

Celsion Corporation (NASDAQ/CLSN)

July 13, 2020

Lowering from BUY to Hold: IDMC Say's ThermoDox Study Should be Halted

Celsion announced that the company received a recommendation from the independent Data Monitoring Committee (DMC) to consider stopping the global Phase 3 OPTIMA Study of ThermoDox in combination with radiofrequency ablation (RFA) for the treatment of hepatocellular carcinoma (HCC), or primary liver cancer. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9th. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903.

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Investment Highlights

As noted above, the DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. It's important to note that statistically, the "2-sided p-value of 0.524" leaves some uncertainty; as such, the DMC has left the final decision of whether or not to stop the OPTIMA Study to Celsion. We are disappointed with the news as it appears whatever effect ThermoDox is having is extremely modest. As such, we are stepping to the sidelines and removing our Buy rating and price target while we assess what management has to say at its scheduled conference call Wednesday.

Conference Call and Webcast: Celsion will be holding a conference call and webcast on Wednesday, July 15, 2020, to discuss its current observations about the results of the OPTIMA Study, the DMC's recommendations, and the company's next steps.

Valuation: We are lowering our rating to Hold based on the lack of visibility with ThermoDox. As a result, we are also removing our price target. As we have previously noted, Celsion's success as a company, in our opinion, is dependent on the clinical outcomes for ThermoDox (which now looks grim) 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 reduce to zero. (U.S. and China). For GEN-1, we assume just a 10% probability of success.

Risk Analysis: (1) commercial; (2) regulatory; (3) clinical; (4) manufacturing; (5) financial; (6) liability; and (7) intellectual property. We review these and other risks in the risk section of this report.

Current Price				\$3.58
Price Target				NA
Estimates	F2019A	F2020E	F2021E	
Expenses (\$000s)	\$ 21,065	\$ 21,701	\$ 15,287	
1Q January	\$ 4,986	\$ 4,891	\$ 3,669	
2Q April	\$ 5,695	\$ 5,530	\$ 3,822	
3Q July	\$ 5,513	\$ 5,530	\$ 3,822	
4Q October	\$ 4,873	\$ 5,751	\$ 3,974	
	F2019A	F2020E	F2021E	
EPS (diluted)	\$ (0.77)	\$ (0.57)	\$ (0.25)	
1Q January	\$ (0.12)	\$ (0.20)	\$ (0.06)	
2Q April	\$ (0.29)	\$ (0.12)	\$ (0.06)	
3Q July	\$ (0.25)	\$ (0.12)	\$ (0.06)	
4Q October	\$ (0.11)	\$ (0.13)	\$ (0.06)	
EBITDA/Share				
EV/EBITDA (x)				
Stock Data				
52-Week Range	\$0.69	-	\$6.50	
Shares Outstanding (mil.)	33.2			
Market Capitalization (mil.)	\$119			
Enterprise Value (mil.)	\$127			
Debt to Capital	7%			
Book Value/Share	\$1.55			
Price/Book	2.7			
Average Three Months Trading Volume (K)	138			
Insider Ownership	7.1%			
Institutional Ownership	8.9%			
Short interest (mil.)	4.9%			
Dividend / Yield	\$0.00/0.0%			



Risk Analysis

Investment Risk: The company faces multiple investment risks from product management, market share adoption, and commercialization to regulatory and competitive environment associated risks.

Clinical and regulatory risk: Celsion is currently in the process of completing its FDA clinical trials. There is no assurance that their product will be approved by the FDA and that even if approved if it will be reimbursed by insurance or successfully commercialized.

Commercial risk: The focus of the company is on successfully developing their products and eventually bring them to the mass market. We can make no assurances that the company will be able to achieve a critical level of market share to become profitable in this indication and or in additional planned indications.

Employee risk: Celsion's core management team is experienced and has clear expectations for the future of the company. Celsion plans to bring their proposed products to market as efficiently as possible, and their success will depend heavily upon the experience, abilities, and continued services of its senior officers, sales staff, and key scientific personnel.

Financial risk: Celsion may need to raise additional capital in the marketplace to continue to fund operations through more trials and eventually an NDA and possible commercial launch. There can be no assurances that the company will be able to successfully raise capital and do so on favorable terms.

Intellectual property risk: Celsion may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed or will be held as valid if challenged, and the company may infringe on third party's patents.

Manufacturing and Liability risk. The company has to be able to manufacture the product(s) and may face certain related product liability.

