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## Cel-Sci (NYSE American/CVM)

**Neutral**      **Multikine Phase 3 nearing 3-Year Milestone**

*Cel-Sci engages in the research and development of drugs and vaccines*

### Investment Highlights

1) Cel-Sci is approaching a milestone in September of this year in its pivotal Phase 3 trial for immunotherapy Multikine (Leukocyte Interleukin, Injection) in head and neck cancer, when at least three years have elapsed for all 928 patients enrolled in the trial. The three-year milestone corresponds with the study protocol, which assumed an overall survival rate of about 55% at 3 years for the Standard of Care (SOC) treatment group alone. The logic behind this assumption was recently confirmed and strengthened via an article published in the *European Journal of Otolaryngology* which displayed similar patient survival curves as those used in the Multikine Phase 3 study protocol. Most recently, in late March, the Company announced that the Independent Data Monitoring Committee (IDMC) for the Phase 3 study had completed its recent review of the study data and recommended to continue the trial until the appropriate number of events (298 deaths) have occurred. The trial's endpoint remains a 10% increase in overall survival in the Multikine regimen treated group versus SOC, or surgery, followed by radiation therapy alone or radio-chemotherapy, which can only be determined when a total of 298 deaths have occurred. The Company is continuing to monitor the enrolled patients for protocol-specific outcomes, and working with its international partners: Teva (TEVA, Not Rated) of Israel and Orient Europharma, based in Taiwan.

2) The Company also continues its work on its LEAPS technology platform, with the most recent development in this program being selected by the US National Institutes of Health (NIH) for sponsorship to exhibit and showcase the LEAPS technology at the BIO International Convention to be held June 3-6, 2019 in Philadelphia. Cel-Sci's product candidate employing the LEAPS technology, CEL-4000, is currently being developed as a therapeutic vaccine for rheumatoid arthritis under a \$1.5 million grant from the NIH and will be featured at the convention's Innovation Zone. After completion of preclinical and Investigational New Drug (IND)-enabling studies the Company intends to file an IND application with the US FDA for CEL-4000.

**Current Price**      **\$6.53**

**Price Target**      **N/A**

Estimates	F2017A	F2018A	F2019E
Revenues(\$000s)	\$69	\$477	\$500
EPS	(\$1.83)	(\$1.87)	(\$0.58)
(FYE September)			
<b>Stock Data</b>			
52-Week Range			\$0.82-\$7.50
Shares Outstanding (mil)			33.0
Market Capitalization (\$mill)			\$215.7
Enterprise Value (\$mill)			\$209.9
Debt to Capital (12/18)			N/A
Book Value/Share (12/18)			\$0.08
Price/Book			N/A
Average Trading Volume (3-Month)			626,000
Insider Ownership			5.4%
Institutional Ownership			8.7%
Short interest			1,960,000
Dividend / Yield			\$0.00/0.0%



**Price target and ratings changes over the past 3 yrs:**  
Initiated - March 2, 2015 - Buy - Price Target \$75 (\$3 Pre-split)  
Updated - Rating Suspended - August 31, 2016 (Different Analyst)  
Updated - October 12, 2017 - Rating re-established at Neutral

**3) In its most recent quarterly earnings filing for Q1/2019 (ending December 2018), Cel-Sci reported grant revenue of \$126,000, operating expenses of \$5.2 million, comprised of R&D expenses of \$3.1 million and General & Administrative costs of \$2.0 million, and net income of \$1.2 million or \$0.02 per fully diluted share, after other gains and charges.** Operating cash burn was approximately \$4.2 million for Cel-Sci during the first quarter, and at the end of the period the Company had about \$6.7 million in cash on its balance sheets. The Company has been able to obtain cash from warrant exercises subsequent to quarter-end, and may continue to do so as this year progresses, allowing for current financial resources to stretch throughout fiscal 2019, at the least. While Company management has not provided specific financial guidance for this year, we are using the most recent quarterly results to project a net loss of \$20.1 million or (\$0.58) per share for Cel-Sci for fiscal 2019E (ending September), which could be significantly different if the Company is able to conclude its Phase 3 Multikine trial before the end of the fiscal year, although work would then still need to be done to complete a final drug approval application with the FDA.

