free and overall survival (Strickland *et al*., 2016; Zhang *et al*., 2003). However, in spite of this the use of anti-PD-(L)1 or anti-CTLA4 antibodies has resulted in only modest response rates of 10-15% and disease control of <50% (Hamanishi *et al*., 2015; Disis *et al*., 2016).

An alternative immunotherapeutic approach to treating ovarian cancer is the use of a powerful, broad-acting immune-modulating agent to stimulate the immune system to attack the cancer cells. IL-12 is one such cytokine as it can stimulate anti-cancer immunity through a number of different mechanisms, including:

- Induction of T_H1 cell differentiation
- Activation of T and natural killer (NK) cells
- Inhibition or reprogramming of tumor associated macrophages (TAMs) and myeloid-derived suppressor cells (MDSCs)
- Induction of Interferon-gamma (IFN-γ)

In preclinical studies, IL-12 has shown the ability to reduce the growth of tumors or eradicate them completely:

- Brunda *et al*., 1993: In this study, the anti-tumor activity of IL-12 was tested against multiple murine tumors. Mice treated with IL-12 exhibited: 1) reduced subcutaneous growth of B16F10 melanoma tumors; 2) effective treatment of established subcutaneous M5076 reticulum cell sarcoma tumors with no gross toxicity; and 3) complete regression of subcutaneous Renca tumors following peritumoral injection of IL-12.

- Noguchi *et al*., 1996: In this study, injection of IL-12 caused a delay in tumor appearance and reduced tumor incidence in mice injected with 3-methylcholanthrene (3-MC), a carcinogenic hydrocarbon. In addition, the tumors that did form were typically flat, soft, and invasive in contrast to normal 3-MC-induced tumors that are round, hard, and well-circumscribed. Lastly, the researchers noted that there was high production of IFN-γ along with a T_H2 to T_H1 shift in CD4 T cells.

- Zaharoff *et al*., 2010: This study showed that intra-tumoral injection of IL-12 in combination with chitosan resulted in complete tumor regression in 80% to 100% of mice harboring MC32a and Panc02 tumors. The researchers also showed that the antitumor response was dependent upon CD8+ T cells and NK cells, as depletion of those cell types eliminated antitumor activity.

Given the robust activity seen in preclinical studies, recombinant IL-12 was tested in clinical trials beginning in the mid-1990's. One of the centers that initiated clinical trials (Genetics Institute) dosed patients with consecutive intravenous daily injections of IL-12 using a dose of 500 ng/kg, which was the maximum tolerated dose in a Phase 1 clinical study. However, in a Phase 2 trial, this dose unexpectedly caused severe side effects in 12 of 17 enrolled patients and two of the patients died (Jenks *et al*., 1996). Following a halt of all IL-12 clinical trials in the U.S., it was determined that a change in dosing schedule between the Phase 1 and Phase 2 trials resulted in different tolerability to the drug. In the Phase 1 study, an initial priming dose of IL-12 was administered to determine its pharmacokinetic profile, and this priming dose was deemed critical for protection against severe toxicity (Leonard *et al*., 1997).

Once a protocol was determined that could allow IL-12 to be safely administered, a number of clinical trials were conducted using recombinant IL-12 evaluating various dosing schedules.

Atkins *et al*., 1997: This was a Phase 1 study in which a total of 40 patients (20 with renal cancer, 12 with melanoma, 5 with colon cancer) were enrolled. Following a test dose, patients were administered IL-12 for five consecutive days starting on Day 15 with treatment cycles repeating every 21 days. One patient with renal cancer experienced a partial response (PR) and one melanoma patient experienced a complete response (CR). The most common side effects in this study were fever, chills, fatigue, and headache along with abnormalities in laboratory parameters including anemia, neutropenia, lymphocytopenia, hyperglycemia, thrombocytopenia, and hypoalbuminemia. Most of laboratory anomalies peaked at Day 5 of a treatment cycle and resolved quickly.

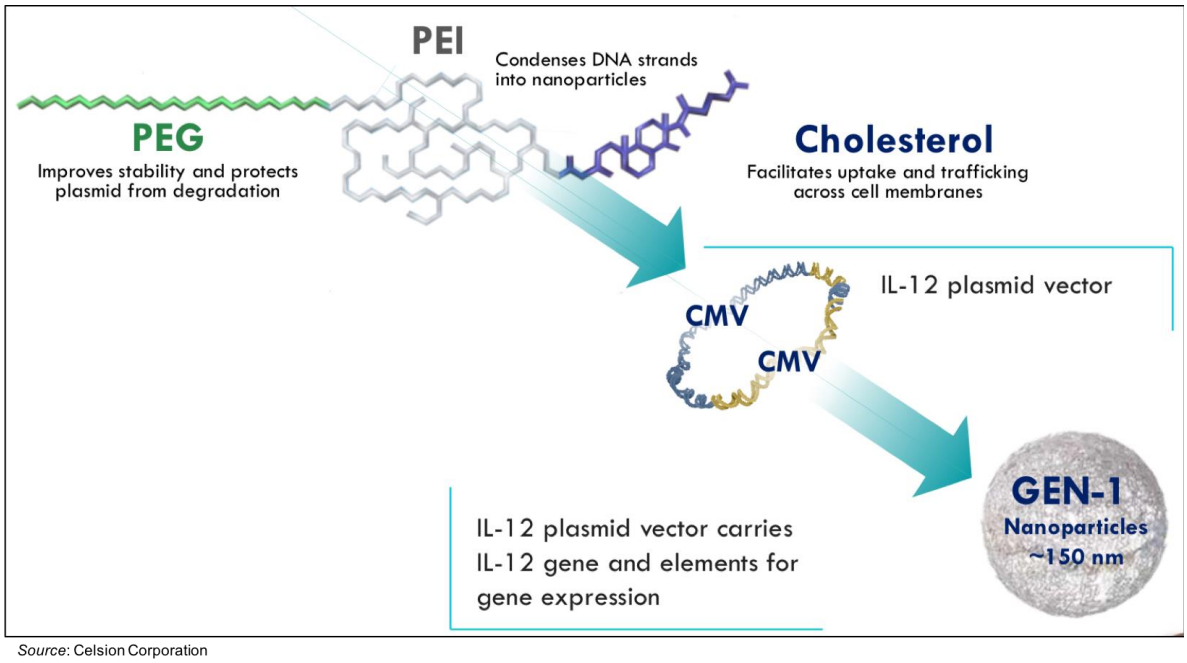
Bajetta *et al*., 1998: This was a Phase 1 study in which 10 patients with progressive metastatic melanoma were enrolled. Patients received 0.5 μg/kg recombinant IL-12 subcutaneously on days 1, 8, and 15 of a 28-day cycle. Flu-like symptoms were the most common side effect. While no PR or CR were noted, tumor shrinkage did occur that involved regression of subcutaneous nodules, superficial adenopathies, and hepatic metastases.

