

## CEL-SCI Corporation (CVM - \$ 0.92)

### First Patient Enters Phase I Clinical Trial for Treatment of Anal Warts

This morning, CEL-SCI announced that the first volunteer patient has been enrolled and administered Multikine in a Phase I trial evaluating peri-anal wart immunotherapy in HIV/HPV co-infected men and women. This is the third indication for which Multikine is being evaluated as a potential immunotherapy.

- First Patient Enrolled and Administered Multikine.** The first volunteer patient has been enrolled and administered Multikine (Leukocyte Interleukin, Injection) in a Phase I trial evaluating peri-anal wart immunotherapy in HIV/HPV co-infected men and women at the Naval Medical Center San Diego (NMCS D). The purpose of this dose escalation study is to evaluate the safety and impact of Multikine as a treatment of Human Papilloma Virus (HPV) associated peri-anal warts and assess the effect on anal intraepithelial dysplasia in HIV/HPV co-infected men and women. The study is being conducted through a Cooperative Research and Development Agreement (CRADA) between CEL-SCI and NMCS D. The Navy will incur most of the costs of this study. CEL-SCI is contributing doses of Multikine and will have the right to exclusively license a new technology developed from the collaboration. The study will enroll up to 15 patients. We expect data to be available from this study in 1H15.
- Additional Indications.** Multikine is being studied in an on-going Phase III trial for head and neck cancer and the company is exploring the treatment of cervical dysplasia in HIV/HPV co-infected women. All three indications represent critical unmet medical needs and we believe any success in treating these diseases with Multikine could translate into significant market opportunities. Ergomed, a CRO working with CEL-SCI on the Phase III trial, is going to conduct a Phase II trial to treat cervical dysplasia in HIV/HPV infected patients and it will assume 50% (up to \$3 million) of the clinical and regulatory costs. We do not expect this trial will start until the Phase I anal warts study is complete.
- Phase III Trial Continues Steady Enrollment.** The company's on-going Phase III trial of Multikine for the treatment of head and neck cancer reached 252 patients or 28.6% enrollment after adding 20 patients in August, an impressive number in our opinion as summer months generally have a slower rate of enrollment for clinical trials. The company expects to enroll 880 total patients by the end of 2015. The consistent increase in enrollment is encouraging and we expect the on-boarding of new clinical sites to accelerate the total patients added each month in the near-term as the company continues to announce new sites.
- Maintain BUY Rating and \$7 Price Target.** Our target is based on the NPV of our probability-adjusted forecasts for Multikine.

#### Earnings Estimates: (per share)

(Sept.)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY_16E</b>	NA	NA	NA	NA	-0.21	NM
<b>FY_15E</b>	NA	NA	NA	NA	-0.45	NM
<b>FY_14E</b>	-0.15A	-0.11A	-0.11A	-0.10	-0.45	NM
<b>FY_13A</b>	-0.18	-0.14	-0.18	-0.17	-0.66	NM

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker: **CVM**  
 Rating: **Buy**  
 Price Target: **\$ 7.00**

#### Trading Data:

Last Price (09/29/2014)	\$ 0.92
52-Week High (3/21/2014)	\$ 1.90
52-Week Low (12/19/2013)	\$ 0.53
Market Cap. (MM)	\$ 73
Shares Out. (MM)	80

#### Edward White

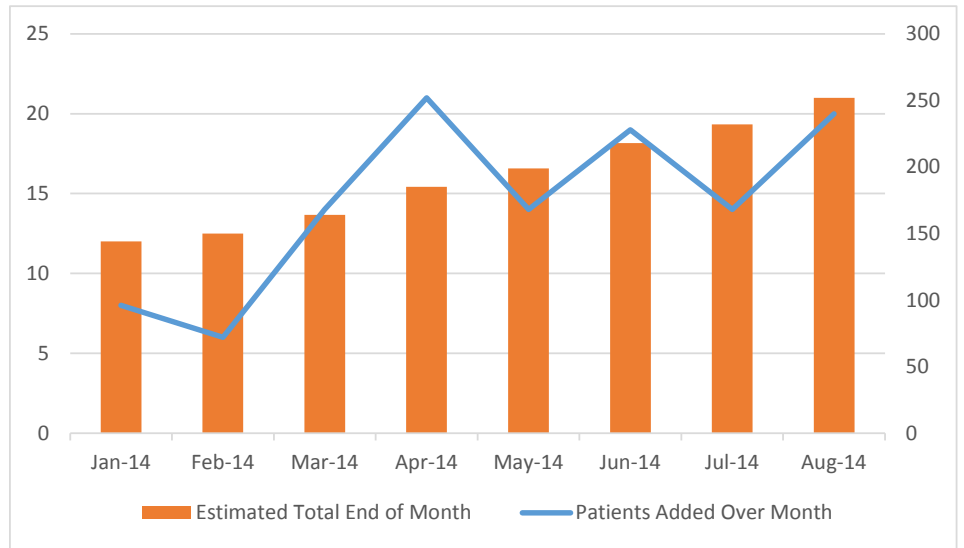
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Figure 1: Multikine Phase III Patient Enrollment