Reimbursement and insurance payment risk: Insurance payment for products may be an additional hurdle for adoption.

Exhibit 1. Income Statement

Celsion Corporation.: Income Statement (\$000)																	
:YE December 31	2018A	2019A	1Q20A	2Q20E	3Q20E	4Q20E	2020E	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 Invasive bladder cancer (Pre-clinical)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Licensing Revenue	500	500	125				125										
Total Product Sales	500	500	125				125					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
										15%	14%	13%	12%	10%	7%	5%	5%
Research and Development	11,866	13,065	3,052	3,430	3,430	3,567	13,719	14,405	15,125	15,881	16,675	17,509	18,384	19,303	20,269	21,282	22,346
General and Administrative	9,700	8,000	1,839	2,100	2,100	2,184	8,400	882	926	972	1,021	1,072	1,126	1,182	1,241	1,303	1,368
Acquisition Costs																	
Total expenses	21,565	21,065	4,891	5,530	5,530	5,751	22,119	15,287	16,051	16,853	17,696	18,925	20,158	21,588	22,494	23,374	24,592
Operating Income (Loss)	(21,065)	(20,565)	(4,766)	(5,530)	(5,530)	(5,751)	(21,994)	(15,287)	(16,051)	(16,853)	(17,696)	(16,277)	(14,755)	(10,565)	(8,438)	(7,602)	(7,040)
Investment income, net	354	501	(41)	(41)	(41)	(41)	(165)	(165)	(165)	(165)	(165)	(165)	(165)	(165)	(165)	(165)	(165)
Interest expense	(712)	(1,393)	(339)	(339)	(339)	(339)	(1,357)	(1,357)	(1,357)	(1,357)	(1,357)	(1,357)	(1,357)	(1,357)	(1,357)	(1,357)	(1,357)
Gain (loss) from change in valuation of common stock warrant liability																	
Loss from impairment of in-process research and development	(4,510)																
Other income (expense)	0	29	88	88	88	88	353	353	353	353	353	353	353	353	353	353	353
Loss from valuation of earn-out milestone liability	3,631	3,189	1	1	1	1	6	6	6	6	6	6	6	6	6	6	6
Fair value of warrants issued in connection with amendment		(400)															
Total other income	(1,237)	29	(291)	(291)	(291)	(291)	(1,164)	(1,164)	(1,164)	(1,164)	(1,164)	(1,164)	(1,164)	(1,164)	(1,164)	(1,164)	(1,164)
Pretax Income	(22,302)	(18,668)	(5,057)	(5,821)	(5,821)	(6,042)	(23,157)	(16,450)	(17,215)	(18,017)	(18,860)	(17,441)	(15,919)	(11,728)	(9,601)	(8,765)	(8,204)
Income Tax Benefit (Provision)	10,419	1,816									(943)	(1,744)	(2,388)	(2,346)	(2,400)	(2,279)	(2,215)
Tax Rate										0%	5%	10%	15%	20%	25%	26%	27%
GAAP Net Income (loss)	(11,883)	(16,852)	(5,057)	(5,821)	(5,821)	(6,042)	(23,157)	(16,450)	(17,215)	(18,017)	(17,917)	(15,697)	(13,531)	(9,383)	(7,201)	(6,486)	(5,989)
Deemed dividend related to warrant modification																	
Net Income attributable to common shareholders(loss)	(11,883)																
Basic and Diluted	(0.68)																
GAAP-EPS	(0.68)	(0.77)	(0.20)	(0.12)	(0.12)	(0.13)	(0.57)	(0.25)	(0.26)	(0.2)	(0.3)	(0.2)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)
GAAP EPS (dil)		(0.77)	(0.20)	(0.12)	(0.12)	(0.13)	(0.57)	(0.25)	(0.26)	(0.2)	(0.3)	(0.2)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)
Wgtd Avg Shrs (Bas) - '000s	17,583	21,832	25,804	46,901	46,948	46,995	41,662	66,804	66,971	67,139	67,307	67,475	67,644	67,813	67,983	68,153	68,324
Wgtd Avg Shrs (Dil) - '000s	17,583	21,832	25,804	46,901	46,948	46,995	41,662	66,804	66,971	67,139	67,307	67,475	67,644	67,813	67,983	68,153	68,324

Source: Company reports and Dawson James Estimates

Source: Dawson James estimates

Companies mentioned in this report

Celsion Corporation

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

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	88%	3	14%
Market Perform (Neutral)	3	12%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	25	100%	4	16%

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