Lenzi *et al*., 2002: This was a Phase 1 study of recombinant IL-12 delivered intraperitoneally to 29 patients with Mullerian carcinomas, gastrointestinal tract carcinomas, and peritoneal mesothelioma. The most frequent adverse events were fever, fatigue, abdominal pain, nausea, and catheter-related infections. Two patients, one of which had ovarian cancer, had no remaining disease at laparoscopy. Another eight patients had stable disease and 19 had progressive disease.

The early clinical trials of IL-12 were disappointing, particularly since the molecule had performed so well in preclinical studies. While severe side effects could be diminished with the proper dosing schedule, there were still a number of side effects that arose from the systemic administration of the molecule, including a high concentration of INF-γ. In addition, recombinant IL-12 does not have a long half-life and thus its effects are likely too diffuse and short lived to have an appreciable anti-cancer effect given the strong immunosuppressive mechanisms that are inherent in the tumor microenvironment. Thus, alternative IL-12 delivery mechanisms may help to increase clinical efficacy and reduce systemic toxicity.

GEN-1

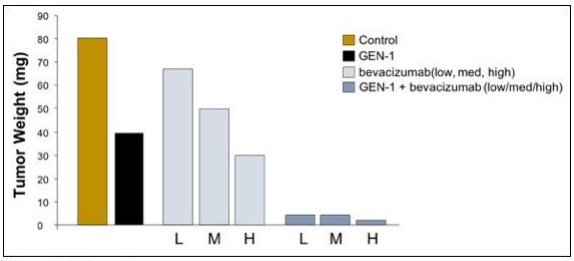
In an effort to develop an alternative approach to IL-12 delivery, a gene-based IL-12 therapeutic was formulated that produced locally increased concentrations of IL-12 and IFN-γ but did not produce systemic toxicity in a mouse model of ovarian cancer (Fewell *et al*., 2005; Fewell *et al*., 2009). These 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

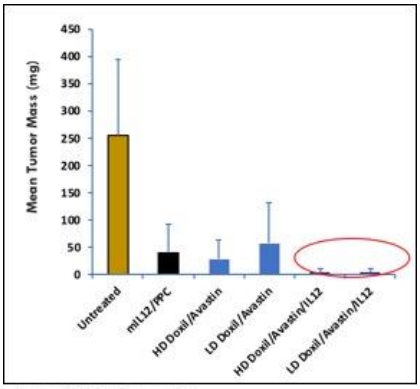
Preclinical work showed that GEN-1 could be used in combination with different ovarian cancer treatment modalities to increase their efficacy. A 2016 study utilizing SKOV-3 cells in a murine model of ovarian cancer

showed that GEN-1 in combination with bevacizumab resulted in a sizeable reduction in total tumor mass for low, medium, and high doses of bevacizumab, as shown in the following figure.



Source: Celsion Corporation

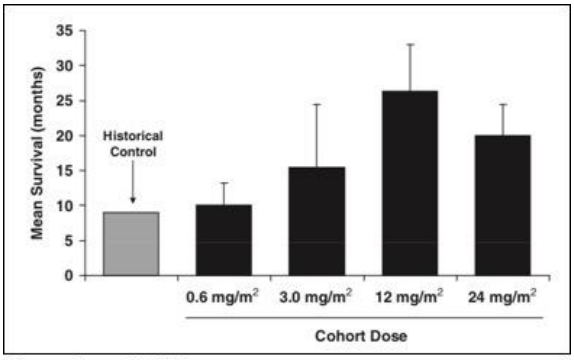
The study also evaluated GEN-1 in combination with bevacizumab and doxorubicin (both high and low dose). The following graph shows a >98% reduction in tumor burden in mice treated with GEN-1 + doxorubicin (Doxil®) + bevacizumab (Avastin®) compared to untreated mice. As mentioned previously, bevacizumab treatment does result in a number of adverse events, thus data showing a substantial reduction in tumor burden when it is used at a lower dose in combination with GEN-1 is particularly encouraging.



Source: Celsion Corporation

GEN-1 has been studied in multiple previous clinical trials, which are summarized below:

Anwer *et al*., 2010: This was a Phase 1, dose-escalating study to evaluate the safety, tolerability, and preliminary efficacy of GEN-1 in women with platinum-resistant recurrent ovarian cancer. A total of 12 patients received four weekly doses of 0.6 mg/m^2, 3.0 mg/m^2, 12 mg/m^2, or 24 mg/m^2 GEN-1 administered intraperitoneal, with another patient discontinuing after two doses (24 mg/m^2) due to infectious peritonitis. Six patients had a decrease or stabilization in the biomarker CA-125. Four to six weeks post-treatment 31% of patients had stable disease and 69% had progressive disease. Overall survival (OS) for all patients was 12.7 months, which is not much different from historical controls, however there did appear to be a positive correlation between OS and dose, as shown in the following figure. GEN-1 could be detected in peritoneal fluid, but not in serum, and there were also treatment-related increases in INF-γ in peritoneal fluid but not in serum. This study provided proof-of-concept that intraperitoneal administration of GEN-1 is well tolerated and leads to increases in anti-tumor cytokines.