## Conclusion/Stock Valuation

We are maintaining our Neutral rating on CVM shares at this time until a more definite timeline on major catalysts, particularly the conclusion of the Multikine trial, can be ascertained. However, average valuations for companies with late-stage oncology pipeline programs are in many cases still considerably higher than that of CVM, even with share price appreciation this year for these shares. For example, there have been a number of buy-outs for public and private oncology biotechnology companies over the past two years (LOXO Oncology, Juno Therapeutics, Kite Pharma, Impact Biomedicines, Bioverativ, and TESARO) with valuations well over \$1 billion, well over the Company's current market capitalization of approximately \$210 million, although this valuation is more in line with a comparable group of currently trading oncology biotechs. (For complete stock valuation methodology please refer to our Initiation Report dated March 2, 2015)

## Risk Factors

**In addition to normal economic and market risk factors that impact most equities and the common risks shared by Cel-Sci with other companies in the industry, we believe an investment in CVM involves the following risks:**

- **FDA and regulatory risks** – Cel-Sci is subject to regulatory review for its ongoing research and development activities, principally the US Food and Drug Administration's IND application process but also other international regulatory agencies. In addition, the Company's pharmaceutical facilities and laboratories are subject to ongoing oversight and regulation, and any negative correspondence from the FDA could have an adverse effect on the ongoing operations of the Company.
- **Lack of historic profitability** – Cel-Sci has not achieved operating profitability on an annual basis for several years, and according to our forecasts is not expected to do so in the near future. Although the Company maintains adequate cash reserves at the present time, the Company will need to raise additional working capital in the future as these operating losses continue.
- **Limited stock liquidity** – Trading volume in CVM stock is comparatively light and these shares have a relatively limited history of trading on major US stock exchanges compared with other biotechnology stocks. As such, news regarding CVM, its target market, partners and/or competitors could lead to significant volatility in the stock price.
- **Need to defend patents and other intellectual property** – Cel-Sci currently holds a number of US patents on its therapeutics and technologies. The Company may be required to defend its patents in the US and overseas in the future, and there can be no assurance these defenses will be successful.

- **Competitive Markets** – The Company may compete with a number of other pharmaceutical companies in its targeted oncology markets, some of which represent much larger companies. There can be no assurance that the Company will be able to successfully launch its products into these competitive markets in the future.