Source: Company reports; Laidlaw & Company estimates

## Risks to Owning the Stock

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There are many standard risks for development stage biotechnology companies that hold true for the entire industry. There are development risks associated with preclinical and clinical studies, and potential delays in the start of trials. There is regulatory risk that the company will be unable to receive regulatory approvals for drugs or that regulatory approval may be delayed. Manufacturing risks are associated with the upgrading of facilities from clinical study production to commercial production. There is also commercial risk for a company to successfully market and sell its drug or drugs. Other risks include financing risk, currency risk, potential governmental price controls, and IP (generic) risks. The stock of biotechnology companies, like all publically traded companies, is subject to market volatility and liquidity risks if there are small trading floats. CEL-SCI is susceptible to all of these risks.

Other downside risks specific to CEL-SCI include the likelihood of the need to sell more stock to raise capital for the continuation for the Multikine Phase III trial, the timing of Multikine regulatory submission and approval, and the ultimate market potential and expectations for Multikine.

We note that this recommendation is speculative in nature due to the company's market cap, cash position and our opinion that the large majority of the value of the stock is hinged on a binary event, the approval of Multikine for the treatment of head and neck cancer.

Figure 1: Income Statement

CEL-SCI Corp. <i>Income Statement (millions, except per share data)</i>	FY 2013				FY 2014E				FY_11 Sept	FY_12 Sept	FY_13 Sept	FY_14E Sept	FY_15E Sept	FY_16E Sept
	Q1_13 Dec	Q2_13 Mar	Q3_13 Jun	Q4_13 Sept	Q1_14 Dec	Q2_14 Mar	Q3_14 Jun	Q4_14E Sept						
Product Sales, net	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant Income and Other Revenue	0.02	0.02	0.11	0.02	0.11	0.07	0.02	0.02	0.96	0.25	0.16	0.22	0.22	0.22
<b>Revenue</b>	<b>0.02</b>	<b>0.02</b>	<b>0.11</b>	<b>0.02</b>	<b>0.11</b>	<b>0.07</b>	<b>0.02</b>	<b>0.02</b>	<b>0.96</b>	<b>0.25</b>	<b>0.16</b>	<b>0.22</b>	<b>0.22</b>	<b>0.22</b>
<b>Cost of sales</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Gross Profit</b>	<b>0.02</b>	<b>0.02</b>	<b>0.11</b>	<b>0.02</b>	<b>0.11</b>	<b>0.07</b>	<b>0.02</b>	<b>0.02</b>	<b>0.96</b>	<b>0.25</b>	<b>0.16</b>	<b>0.22</b>	<b>0.22</b>	<b>0.22</b>
<i>Operating expenses:</i>														
Selling, general and administrative	2.00	1.65	1.78	1.55	1.97	2.09	2.40	1.66	6.66	6.60	6.98	8.12	8.63	8.84
Research and development	2.92	2.52	3.77	3.47	4.02	4.15	4.45	4.99	11.75	10.37	12.68	17.62	20.70	6.48
Depreciation and amortization	0.13	0.09	0.08	0.06	0.06	0.05	0.07	0.07	0.53	0.53	0.36	0.24	0.24	0.24
<b>Total Operating Expenses</b>	<b>5.06</b>	<b>4.26</b>	<b>5.63</b>	<b>5.09</b>	<b>6.05</b>	<b>6.29</b>	<b>6.92</b>	<b>6.72</b>	<b>18.94</b>	<b>17.50</b>	<b>20.0</b>	<b>25.98</b>	<b>29.57</b>	<b>15.56</b>