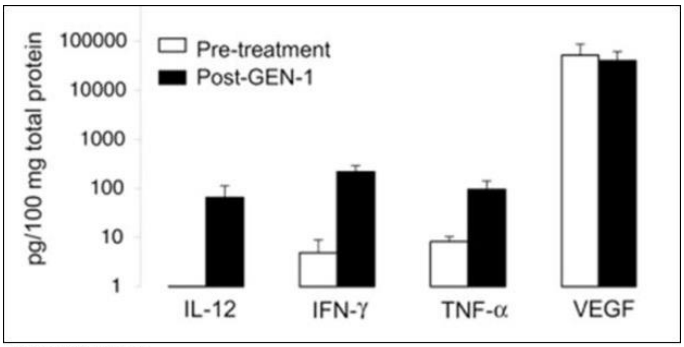


Source: Anwer *et al*., 2010

Anwer *et al*., 2013: This study examined GEN-1 in combination with carboplatin and docetaxel in patients with platinum-sensitive ovarian cancer. A total of 13 patients received intraperitoneal infusions of 12, 18, or 24 mg/m^2 GEN-1 once every 10-11 days for a total of four treatments, with another cohort at 24 mg/m^2 receiving eight total treatments. Docetaxel and carboplatin were administered every three weeks for up to six cycles. Consistent with previous results in a platinum-sensitive cohort, the best overall response was 17% complete response (CR), 33% partial response (PR), 42% stable disease (SD), and 8% progressive disease. Importantly, the addition of GEN-1 did not appear to attenuate the efficacy of chemotherapy treatment and there were dose-dependent increases in both INF-γ and tumor necrosis factor alpha (TNF-α). This study showed that higher doses of GEN-1 are well tolerated and it could be used in conjunction with standard of care chemotherapy.

Alvarez *et al*., 2014: This was a Phase 2 study of GEN-1 in 20 patients with persistent or recurrent ovarian or primary peritoneal cancer. Patients were treated by intraperitoneal infusion with 24 mg/m^2 GEN-1 weekly for four consecutive weeks (one cycle). A median of two cycles (range 1-9) was administered with six patients receiving one cycle or less due to adverse events or disease progression. As with other clinical trials of GEN-1, the most commonly reported adverse events were fatigue, fever, chills, abdominal pain, nausea, and vomiting. Of the 16 evaluable patients, seven (35%) had stable disease and nine (45%) had progressive disease. Six (30%) patients had a progression free survival (PFS) > six months. The median PFS was 2.9 months and the median overall survival (OS) was 9.2 months. This study showed that GEN-1 at the tested dosage is unlikely to have a meaningful impact on patients with platinum-resistant ovarian cancer as a monotherapy.

Thaker *et al*., 2017: This was a Phase 1 study of GEN-1 in combination with pegylated liposomal doxorubicin (PLD). Sixteen patients with platinum-resistant ovarian cancer were enrolled into the trial. PLD was administered IV at 40 mg/m^2 or 50 mg/m^2 every 28 days and GEN-1 was administered IP at 24 mg/m^2 or 36 mg/m^2 weekly for four consecutive weeks (1 cycle). A median of four cycles of GEN-1 were administered (range 1-8). The majority of adverse events were grade 1/2 and transient. Of the fourteen patients evaluable for response, three had a partial response and five had stable disease (all received 36 mg/m^2 GEN-1). Peritoneal fluid was collected from 13 patients and showed that treatment with GEN-1 led to an increase in IL-12, IFN-γ, and TNF-α, as shown in the following figure. This study showed that GEN-1 had encouraging activity and clinical benefit in combination with doxorubicin.



Source: Thaker *et al*., 2017

Thaker *et al*., 2021: The OVATION 1 study was a Phase 1b, open label, nonrandomized trial to evaluate the safety and preliminary antitumor activity of GEN-1 administered intraperitoneal in combination with NACT carboplatin-paclitaxel in patients with newly diagnosed stage IIIC and IV ovarian cancer. A total of 18 patients were enrolled into the trial with a standard 3+3 dose-escalation testing GEN-1 at four different doses (36, 47, 61, 79 mg/m^2). GEN-1 was administered once weekly for eight consecutive weeks, with NACT starting at cycle 1 week 2 (carboplatin AUC 6 mg/mL/min i.v. every three weeks; paclitaxel 80 mg/m^2 every week i.v. for 9 weeks). The use of GEN-1 in the neoadjuvant setting allowed for tissue collection in the pre-treatment and post-treatment setting following interval debulking.

Of the 18 patients enrolled, six patients did not receive the full eight-week regimen of GEN-1 due to port-relation infection, bowel perforation, bowel obstruction, myelotoxicity, sepsis and congestive heart failure, and altered taste. Fifteen patients were evaluable for safety of dose (received at least four doses of GEN-1) and 14

patients underwent interval debulking and could be evaluated for RECIST, resection status, and pathologic response.

