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Celsion Corporation (NASDAQ/CLSN)

August 14, 2019

BUY: NIH Analysis of ThermoDox HEAT Study is Published.

NIH's Independent Analysis of Celsion's Phase III HEAT Study Confirms Increasing Radiofrequency Ablation (RFA) Heating Time + ThermoDox® Improves Overall Survival with Significance in Patients with Primary Liver Cancer. NIH Analysis Supports the OPTIMA Study Design, Celsion's Fully Enrolled Global Phase II Study of ThermoDox® to Treat Primary Liver Cancer; First Pre-Planned Efficacy Analysis of the Phase II OPTIMA Study Planned for October 2019. Published in Journal of Vascular Radiology.

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Investment Highlights

Events Reached for First Interim Analysis. Celsion (on August 5, 2019) announced the prescribed number of events has been reached for the first pre-planned interim analysis of the OPTIMA Phase 3 Study with ThermoDox plus RFA in patients with HCC.

Results in October. In accordance with the statistical plan, this initial interim analysis has a target of 118 events, or 60% of the total number required for the final analysis. At the time of the data cutoff, the Company received reports of 128 events. The hazard ratio for success at 128 events is approximately 0.637, which represents an approximate 36.3% reduction in the risk of death, consistent with the 0.65 hazard ratio that was observed in the prospective HEAT Study subgroup, which demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years.

Two Novel Nanoparticle-Based Technology Platforms. Celsion currently has two nanoparticle-based product candidates in development with their fight against cancer. The first, ThermoDox, takes advantage of LTSL (lysolipid thermally sensitive liposome) technology to encapsulate the commonly used cancer drug doxorubicin. This heat sensitive liposome is able to change its structure when exposed to temperatures between 40-45 degrees Celsius, allowing for openings that release doxorubicin into and around the targeted tumor. With ThermoDox, LTSL for delivery of known chemotherapeutics is the primary objective. The second, GEN-1, takes advantage of Celsion's TheraPlas technology platform to provide localized immunotherapies. GEN-1 consists of an interleukin-12 (IL-12) DNA plasmid vector formed into nanoparticles with a lipopolymeric delivery system.

ThermoDox and GEN-1. Celsion has recently completed enrollment of its Phase 3 OPTIMA study using ThermoDox to treat Primary Liver Cancer (hepatocellular carcinoma). The OPTIMA study is a global Phase 3 trial in HCC with first interim data expected in the second half of 2019. ThermoDox has also shown potential in treating non-muscle invasive bladder cancer and is currently in early development for that indication. Celsion is also currently enrolling the Phase 1/2 OVATION study with GEN-1 in treating Ovarian cancer. Phase 1 data from this trial is expected in the second half of 2019 as well. GEN-1 has also shown potential to treat Glioblastoma. The principal target indications are hepatocellular (HCC) and ovarian cancer, both of which represent large commercial opportunities for these nanoparticle-based platforms, as the need for effective treatments is great. HCC represents a global incidence of over 755,000 people, growing 3% annually. With a median survival time less than three years, and the 5-year survival rate less than 10%, the need for more effective treatment is apparent and Celsion hopes to deliver incremental improvements to the treatment paradigm.

Current Price **\$1.70**
 Price Target **\$ 4.00**

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 22,643	\$ 23,775	\$ 14,859
1Q January	\$ 4,986	\$ 5,706	\$ 3,566
2Q April	\$ 5,661	\$ 5,944	\$ 3,715
3Q July	\$ 5,661	\$ 5,944	\$ 3,715
4Q October	\$ 6,336	\$ 6,182	\$ 3,863
	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.65)	\$ (0.31)	\$ (0.07)
1Q January	\$ (0.12)	\$ (0.07)	\$ (0.02)
2Q April	\$ (0.16)	\$ (0.08)	\$ (0.02)
3Q July	\$ (0.16)	\$ (0.08)	\$ (0.02)
4Q October	\$ (0.20)	\$ (0.08)	\$ (0.02)

EBITDA/Share	
EV/EBITDA (x)	
Stock Data	
52-Week Range	\$1.35 - \$3.10
Shares Outstanding (mil.)	20.5
Market Capitalization (mil.)	\$35
Enterprise Value (mil.)	\$44
Debt to Capital	27%
Book Value/Share	\$1.55
Price/Book	1.3
Average Three Months Trading Volume (K)	124
Insider Ownership	0.8%
Institutional Ownership	4.8%
Short interest (mil.)	1.4%
Dividend / Yield	\$0.00/0.0%



