

### INSTITUTIONAL RESEARCH

# **Biotechnology**UPDATE REPORT

Member FINRA/SIPC

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## **Celsion Corporation (NASDAQ/CLSN) Neutral Rated**

February 23, 2022

The DSMB Recommends to Continue Dosing Patients: GEN-1 in Advanced Ovarian Cancer. We Remain Neutral on the Stock

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The Data Safety Monitoring Board (DSMB) unanimously recommended that the OVATION 2 Study continue treating patients with 100 mg/m2. The DSMB also determined that safety is satisfactory with an acceptable risk/benefit and that patients tolerate up to 17 doses of GEN-1 during a course of treatment that lasts up to six months. No dose-limiting toxicities were reported. Celsion is now highly dependent on the outcome of GEN-1. We continue to be Neutral Rated.

#### **Investment Highlights**

Celsion previously announced Interim Clinical data on the OVATION 2 (Phase 1/2 Study with GEN-1 in Patients with Advanced Ovarian Cancer. The OVATION 2 Study combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink cancer as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three adjuvant cycles of chemotherapy and up to nine additional weekly GEN-1 treatments, the goal of which is to delay disease progression and improve overall survival. To date, the Company has enrolled approximately 70% of the anticipated 110 patients to be enrolled into the OVATION 2 Study (expected by 1H22).

**Study Statistical Design:** The OVATION 2 Study is designed with an 80% confidence interval for an observed Progression-Free Survival (PFS) Hazard Ratio of 0.75, which would mean an approximate 33% improvement in risk for cancer progression when comparing the treatment arm (NACT + GEN-1) with the control arm (NACT only).

What is GEN-1? GEN-1 is an immunotherapy that produces safe and durable local levels of IL-12, a pluripotent cytokine associated with the stimulation of innate and adaptive immune response against cancer. The GEN-1 nanoparticle comprises a DNA plasmid encoding IL-12 gene and a synthetic polymer facilitating plasmid delivery vector. Cell transfection is followed by persistent, local secretion of the IL-12 protein at therapeutic levels.

Valuation: Last July, we lowered our rating to Hold based on the lack of visibility with ThermoDox and removed our price target. As we have previously noted, Celsion's success as a company, in our opinion, has been dependent on the clinical outcomes for ThermoDox (which has failed) and GEN-1. Our therapeutic models are risk-adjusted. For the U.S. for ThermoDox, we previously used a 75% risk rate (25% probability of success), which we now consider as 100% (zero likelihood of success). For GEN-1, we assume just a 10% probability of success.

**Risk Analysis:** Risks include (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property.



Stock Data		
52-Week Range	\$0.35 -	\$2.47
Shares Outstanding (mil.)		86.6
Market Capitalization (mil.)		\$31
Enterprise Value (mil.)		\$39
Debt to Capital		26%
Book Value/Share		\$1.55
Price/Book		1.6
Average Three Months Trad	ing Volume (K)	854
Insider Ownership		0.6%
Institutional Ownership		19.9%
Short interest (mil.)		1.1%
Dividend / Yield		\$0.00/0.0%