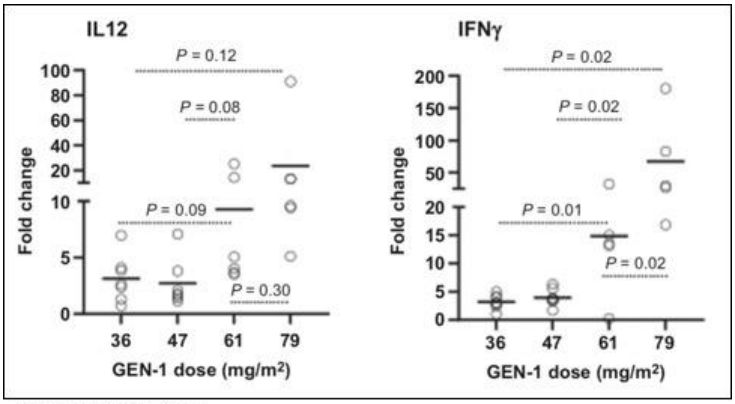
In general, all doses of GEN-1 were well tolerated and most of the adverse events (AEs) were grade 1 or 2 in nature. The most commonly reported AEs were nausea, fatigue, abdominal pain/cramping, anorexia, diarrhea, and vomiting. Grade 3/4 AEs possibly related to GEN-1 included nausea, fatigue, abdominal pain/cramping, diarrhea, dehydration, vomiting, hypokalemia, sepsis, and vasovagal reaction. There were no dose limiting toxicities and the maximum tolerated dose was not reached.

All patients were evaluated for efficacy (ITT, n=18) and the patients who underwent interval debulking were part of the per-protocol assessment (n=14). Time to treatment failure (TTF) was 18.4 months (95% CI 9.2-24.5; range 0.1 – 48.4 months) in the ITT population, while the TTF was 21 months (95% CI 11.5-33.8; range 9.3-48.4) for the per-protocol population. For tumor response, higher doses of GEN-1 were associated with higher objective response rates. In the high dose GEN-1 cohorts 100% of patients had a complete or partial response and 88% achieved R0 resection. In addition, one patient remains progression free at 4 years of follow-up.

Radiographic response		Total (*n*)	Cohort 1 36 mg/m^2	Cohort 2 47 mg/m^2	Cohort 3 61 mg/m^2	Cohort 4 79 mg/m^2
Tumor response	CR	2	1	0	0	1
	PR	10	0	3	3	4
	SD	2	2	0	0	0
Objective response rate			**67%**		**100%**	
Surgical outcome	R0	9	2	0	2	5
	R1	3	1	2	0	0
	R2	2	0	1	1	0
R0 resection rate			**33%**		**88%**	
Pathologic response	cPR	1	1	0	0	0
	Micro	8	1	2	1	4
	Macro	5	1	1	2	1
cPR/micro rate			**60%**		**63%**	
Chemotherapy	CRS 3	5	1	0	2	2
Response	CRS 2	5	2	1	0	2
Score	CRS 1	4	0	2	1	1
CRS 3 rate			**17%**		**50%**	

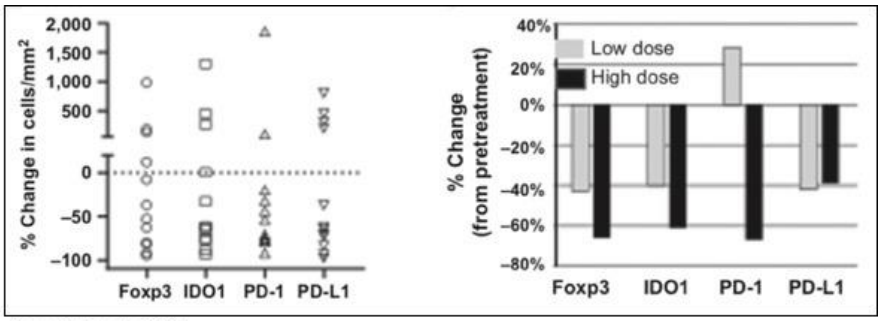
Source: Thaker *et al.*, 2021

A number of translational studies were conducted to evaluate the effect of GEN-1 on immunological outcomes. The following figure shows the fold-change in IL-12 and IFN-γ levels in peritoneal fluid before and after GEN-1 administration. IL-12 levels increased 3.2- and 23-fold at the lowest and highest GEN-1 doses (36 and 79 mg/m^2), respectively, while IFN-γ levels increased 3.1- and 67-fold, respectively. The increase in IFN-γ levels between the different dose levels was statistically significant, and while the increase in IL-12 followed a similar pattern it did not rise to the level of statistical significance.



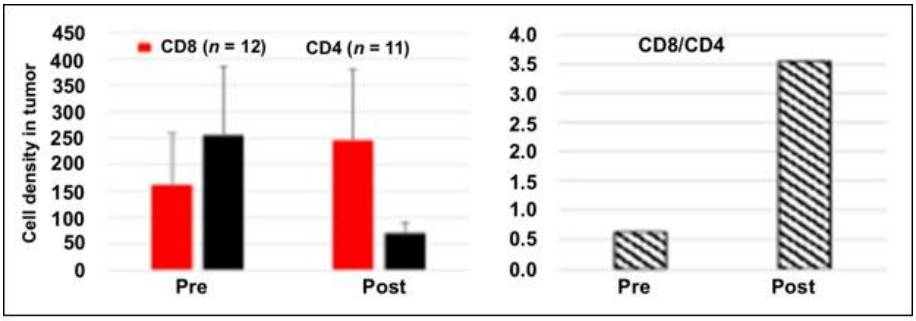
Source: Thaker *et al.*, 2021

The effect of GEN-1/NACT on different immunosuppressive markers in the tumor microenvironment are shown in the following figures. Four markers were evaluated (Foxp3, IDO1, PD-1, PD-L1) using biopsy and tumor resection samples. The figure on the lower left shows the percent change in each of the markers for each patient, while the figure on the lower right shows the percent change in each marker for the low dose (36 and 47 mg/m^2; n=4) and the high dose (61 and 79 mg/m^2; n=8) cohorts. The changes in Foxp3, IDO1, and PD-1 appeared to be dependent on GEN-1 dose, which is consistent with what was seen for changes in IFN-γ and IL-12.



Source: Thaker *et al.*, 2021

Lastly, treatment with GEN-1/NACT also changed the density of CD4 and CD8 T cells in tumors, as shown in the following figures. Compared to tumor samples collected at biopsy (pre-treatment), tumors following treatment with GEN-1/NACT had a higher number of CD8 T cells, a lower number of CD4 T cells, and an increased CD8/CD4 ratio. The CD8 cell density increased in 67% of patients and the CD4 cell density decreased in 82% of patients, demonstrating greater anti-cancer activity.