<b>Total Operating Expenses (non-GAAP)</b>	<b>5.06</b>	<b>4.26</b>	<b>5.63</b>	<b>5.09</b>	<b>6.05</b>	<b>6.29</b>	<b>6.92</b>	<b>6.72</b>	<b>18.94</b>	<b>17.50</b>	<b>20.03</b>	<b>25.98</b>	<b>29.57</b>	<b>15.56</b>
<b>Operating Income/(loss)</b>	<b>(5.04)</b>	<b>(4.24)</b>	<b>(5.51)</b>	<b>(5.07)</b>	<b>(5.93)</b>	<b>(6.23)</b>	<b>(6.90)</b>	<b>(6.70)</b>	<b>(17.99)</b>	<b>(17.24)</b>	<b>(19.87)</b>	<b>(25.76)</b>	<b>(29.35)</b>	<b>(15.34)</b>
<b>Operating Income/(loss) non-GAAP</b>	<b>(5.04)</b>	<b>(4.24)</b>	<b>(5.51)</b>	<b>(5.07)</b>	<b>(5.93)</b>	<b>(6.23)</b>	<b>(6.90)</b>	<b>(6.70)</b>	<b>(17.99)</b>	<b>(17.24)</b>	<b>(19.87)</b>	<b>(25.76)</b>	<b>(29.35)</b>	<b>(15.34)</b>
<i>Other Income:</i>														
Gain on derivative instruments	2.75	3.54	1.08	3.39	1.61	(7.13)	4.47	0.00	4.43	1.91	10.75	(1.05)	0.00	0.00
Interest income	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.16	0.12	0.12	0.12	0.12	0.12
Interest expense	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)	(0.04)	(0.32)	(0.26)	(0.17)	(0.16)	(0.16)	(0.16)
Other expenses	0.00	0.00	0.00	0.00	(1.12)	0.00	0.00	0.00	(12.00)	0.00	0.00	(1.12)	0.00	0.00
<b>Income (loss) before provision for income taxes (GAAP)</b>	<b>(2.31)</b>	<b>(0.71)</b>	<b>(4.45)</b>	<b>(1.70)</b>	<b>(5.45)</b>	<b>(13.37)</b>	<b>(2.44)</b>	<b>(6.71)</b>	<b>(25.71)</b>	<b>(15.48)</b>	<b>(9.17)</b>	<b>(27.97)</b>	<b>(29.39)</b>	<b>(15.38)</b>
<b>Income (loss) before provision for income taxes (non-GAAP)</b>	<b>(5.06)</b>	<b>(4.25)</b>	<b>(5.53)</b>	<b>(5.09)</b>	<b>(7.06)</b>	<b>(6.23)</b>	<b>(6.91)</b>	<b>(6.71)</b>	<b>(30.14)</b>	<b>(17.39)</b>	<b>(19.92)</b>	<b>(26.92)</b>	<b>(29.39)</b>	<b>(15.38)</b>
<i>Tax: (%) non-GAAP</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>
<b>Income tax provision GAAP</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) GAAP	(2.31)	(0.71)	(4.45)	(1.70)	(5.45)	(13.37)	(2.44)	(6.71)	(25.71)	(15.48)	(9.17)	(27.97)	(29.39)	(15.38)
Net income (loss) non-GAAP	(5.06)	(4.25)	(5.53)	(5.09)	(7.06)	(6.23)	(6.91)	(6.71)	(30.14)	(17.39)	(19.92)	(26.92)	(29.39)	(15.38)
Modifications of Warrants/Inducement Warrants	0.0	0.0	(0.1)	0.0	0.00	0.00	0.00	0.00	(1.07)	(2.17)	(0.06)	0.00	0.00	0.00
Net income (loss) available to common shareholders GAAP	(2.31)	(0.71)	(4.51)	(1.70)	(5.45)	(13.37)	(2.44)	(6.71)	(26.78)	(17.65)	(9.23)	(27.97)	(29.39)	(15.38)
Net income (loss) available to common shareholders non-GAAP	(5.06)	(4.25)	(5.59)	(5.09)	(7.06)	(6.23)	(6.91)	(6.71)	(31.21)	(19.56)	(19.98)	(26.92)	(29.39)	(15.38)
<b>Diluted EPS (GAAP)</b>	<b>(0.08)</b>	<b>(0.02)</b>	<b>(0.15)</b>	<b>(0.06)</b>	<b>(0.11)</b>	<b>(0.24)</b>	<b>(0.04)</b>	<b>(0.10)</b>	<b>(1.28)</b>	<b>(0.70)</b>	<b>(0.30)</b>	<b>(0.47)</b>	<b>(0.45)</b>	<b>(0.21)</b>
<b>Diluted EPS (non-GAAP)</b>	<b>(0.18)</b>	<b>(0.14)</b>	<b>(0.18)</b>	<b>(0.17)</b>	<b>(0.15)</b>	<b>(0.11)</b>	<b>(0.11)</b>	<b>(0.10)</b>	<b>(1.50)</b>	<b>(0.78)</b>	<b>(0.66)</b>	<b>(0.45)</b>	<b>(0.45)</b>	<b>(0.21)</b>
Weighted Diluted Shares outstanding (000s)	28.3	30.9	30.9	30.3	48.2	56.2	64.7	69.2	20.8	25.2	30.3	59.6	66.0	72.3
Weighted Diluted Shares outstanding YOY change (%)	23.9%	24.9%	19.7%	10.9%	70.3%	82.0%	109.1%	128.4%	-57.9%	20.8%	20.2%	96.7%	10.8%	9.4%

Source: Bloomberg LP; