

Celsion Corporation (NASDAQ/CLSN)

May 18, 2020

BUY: Celsion – 1Q20 Results, \$17.5M in Cash on Hand

Celsion announced the quarter spending \$5M and ending the period with \$17.5M, and Management reviewed all the progress with ThermoDox and GEN-1. Last month the Company announced that the prescribed minimum number of events (158 patient deaths) was reached for the second pre-specified interim analysis of the OPTIMA Phase 3 Study with ThermoDox plus RFA (radiofrequency ablation) in patients with HCC. GEN-1 Showed Strong Progression-Free Survival Treatment Effect versus the “synthetic” Control Arm.

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Investment Highlights

What’s Next? The Independent Data Monitoring Committee (iDMC) is expected to meet in July to conduct the second interim analysis. Celsion expects to announce iDMC recommendations as soon as possible after the meeting. The hazard ratio for success at 158 deaths is 0.70, which represents a 30% reduction in the risk of death compared with RFA alone. This compares favorably with the hazard ratio of 0.65 observed in the prospective HEAT Study subgroup upon which the OPTIMA Study is based.

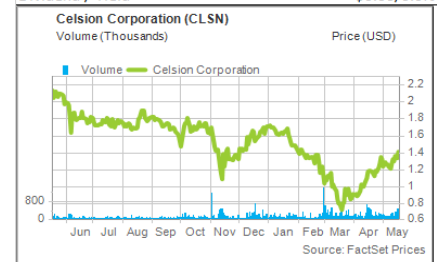
As a reminder, the independent Data Monitoring Committee (iDMC) unanimously recommends the OPTIMA Study (Liver Cancer) continue according to protocol. The reported interim analysis reviewed 128 events (from 556 patients) or >60% of the total number required for the final analysis. The hazard ratio for success at 128 events is approximately 0.637, which represents a 57% improvement in immediate survival vs. control. We note that this is consistent with the 0.65 hazard ratio, or 55% improvement seen in the prospective HEAT Study subgroup (which OPTIMA is based upon), which demonstrated a two-year overall survival advantage and a median time to death of more than 7 ½ years.

GEN-1 Update: This new immunotherapy showed strong Progression-Free Survival Treatment Effect vs. the (“synthetic” control arm). Celsion previously announced that the results from the Phase Ib dose-escalating OVATION 1 Study with GEN-1 in Stage III/IV ovarian cancer patients showed positive results in progression-free survival (PFS). The HR was 0.53 in the intent-to-treat group, showing strong signals of efficacy. The data leaves us encouraged.

Valuation: Celsion’s success as a company is dependent on the clinical outcomes for ThermoDox and GEN-1. For the purposes of our model we project timelines through the year 2030. Our therapeutic models are risk-adjusted. For the U.S. for ThermoDox we use just a 75% risk rate (25% probability of success), and in China we reduce this to 50%. For GEN-1 we assume just a 10% probability of success. Our models factor in assumed financings and use a fully diluted out-year (2030) share count. We triangulate FCFF, discounted EPS, and sum-of-the-parts models. We then averaged and equally weighted each model to derive the NPV and round to the nearest whole number to set our target price.

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				\$1.41
Price Target				\$ 4.00
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	-	\$2.18	
Shares Outstanding (mil.)				27.8
Market Capitalization (mil.)				\$39
Enterprise Value (mil.)				\$47
Debt to Capital				20%
Book Value/Share				\$1.55
Price/Book				2.7
Average Three Months Trading Volume (K)				79
Insider Ownership				7.1%
Institutional Ownership				8.5%
Short interest (mil.)				0.4%
Dividend / Yield				\$0.00/0.0%



VALUATION

Our valuation is derived by our revenue projections for ThermoDox and GEN-1 in their respective indications of Hepatocellular carcinoma and ovarian cancer. We do not model any potential revenues from these programs until at least 2023 and project our model through the year 2030. Our therapeutic models are risk-adjusted. For the U.S. for ThermoDox we use just a 75% risk rate (25% probability of success), and in China we reduce this to 50%. For GEN-1 we assume just a 10% probability of success. Our models factor in assumed financings and use a fully diluted out-year (2030) share count. We triangulate FCF, discounted EPS, and sum-of-the-parts models. We then averaged and equally weighted each model to derive the NPV and round to the nearest whole number to set our target price. Investors should recognize that this modeling exercise, which models out for ten years, while projected based on the current data and estimates, is limited in its ability to predict a 12-month target. The price of the stock will ultimately be driven near term by factors such as news flow, early trial data, and cyclic concerns of financings (dilution).