Source: Thaker *et al.*, 2021

Synthetic Control Arm

In March 2020, Celsion announced a partnership with Medidata, a Dassault Systèmes company, that included the construction of a synthetic control arm (SCA) for comparison to the results from the OVATION 1 clinical trial. Medidata has access to records from over six million anonymized patients from approximately 20,000 previously conducted clinical trials. SCAs are formed through matching of control patients from historical clinical trials that have the same demographic and disease characteristics of the participants in a trial for a new investigation product. The advantage of SCAs is that they can provide a comparison between a treated and control group for a single arm trial, reduce the number of patients who are exposed to placebo treatments, and reduce the time and cost to conduct clinical trials.

The results of the analysis comparing the PFS from the OVATION 1 study and the SCA are shown below.

GEN-1 Population	PFS Hazard Ratio (Confidence Interval)
Intent-to-treat, n=15	0.53 (95% CI 0.16, 1.73); log-rank p=0.29
Per-protocol, n=14	0.33 (95% CI 0.08, 1.37); log-rank p=0.11

Source: Celsion Corporation

While the results are not statistically significant due to the small number of patients, the data show that the patients in the OVATION 1 study virtually doubled the control of their cancer when compared to the SCA. These results are a strong indication that GEN-1 is having a positive treatment effect in patients with advanced ovarian cancer.

OVATION 2 Trial

To follow up on the results of the OVATION 1 trial, Celsion has initiated the OVATION 2 clinical trial. It is a Phase 1/2 randomized, open label, multicenter trial to evaluate the safety, efficacy, and biological activity of intraperitoneal GEN-1 plus 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 thus far is 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.

In July 2021, Celsion reported the Data Safety Monitoring Board (DSMB) recommended to continue dosing patients in the Phase 2 portion of the OVATION 2 study. Following a pre-planned interim safety review of 55 treated patients, the DSMB determined that the safety of GEN-1 dosing at 100 mg/m^2 had an acceptable risk/benefit ratio, that patients tolerate up to 17 doses of GEN-1 during a course of the treatment that lasts up to six months, and no dose-limiting toxicities were reported.

Thus far, over 50% 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:

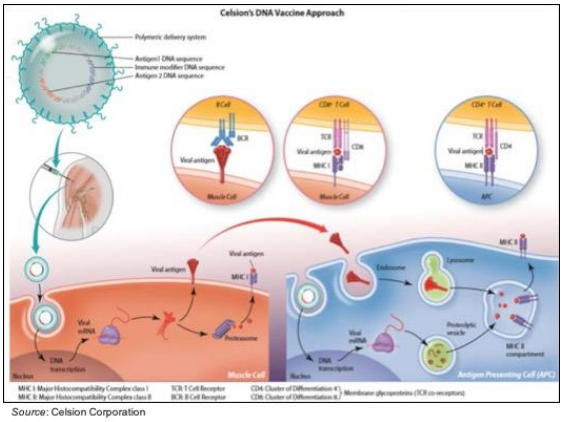
- 16/20 (80%) patients treated with GEN-1 (100 mg/m^2) + NACT had a complete tumor resection (R0) following interval debulking surgery, compared to only 9/16 (56%) of patients receiving NACT only

- Both cohorts of patients had similar ORR of approximately 80%

We anticipate enrollment being completed in the OVATION 2 trial in the first half of 2022.

PLACCINE Technology

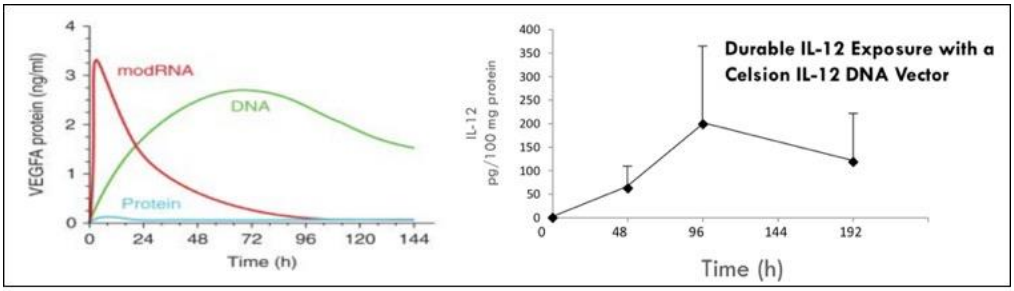
In January 2021, Celsion filed a provisional U.S. patent application for a DNA-based, investigational vaccine for preventing infection from a wide range of infectious agents using its PLACCINE DNA vaccine technology. The PLACCINE technology is characterized by a single multi-cistronic DNA plasmid vector that encodes for multiple antigens, an immune modifier, and is administered with a synthetic delivery system. It is an extension of the TheraPlas delivery technology that is used for GEN-1. An overview of the vaccine technology is shown in the following figure.



Source: Celsion Corporation

The initial demonstration of capability for the PLACCINE platform will be the development of a SARS-CoV-2 vaccine. Once established, its adaptability for creating vaccines for a wide range of pathogens, including common pathogens and those with the potential to be used in bioterrorism will be the focus of Celsion's research. In addition, there is the option for multiple modes of administration, including intramuscular, subcutaneous, intradermal, and inhalation. The vaccines can also be designed to express multiple antigens along with co-expression of cytokines and/or chemokines to enhance the immune response.

The utilization of a DNA vaccine yields durable antigen levels that are sustained for longer than for modified RNA vaccines or protein antigens, as shown in the following figure. The figure on the lower left shows the level of VEGFA protein following immunization with a DNA vector, a modified RNA vector, or the protein itself. The peak level of protein from the DNA vector is very similar to that for the modified RNA vector, however sustained expression leads to presence of the antigen for much longer than either of the other two delivery systems. The figure on the lower right shows the sustained expression of IL-12 following GEN-1 administration to a patient with ovarian cancer, which is similar to what should occur in a patient immunized with a DNA vector.