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

Market Opportunity for Hepatocellular Carcinoma and Ovarian Cancer. Celsion is targeting its efforts towards HCC in the global market. As HCC continues to rise in incidence, it is expected to become the most common type of cancer, surpassing lung cancer by 2020. About half of all new cases arise in China, and almost three quarters of all new cases occur in Asia. Current curative treatment options are almost exclusively limited to surgery, which is only possible in about 20% of patients. RFA remains the therapy of choice for non-surgical candidates and is the current standard of treatment for non-resectable liver cancers. Despite this, the recurrence rate for lesions over three centimeters is about 50%, leaving a highly underserved population. ThermoDox, in combination with RFA, addresses the limitations of the current standard of care by expanding the treatment zone and using a probe placed directly in the tumor, killing tumor cells within its immediate vicinity. The RFA then creates a thermal zone in the margin surrounding the tumor where RFA misses micro-metastases outside the ablation zone. Doxorubicin is then released in the thermal zone, expanding treatment and surrounding areas, killing the metastases outside the ablation zone.

Ovarian Cancer. Celsion's GEN-1 IL-12 is a powerful immune-modulating agent, capable of inducing anti-cancer immunity through multiple mechanisms. With an incidence of 225,000 women worldwide and over 22,280 women in the US, ovarian cancer ranks fifth among the highest cancer mortality rates among women. The five-year survival rate is below 50%, and only about 15% of diagnosed patients with localized cancer are eligible for potentially curative surgery. With an addressable market opportunity over 100,000 patients and a lack of treatment options in advanced ovarian cancer, Using Interleukin 12 (IL-12), Celsion has developed mechanisms that can induce anti-cancer immunity such as activation/proliferation, maturation/proliferation, anti-angiogenesis, and inhibition of immune suppression.

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. Investors should recognize that this modeling exercise, which models out for 10 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).

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.

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 10 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	\$	3.76
Price Target	\$	3.78
Year		2019

DCF Valuation Using FCF (mln):

units ('000)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(12,546)	(13,803)	(4,886)	(5,629)	12,927	14,512	37,029	41,621	70,370	98,405	126,324	152,873
TaxRate	0%	0%	0%	0%	0%	5%	10%	15%	20%	25%	26%	27%
EBIT(1-)	(12,546)	(13,803)	(4,886)	(5,629)	12,927	13,787	33,326	35,378	56,296	73,804	93,480	111,597
CapEx	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation	-	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(12,546)	(13,803)	(4,886)	(5,629)	12,927	13,787	33,326	35,378	56,296	73,804	93,480	111,597
PV of FCF	(12,546)	(12,003)	(3,695)	(3,701)	7,391	6,854	14,408	13,300	18,403	20,980	23,107	23,987
Discount Rate	15%											
Long Term Growth Rate	1%											
Terminal Cash Flow	805,095											
Terminal Value YE2030	173,050											
NPV	269,535											
NPV-Debt												
Shares out (thousands)	71,212	2030E										
NPV Per Share	\$	3.78										

Source: Dawson James Estimates

Source: Dawson James

Exhibit 2. Discounted EPS Model

Current Year	2019
Year of EPS	2030
Earnings Multiple	10
Discount Factor	15%
Selected Year EPS	\$ 1.54
NPV	\$ 3.31

Source: Dawson James Estimates

		Discount Rate and Earnings Multiple Varies, Year is Constant 2030 EPS					
		5%	10%	15%	20%	25%	30%
Earnings Multiple	1	\$0.90	\$0.54	\$0.33	\$0.21	\$0.13	\$ 0.09
	5	\$4.51	\$2.70	\$1.66	\$1.04	\$0.66	\$ 0.43
	10	\$9.01	\$5.40	\$3.31	\$2.07	\$1.32	\$ 0.86
	15	\$13.52	\$8.10	\$4.97	\$3.11	\$1.99	\$ 1.29
	20	\$18.03	\$10.81	\$6.63	\$4.15	\$2.65	\$ 1.72
	25	\$22.53	\$13.51	\$8.28	\$5.19	\$3.31	\$ 2.15
	30	\$27.04	\$16.21	\$9.94	\$6.22	\$3.97	\$ 2.58
	35	\$31.54	\$18.91	\$11.60	\$7.26	\$4.63	\$ 3.01

Source: Dawson James

Exhibit 3. Sum of the Parts Model

	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	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						\$3.60
Gen1/Ovarian Cancer (US)	1%	15%	6	65%	\$18	\$125
NPV						\$0.33
Net Margin						65%
MM Shrs OS (2030E)						70
Total						\$4.19