**CEL-SCI Corporation**  
**Consolidated Statements of Income**  
 (in \$000s, except EPS)

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Fiscal Year Ending September	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019E
<b>Revenues</b>										
Grant income and other	\$153.3	\$956.2	\$254.6	\$159.6	\$264.0	\$657.4	\$285.1	\$69.0	\$476.6	\$500.0
Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Milestone payments and license fees	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total revenues</b>	<b>153.3</b>	<b>956.2</b>	<b>254.6</b>	<b>159.6</b>	<b>264.0</b>	<b>657.4</b>	<b>285.1</b>	<b>69.0</b>	<b>476.6</b>	<b>500.0</b>
<b>Expenses</b>										
Research and development	11,911.6	11,745.6	10,368.7	12,681.0	17,000.1	20,949.2	19,351.8	15,607.0	9,400.3	12,500.0
Depreciation and amortization	516.1	531.3	533.5	364.1	231.8	206.8	150.2	630.0	650.1	700.0
General and administrative	6,285.8	6,664.9	6,595.3	6,982.7	10,606.2	13,798.0	6,336.3	5,170.3	7,198.4	7,500.0
<b>Total operating expenses</b>	<b>18,713.6</b>	<b>18,941.8</b>	<b>17,497.5</b>	<b>20,027.9</b>	<b>27,838.1</b>	<b>34,953.9</b>	<b>25,838.3</b>	<b>21,407.3</b>	<b>17,248.8</b>	<b>20,700.0</b>
Loss from operations	(18,560.3)	(17,985.7)	(17,242.8)	(19,868.3)	(27,574.1)	(34,296.5)	(25,553.2)	(21,338.3)	(16,772.2)	(20,200.0)
Interest expense, net	199.9	(158.8)	(146.2)	(53.3)	(40.9)	(19.4)	73.0	(4,032.2)	(6,492.3)	(2,000.0)
Other expense, net	28,843.8	(7,567.9)	1,911.7	10,750.7	248.8	(358.7)	0.0	0.0	70.9	100.0
Net income (loss)	10,483.4	(25,712.3)	(15,477.3)	(9,170.9)	(27,366.3)	(34,674.6)	(25,480.2)	(25,370.5)	(23,193.6)	(22,100.0)
Warrant-related expenses	(1,532.5)	(1,068.4)	(2,168.6)	(59.5)	(1,117.4)	0.0	14,013.7	10,943.4	(8,657.9)	2,000.0
Net income available to common shareholders	8,951.0	(26,780.7)	(17,645.9)	(9,230.5)	(28,483.7)	(34,674.6)	(11,466.5)	(14,427.1)	(31,851.6)	(20,100.0)
<b>Basic income (loss) per share</b>										
Basic income (loss) per share	\$11.07	(\$32.11)	(\$17.52)	(\$7.62)	(\$12.11)	(\$10.51)	(\$2.36)	(\$1.83)	(\$1.87)	(\$0.61)
<b>Diluted income (loss) per share</b>										
Diluted income (loss) per share	(\$0.55)	(\$37.43)	(\$19.41)	(\$16.50)	(\$12.22)	(\$10.40)	(\$2.36)	(\$1.83)	(\$1.87)	(\$0.58)
<b>Basic shares outstanding</b>										
Basic shares outstanding	808.4	834.0	1,007.3	1,211.2	2,352.2	3,300.8	4,866.2	7,902.6	17,004.7	33,030.0
<b>Diluted shares outstanding</b>										
Diluted shares outstanding	808.4	834.0	1,007.3	1,211.2	2,352.2	3,300.8	4,866.2	7,902.6	17,004.7	35,030.0
<b>Key ratios:</b>										
Non-cash items	(\$26,795.2)	\$9,167.5	\$790.4	(\$10,327.0)	\$5,100.4	\$6,100.0	\$8,100.0	\$4,100.0	\$10,000.0	\$10,000.0
Cash Flow/share	(\$22.07)	(\$21.12)	(\$16.73)	(\$16.15)	(\$11.64)	(\$4.37)	(\$2.27)	(\$2.04)	(\$0.36)	(\$0.13)

**Balance Sheets**

(\$000s)

Assets:	9/30/18	12/31/18
Cash and equivalents	\$10,310.0	\$6,682.2
Receivables	118.7	128.8
Prepaid expenses	364.6	433.8
Inventory	645.2	682.5
<b>Total current</b>	<b>11,438.6</b>	<b>7,927.3</b>
Property & equip., net	16,218.9	16,082.1
Patent costs, net	258.1	252.9
Deposits	1,670.9	1,670.9
<b>TOTAL ASSETS</b>	<b>29,586.4</b>	<b>25,933.2</b>
<b>Liabilities:</b>		
Accounts payable	\$5,743.9	\$4,903.2
Accrued expenses & due to employees	205.3	77.7
Due to employees	764.9	896.8
Derivative instruments & other current	2,512.6	13.8
<b>Total current</b>	<b>9,226.8</b>	<b>5,891.5</b>
Other non-current liabilities	20,358.7	17,333.9
Stockholders' equity	0.9	2,707.9
<b>TOTAL LIAB &amp; EQ</b>	<b>29,586.4</b>	<b>25,933.2</b>

Source: Dawson James Securities, Inc. estimates; Company documents

**Important Disclosures:**

**Price Chart:**



Price target and ratings changes over the past 3 years:

Initiated – March 2, 2015 – Buy – Price Target \$75 (\$3 pre-split)  
 Updated – Rating Suspended – August 31, 2016 (Different Analyst)  
 Updated – October 12, 2017 – Rating re-established at Neutral

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- 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)	37	86%	10	27%
Market Perform (Neutral)	6	14%	0	0%
Market Underperform (Sell)	0	0%	0	0%
<b>Total</b>	<b>43</b>	<b>100%</b>	<b>10</b>	<b>23%</b>

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