Exhibit 1. Free Cash Flow Model

Average	\$	3.61
Price Target	\$	3.13
Year		2020

DCF Valuation Using FCF (mln):

units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(20,899)	(24,595)	(15,678)	(16,421)	2,135	3,721	26,237	30,830	59,579	87,613	115,532	142,081
TaxRate	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	26%	27%
EBIT(1-)	(20,899)	(24,595)	(15,678)	(16,421)	2,135	3,535	23,613	26,205	47,663	65,710	85,494	103,719
CapEx	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(20,899)	(24,595)	(15,678)	(16,421)	2,135	3,535	23,613	26,205	47,663	65,710	85,494	103,719
PV of FCF	(24,034)	(24,595)	(13,633)	(12,417)	1,404	2,021	11,740	11,329	17,918	21,481	24,303	25,638
Discount Rate	15%											
Long Term Growth Rate	1%											
Terminal Cash Flow	748,261											
Terminal Value YE2030	184,959											
NPV	226,114											
NPV-Debt	72,232											
Shares out (thousands)	72,232	2030E										
NPV Per Share	\$	3.13										

Source: Dawson James

Exhibit 2. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	15%
Selected Year EPS	\$ 1.44
NPV	\$ 3.55

Source: Dawson James Estimates

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
Earnings Multiple		5%	10%	15%	20%	25%	30%
		1		\$0.88	\$0.55	\$0.36	\$0.23
5		\$4.41	\$2.77	\$1.78	\$1.16	\$0.77	\$ 0.52
10		\$8.83	\$5.54	\$3.55	\$2.32	\$1.54	\$ 1.04
15		\$13.24	\$8.32	\$5.33	\$3.48	\$2.32	\$ 1.56
20		\$17.65	\$11.09	\$7.11	\$4.64	\$3.09	\$ 2.09
25		\$22.07	\$13.86	\$8.89	\$5.81	\$3.86	\$ 2.61
30		\$26.48	\$16.63	\$10.66	\$6.97	\$4.63	\$ 3.13
35		\$30.90	\$19.40	\$12.44	\$8.13	\$5.40	\$ 3.65

Source: Dawson James

Exhibit 3. Sum of the Parts Model

	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM's	Term Val
ThermoDox/HCC (US)	1%	15%	4	65%	\$11	\$76.51
NPV						\$0.26
Thermodox/HCC (China)	1%	15%	4	65%	\$146	\$1,046
NPV						\$3.55
Gen1/Ovarian Cancer (US)	1%	15%	6	65%	\$18	\$125
NPV						\$0.32
Net Margin						65%
MM Shrs OS (2030E)						71
Total						\$4.13

Source: Dawson James

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.

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

Exhibit 4. 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)	-	-					-	-	-	1,518	3,190	5,026	7,039	9,242	9,708	10,197	10,711
Hepatocellular Carcinoma: (China) (ThermoDox)	-	-					-	-	-	21,230	22,090	44,185	45,073	68,968	93,806	119,615	146,423
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			22,749	25,280	51,859	57,515	89,234	117,570	145,584	174,686
Operating Expenses																	
Cost of Goods Sold										3,412	3,539	6,742	6,902	8,923	8,230	7,279	8,734
										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										4%							
Total expenses	21,565	21,065	4,891	5,530	5,530	5,751	22,119	15,287	16,051	20,266	21,235	25,323	26,412	29,409	29,740	29,864	32,449
Operating Income (Loss)	(21,065)	(20,565)	(4,766)	(5,530)	(5,530)	(5,751)	(21,994)	(15,287)	(16,051)	2,483	4,045	26,536	31,103	59,825	87,830	115,720	142,237
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)		88	88	88	88	353	353	353	353	353	353	353	353	353	353	353
Other income (expense)	0	29					6	6	6	6	6	6	6	6	6	6	6
Loss from valuation of earn-out milestone liability	3,631	3,189	1	1	1	1											
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)	1,319	2,881	25,373	29,939	58,661	86,667	114,556	141,073
Income Tax Benefit (Provision)	10,419	1,816									144	2,537	4,491	11,732	21,667	29,785	38,090
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)	1,319	2,737	22,836	25,449	46,929	65,000	84,771	102,984
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)	0.1	0.0	0.3	0.4	0.7	1.0	1.2	1.5
GAAP EPS (dil)		(0.77)	(0.20)	(0.12)	(0.12)	(0.13)	(0.57)	(0.25)	(0.26)	0.1	0.0	0.3	0.4	0.7	1.0	1.2	1.5
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: 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

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	21	88%	3	14%
Market Perform (Neutral)	3	13%	1	33%
Market Underperform (Sell)	0	0%	0	0%
Total	24	100%	4	17%

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