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 their 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. Atossa 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	1Q18A	2Q18A	3Q18A	4Q18A	2018A	1Q19A	2Q19E	3Q19E	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Product sales																					
Hepatocellular Carcinoma; (US) (ThermoDox)				0	-					-	-	-	-	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	125	125	125	125	500	125															
Total Product Sales	125	125	125	125	500	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	2,741	4,594	2,187	2,344	11,866	2,768	3,115	3,115	3,462	12,459	13,082	13,736	14,423	15,144	15,901	16,696	17,531	18,407	19,328	20,294	21,309
General and Administrative	1,665	3,543	1,960	2,532	9,700	2,218	2,546	2,546	2,874	10,184	10,694	1,123	1,179	1,238	1,300	1,365	1,433	1,505	1,580	1,659	1,742
														5%							
Acquisition Costs																					
Total expenses	4,406	8,136	4,147	4,875	21,565	4,986	5,661	5,661	6,336	22,643	23,775	14,859	15,602	19,794	20,740	24,802	25,866	28,835	29,138	29,232	31,785
Operating Income (Loss)	(4,281)	(8,011)	(4,022)	(4,750)	(21,065)	(4,861)	(5,661)	(5,661)	(6,336)	(22,643)	(23,775)	(14,859)	(15,602)	2,955	4,540	27,057	31,649	60,398	88,432	116,352	142,901
Investment income, net	74	73	107	100	354	114	114	114	114	455	455	455	455	455	455	455	455	455	455	455	455
Interest expense	-	(15)	(346)	(351)	(712)	(351)	(351)	(351)	(351)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)	(1,403)
Gain (loss) from change in valuation of common stock warrant liability																					
Loss from impairment of in-process research and development			(4,510)	-	(4,510)																
Other income (expense)	1	(1)	0	(0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Loss from valuation of earn-out milestone liability	(270)	(277)	4,115	63	3,631	3,130	3,130	3,130	3,130	12,520	12,520	12,520	12,520	12,520	12,520	12,520	12,520	12,520	12,520	12,520	12,520
Fair value of warrants issued in connection with amendment						(400)	(400)	(400)	(400)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)	(1,600)
Total other income	(196)	(219)	(634)	(188)	(1,237)	2,493	2,493	2,493	2,493	9,972	9,972	9,972	9,972	9,972	9,972	9,972	9,972	9,972	9,972	9,972	9,972
Pretax Income	(4,477)	(8,231)	(4,656)	(4,939)	(22,302)	(2,367)	(3,168)	(3,168)	(3,843)	(12,546)	(13,803)	(4,886)	(5,629)	12,927	14,512	37,029	41,621	70,370	98,405	126,324	152,873
Income Tax Benefit (Provision)					10,419									-	726	3,703	6,243	14,074	24,601	32,844	41,276
Tax Rate														0%	5%	10%	15%	20%	25%	26%	27%
GAAP Net Income (loss)	(4,477)	(8,231)	(4,656)	(4,939)	(11,883)	(2,367)	(3,168)	(3,168)	(3,843)	(12,546)	(13,803)	(4,886)	(5,629)	12,927	13,787	33,326	35,378	56,296	73,804	93,480	111,597
Deemed dividend related to warrant modification																					
Net Income attributable to common shareholders(loss)					(11,883)																
Basic and Diluted	0.25	(0.46)	(0.26)	(0.21)	(0.68)	(0.12)															
GAAP-EPS	(0.25)	(0.46)	(0.26)	(0.28)	(0.68)	(0.12)	(0.16)	(0.16)	(0.20)	(0.65)	(0.31)	(0.07)	(0.08)	0.2	0.2	0.5	0.5	0.8	1.0	1.3	1.5
GAAP EPS (dil)						(0.12)	(0.16)	(0.16)	(0.20)	(0.65)	(0.31)	(0.07)	(0.08)	0.2	0.2	0.5	0.5	0.8	1.0	1.3	1.5
Wgtd Avg Shrs (Bas) - '000s	17,684	17,743	17,801	17,801	17,583	19,105	19,296	19,489	19,684	19,393	44,479	69,628	69,802	69,977	70,152	70,328	70,504	70,680	70,857	71,034	71,212
Wgtd Avg Shrs (Dil) - '000s					17,583	19,105	19,296	19,489	19,684	19,393	44,479	69,628	69,802	69,977	70,152	70,328	70,504	70,680	70,857	71,034	71,212

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

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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	42	84%	13	31%
Market Perform (Neutral)	8	16%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	50	100%	13	26%

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