Source: Celsion Corporation

In addition to providing sustained antigen expression upon administration, the DNA-polymer nanoparticles that are inherent to the PLACCINE technology have a long shelf life at 5ºC (8-12 months as dry powder; 6-9 months reconstituted) and are even stable at 25ºC for 14 days as a dry powder and ≥ 6 days reconstituted.

Celsion will be developing a SARS-CoV-2 vaccine that also expresses IL-12. The use of IL-12 should lead to an enhanced immune response, which was previously shown when utilized in vaccine candidates against HIV (Elizaga *et al*., 2018), hepatitis C (Gorzin *et al*., 2014), and Toxoplasma gondii (Ghaffarifar *et al*., 2019). In a clinical trial involving 62 HIV-1 infected patients, a quadvalent DNA vaccine encoding HIV-1 Gag/Pl, Nef/Tat/Vif, Envelope (Env), and IL-12 caused an increase in IFN-γ expressing CD4 T cells to Gag, Pol, and Env from baseline to week 14, thus showing the utility of using IL-12 as a vaccine adjuvant (Jacobson *et al*., 2016).

Thus far, all SARS-CoV-2 vaccines that have been approved or are in development have been monovalent (only targeting the Spike [S] protein), however Celsion is planning to develop a multivalent vaccine that includes both S antigen in combination with either membrane (M) or nucleocapsid (N) antigen. A multivalent vaccine may act more like a whole virus vaccine and could be less susceptible to immune escape by variants of the virus. We anticipate an IND being filed before the end of 2021 such that a Phase 1 clinical trial can initiate in mid-2022.

Intellectual Property

Celsion owns three U.S. and international patents and related applications with claims, methods, and compositions of matter that cover various aspects of the TheraPlas and GEN-1 technologies, with expiration dates ranging from 2020 to 2028. The FDA granted orphan drug designation (ODD) to GEN-1 for the treatment of ovarian cancer. If a product with ODD receives the first FDA approval for the indication for which it is designated, that product is entitled to orphan drug protection, which means that the FDA may not approve another application to market the same drug for the same indication for seven years (in limited circumstances, such as a product that shows clinical superiority to the product with orphan exclusivity, the FDA may bypass this limitation). In addition, due to the Biologics Price Competition and Innovation Act of 2009, new licensed biological products (such as GEN-1) that are approved through a Biologics License Application (BLA) receive

12 years of market exclusivity. This means the FDA cannot license any 351(k) application for a biosimilar or interchangeable product that relies on the previously approved product as a reference for biosimilarity during that time period.

Financials and Capital Structure

On August 12, 2021, Celsion reported financial results for the second quarter of 2021. The company reported licensing revenue of $125,000 for the second 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 second quarter of 2021 were $2.6 million, compared to $3.0 million for the second quarter of 2020. The decrease was primarily due to a decrease in clinical development costs for the Phase 3 OPTIMA study and decreased clinical supplies and regulatory support partially offset by an increase in costs associated with the OVATION 2 study. G&A expenses in the second quarter of 2021 were $2.6 million, compared to $1.9 million for the second 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 June 30, 2021, Celsion had approximately $64.5 million in cash, cash equivalents, and short-term investments. We estimate the company has sufficient capital to fund operations through 2024. As of August 11, 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 95.9 million.

Risks to Consider

Clinical Risk: While the results for the OVATION 1 trial were encouraging, there were a very small number of participants in the open label study, thus there is no guarantee that the results will be replicated in a larger clinical trial. In addition, the OVATION 1 study showed that GEN-1 was well tolerated with no safety concerns, however there is no guarantee that safety signals will not be seen in future clinical trials. The highest dose tested in the OVATION 1 study was 79 mg/m^2 and the OVATION 2 study will be evaluating a 100 mg/m^2 dose, thus there is the possibility that the drug will not be as well tolerated at the higher dose.

Development Risk: GEN-1 is the only product in clinical development for Celsion, thus if it were to fail to advance in the clinic and on to approval the company would be highly negatively affected. There are multiple treatments available for ovarian cancer, with platinum-based chemotherapy and tumor resection being the standard of care for first-line treatment. The company PLACCINE technology is still in pre-clinical development and there are a number of approved vaccines and other vaccines under development for SARS-CoV-2, the company's first indication for PLACCINE. Thus, even if successful in developing a safe and effective SARS-CoV-2 vaccine, there is no guarantee that the product would be commercially successful.

Financing Risk: Celsion is a pre-revenue company and is not yet profitable. As of June 30, 2021, the company had approximately $64.5 million in cash, cash equivalents, and short-term investments, which we estimate is sufficient to fund operations through 2024. However, Celsion will require substantial additional capital to advance GEN-1 through clinical testing and to approval.

MANAGEMENT PROFILES

Michael H. Tardugno – Chairman, President, and Chief Executive Officer
Michael H. Tardugno has 30 years of experience in the pharmaceutical and medical device industries. Mr. Tardugno was appointed President and Chief Executive Officer of Celsion on January 3, 2007, and was elected to the Board of Directors on January 22, 2007. Prior to joining the company, Mr. Tardugno served as Senior Vice President and General Manager of Mylan Technologies Inc., a subsidiary of Mylan Laboratories, a transdermal drug company. He was a founding member of management of Songbird Hearing, Inc., a privately held startup, and held the positions of Senior Vice President of Technical Operations at Bristol-Myers Squibb and Senior Vice President of Technology Development and Manufacturing for Bausch & Lomb. Mr. Tardugno began his career in 1977 with Abbott Laboratories, where he held positions in pharmaceutical operations. Mr. Tardugno holds a BS in Biology from St. Bonaventure University and completed the Harvard Business School executive program.