#### **Exhibit 1. Income Statement**

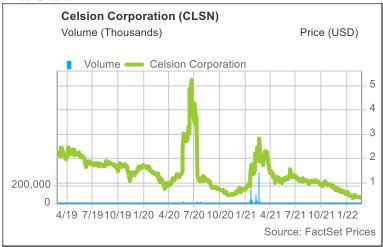
Celsion Corporation.: Income Statement (\$000)																		
.: YE December 31		2018A	2019A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Product sales																		
Hepatocellular Carcinoma; (US) (ThermoDox)		-	-	-					-	-	-	-	-	-	-	-	-	-
Hepatocellular Carcinoma; (China) (ThermoDox)		-	-	-					-	-	-	-	-	-	-	-	-	-
Ovarian Cancer (Gen-1)		-	-	-					-	-	-	-	2,648	5,403	11,023	14,056	15,772	17,552
Glioblastoma (pre-clinical)		-	-	-					-	-	-	-	-	-	-	-	-	-
Non-Muscle Invasice bladder cancer (Pre-clinical)		-	-	-					-	-	-	-	-	-	-	-	-	-
Licensing Revenue		500	500	500	125	125	125		375									
Total Product Sales		500	500	500	125	125	125		375			-	2,648	5,403	11,023	14,056	15,772	17,552
Operating Expenses																		
Cost of Goods Sold											_	_	344	648	1,102	984	789	878
	%COGS										15%	14%	13%	12%	10%	7%	5%	5%
Research and Development		11,866	13,065	11,345	2,572	2,593	2,468	3,097	11,912	12,508	13,133	13,790	14,479	15,203	15,963	16,761	17,600	18,480
	%R&D	,	.,	,,	,-	,	,	.,	**	,	-,	-,	, -	-,	.,	-,-	,,,,,	.,
General and Administrative	70.10.2	9.700	8,000	7,642	2,937	2,602	2,718	1,500	9,757	10,245	10,757	11,295	11,860	12,453	13,075	13,729	14,416	15,136
Contral and / Eliminostatio	%SG&A	0,700	0,000	7,012	2,001	2,002	2,7.10	1,000	0,707	10,210	10,707	11,200	11,000	12,100	10,010	10,720	,	10,100
Acquistion Costs	,000a, t																	
Total expenses		21,565	21,065	18,986	5,508	5.196	5,186	4,597	21,669	22,753	23,890	25,085	26,683	28,304	30,141	31,475	32,804	34,494
Operating Income (Loss)		(21,065)	(20,565)	(18,486)	(5,383)	5,071	(5,061)	(4,597)	(21,294)	(22,753)	(23,890)	(25,085)	(24,035)	(22,901)	(19,118)	(17,419)	(17,032)	(16,942)
Investment income, net		354	501	(10,100)	(151)	81	(257)	(257)	(584)	(1,028)	(1,028)	(1,028)	(1,028)	(1,028)	(1,028)	(1,028)	(1,028)	(1,028)
Interest expense		(712)	(1,393)	(1,300)	(158)	(0)	(==-/	- (/	(158)	(.,===)	(-,,	(.,==,	(-,)	(.,===)	(.,===)	(1,020)	(.,===)	(-,/
Gain (loss) from change in valuation of common stock warrant liability		(/	(.,)	(2,370)	(100)	(234)	4		(,									
Loss from impairment of in-process research and development		(4,510)		120		(221)	(96)											
Other income (expense)		0	29	(1,292)	1		-	-	1	-	-	-	-	-	-	-	-	-
Loss from valuation of earn-out milestone liability		3,631	3,189		2	(2)		-	0	-	-	-	-	-	-	-	-	-
Fair value of warrants issued in connection with amendment  Total other income		(1,237)	(400) <b>29</b>	(1,164)	(306)	(377)	(349)	(257)	(1,289)	(1,028)	(1,028)	(1,028)	(1,028)	(1,028)	- (1,028)	(1,028)	(1,028)	(1,028)
		1		` ` ` `			` '	` '		` ' '		( )	, , , ,	, , , ,		` ` '		, , , ,
Pretax Income Income Tax Benefit (Provision)		(22,302) 10,419	(18,668) 1,816	(23,329) 1,846	(5,689)	5,448	(5,410)	(4,854)	(10,505)	(23,781)	(24,918)	(26,113) (1,306)	(25,063) (2,506)	(23,929) (3,589)	(20,146) (4,029)	(18,447) (4,612)	(18,060) (4,696)	(17,970) (4,852)
Tax Rate		10,413	1,010	1,040							0%	(1,500)	10%	15%	20%	25%	26%	27%
GAAP Net Income (loss)		(11,883)	(16,852)	(21,484)	(5,689)	5,448	(5,410)	(4,854)	(10,505)	(23,781)	(24,918)	(24,807)	(22,557)	(20,340)	(16,117)	(13,835)	(13,364)	(13,118)
Deemed dividend related to warrant modification		(11,863)	(10,032)	(21,404)	(3,083)	3,440	(3,410)	(4,054)	(10,505)	(23,761)	(24,910)	(24,807)	(22,331)	(20,340)	(10,117)	(13,833)	(13,304)	(13,118)
Net Income attributable to common shareholders(loss)		(11,883)																
Basic and Diluted		(0.68)																
GAAP-EPS		(0.68)	(0.77)	(0.67)	(0.09)	0.06	(0.06)	(0.06)	(0.14)	(0.29)	(0.2)	(0.2)	(0.3)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
GAAP EPS (dil)		(86.0)	(0.77) (0.77)	(0.67)	(0.09)	0.06	(0.06)	(0.06)	(0.14) (0.14)	(0.29)	(0.3)	(0.3)	(0.3)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
* 7		17,583	21,832	31,961	66,298	85,294	86,557	(0.06) 86,644	` '	· 'I	(0.3) 81,605	(0.3) 81,809	82,014	82,219	(0.2) 82,425	(0.2) 82,631	(0.2) 82,838	83,045
Wgtd Avg Shrs (Bas) - '000s	-								81,198	81,401								
Wgtd Avg Shrs (Dil) - '000s		17,583	21,832	31,961	66,298	85,294	86,557	86,644	81,198	81,401	81,605	81,809	82,014	82,219	82,425	82,631	82,838	83,045

Source: Dawson James estimates, company reports



#### **Important Disclosures:**

#### **Price Chart:**



Price target and rating changes over the past three years:

Initiated – Buy – August 5, 2019 – Price Target \$4.00

Update - Buy - August 14, 2019 - Price Target \$4.00

Update – Buy – August 19, 2019 – Price Target \$4.00

Update - Buy - November 5, 2019 - Price Target \$4.00

Update – Buy – February 6, 2020 – Price Target \$4.00

Update – Buy – April 16, 2020 – Price Target \$4.00

Update – Buy – May 18, 2020 – Price Target \$4.00

Price Target Change – Buy – June 25, 2020 – Price Target Increase from \$4.00 to \$5.00

Rating Change – Buy to Hold – July 25, 2020 – Price Target Removed

Update - Neutral - May 24, 2021 - Price Target NA

Update - Neutral - December 15, 2021 - Price Target NA

Update - Neutral - February 23, 2022 - Price Target NA

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- 1) **Buy**: The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- Neutral: The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sel**l: The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of... 8-Feb-22

	Company		Investment	
	Coverage		Banking	
				% of
Ratings Distribution	# of Companies	% of Total	# of Companies	Totals
Market Outperform (Buy)	31	76%	6	19%
Market Perform (Neutral)	10	24%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	41	100%	6	15%

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