Khursheed Anwer, PhD, MBA – Executive Vice President and Chief Scientific Officer
Khursheed Anwer, PhD, MBA, assumed the title of Executive Vice President and Chief Science Officer, EGEN, upon Celsion's June 2014 acquisition of EGEN, Inc., where he was President and Chief Science Officer, a position he held since 2009. He joined EGEN, Inc. in July, 2002, as Vice President of Research and Development, and directed the company's clinical and research and development functions throughout his tenure at EGEN, Inc. Dr. Anwer has a PhD in Physiology/Pharmacology from Ohio University and received postdoctoral training from the University of Texas Health Science Center at Houston. Before joining EGEN, Inc., Dr. Anwer was Director of Pre-Clinical Development at Valentis, Inc. From 1993 to 1999, he served in several positions at GeneMedicine, Inc., where he led several research projects in the area of nonviral gene therapy. He has authored more than 40 publications in the area of nonviral gene therapy, resulting from his active career in research and development. Dr. Anwer is an adjunct faculty member in the Biology Department at the University of Alabama in Huntsville and a board member of the University of Alabama Business School, STEP.

Nicholas Borys, MD – Executive Vice President and Chief Medical Officer
Nicholas Borys, MD, joined Celsion in October 2007 as Vice President and Chief Medical Officer. In this position Dr. Borys manages the clinical development program for Celsion. Dr. Borys, who was most recently Chief Medical Officer at Molecular Insight Pharmaceuticals, Inc., has accumulated extensive experience in all phases of pharmaceutical development, with a focus in oncology. Prior to joining Celsion, he held increasingly senior positions at Cytogen Corporation, Anthra Pharmaceuticals, Inc., Amersham Healthcare, Inc., and Hoffmann La-Roche Inc. Dr. Borys attended Rutgers University and holds an MD degree from American University of the Caribbean School of Medicine.

Jeffrey W. Church – Executive Vice President, Chief Financial Officer and Corporate Secretary
Jeffrey W. Church was appointed Senior Vice President and Chief Financial Officer of Celsion in July 2013. The appointment marked Mr. Church's resumption of the role of Chief Financial Officer, a position he held prior to his promotion to Senior Vice President in July 2011, while also granting him responsibility for corporate investor relations. Mr. Church joined Celsion in July 2010 as Vice President and Chief Financial Officer. He brings more than 30 years of experience in corporate finance, mergers and acquisitions, investor relations, and SEC reporting. Prior to joining Celsion, Mr. Church held senior financial executive positions with several private and public clinical-stage life science companies, including Alba Therapeutics Corporation, Novavax, Inc., GenVec, Inc., and Meridian Medical Technologies, Inc. Mr. Church started his career in 1979 with the public accounting firm Price Waterhouse. Mr. Church holds a BS degree from the University of Maryland and received his Maryland Certified Public Accountant accreditation in 1979.

VALUATION

We are initiating coverage of Celsion Corporation (CLSN) with a valuation of $3.50. Celsion is a biopharmaceutical company developing DNA-based immunotherapies and proof-of-concept for next-generation vaccines. The company has two platform technologies, TheraPlas and PLACCINE, each of which is based on non-viral delivery of non-integrating nucleic acid molecules for therapeutic and prophylactic treatment. The delivery system of TheraPlas is based on polyethyleneimine (PEI) coupled to polyethylene glycol (PEG) and cholesterol to form PEG-PEI-Cholesterol (PPC). The lead TheraPlas product, GEN-1, is in clinical development for the first-line treatment of advanced ovarian cancer. It consists of an interleukin (IL)-12 encoding DNA plasmid that is infused intraperitoneally to increase the concentration of IL-12 at the tumor site. Celsion's lead vaccine development candidate is based on the PLACCINE technology and consists of a multi-cistronic DNA plasmid vector that encodes for multiple antigens of the SARS-CoV-2 virus. In its earliest form IL-12 is included as an adjuvant.

GEN-1

GEN-1 is a gene-based IL-12 therapeutic formulated to produce locally increased concentrations of IL-12 and IFN-γ but without producing systemic toxicity. It comprises a plasmid encoding human IL-12 coupled to a non-viral DNA delivery system, 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.

GEN-1 has been studied in multiple previous clinical trials, with results from those studies showing that the treatment is generally safe and well tolerated, results in localized increases in IL-12 and IFN-γ, and in the most recent clinical study (OVATION 1) higher doses of GEN-1 were associated with increased tumor response rates.

Celsion is currently conducting the OVATION 2 clinical trial. It is a Phase 1/2 randomized, open label, multicenter trial to evaluate the safety, efficacy, and biological activity of intraperitoneal GEN-1 plus NACT, compared to NACT alone. Up to 110 patients are anticipated to be enrolled in the trial. The primary endpoint is progression free survival (PFS), which will be evaluated following 80 PFS events or 16 months, whichever is longer. We anticipate enrollment in the OVATION 2 trial to be completed in the first half of 2022.

PLACCINE Technology

The PLACCINE technology is characterized by a single multi-cistronic DNA plasmid vector that encodes for multiple antigens, an immune modifier, and is administered with a synthetic delivery system. It is an extension of the TheraPlas delivery technology that is used for GEN-1. The initial demonstration of capability for the PLACCINE platform will be the development of a SARS-CoV-2 vaccine. Once established, its adaptability for creating vaccines for a wide range of pathogens, including common pathogens and those with the potential to be used in bioterrorism will be the focus of Celsion's research. In addition, there is the option for multiple modes of administration, including intramuscular, subcutaneous, intradermal, and inhalation. The vaccines can also be designed to express multiple antigens along with co-expression of cytokines and/or chemokines to enhance the immune response. We anticipate an IND being filed for a SARS-CoV-2 vaccine before the end of 2021 such that a Phase 1 clinical trial can initiate in mid-2022.

Valuation

We value Celsion using a probability-adjusted discounted cash flow model that takes into account potential future revenues of GEN-1 in the treatment of ovarian cancer and the potential value of the PLACCINE technology. We model for Celsion to partner GEN-1 and to receive a 15% royalty on net sales.

As mentioned previously, we anticipate enrollment completing in the OVATION 2 trial in the first half of 2022. We model for a Phase 3 trial to initiate in 2023, a BLA filing in 2026 and approval in 2027 in the U.S. and in

2028 in the E.U. There are approximately 22,000 newly diagnosed cases of ovarian cancer every year in the U.S. and another 40,000 in the E.U., with the vast majority of them being advanced stage cancer. We model for GEN-1 to achieve 30% peak market penetration and generate approximately $1 billion in peak annual revenues in each jurisdiction. Using a 15% royalty rate, a 50% chance of approval, and a 13% discount rate leads to a net present value for GEN-1 in ovarian cancer of approximately $224 million.

For the PLACCINE technology, we assign a value of $50 million for its use in generating vaccines against important infectious diseases, including COVID-19. The technology is still in pre-clinical development and as more data becomes available for it we will be better able to derive a more precise valuation.

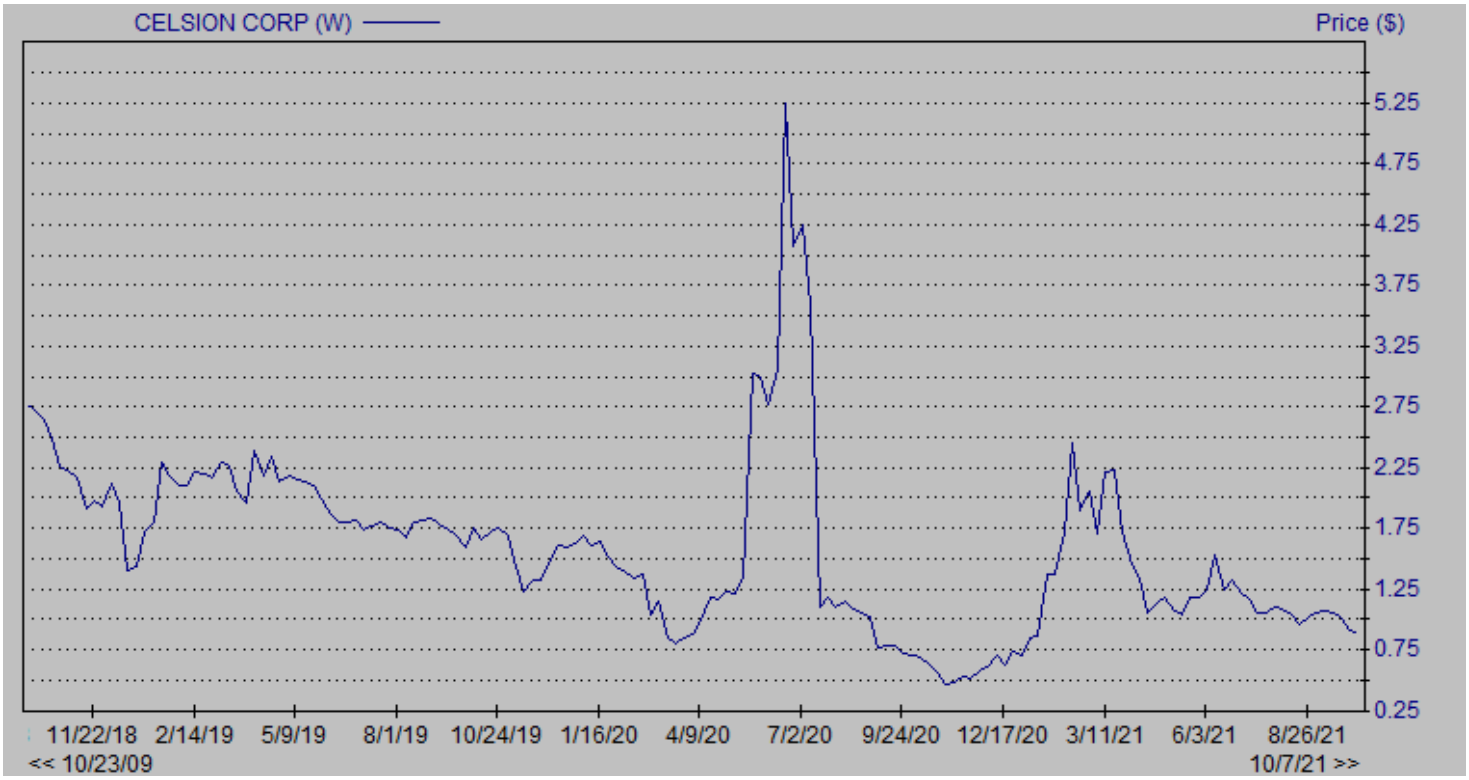
Combining the valuation for GEN-1, the PLACCINE technology, and the company's current cash balance leads to a net present value for the company of $336 million. Celsion's current fully diluted share count is approximately 95.9 million, which leads to a valuation of $3.50 per share.

PROJECTED FINANCIALS

Celsion Corporation	2020 A	Q1 A	Q2 A	Q3 E	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	$2.7	$2.8	$10.7	$12.0	$14.0
SG&A	$7.6	$2.9	$2.6	$2.8	$2.9	$11.2	$12.0	$13.0
Operating Income	($18.5)	($5.4)	($5.1)	($5.4)	($5.6)	($21.4)	($23.5)	($27.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($4.8)	$0.3	$0.4	$0.0	$0.0	($0.6)	$0.2	$0.2
Pre-Tax Income	($23.3)	($5.7)	($5.4)	($5.3)	($5.5)	($22.0)	($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)	($5.3)	($5.5)	($22.0)	($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	81.5	90.0	93.0

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

HISTORICAL STOCK PRICE



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.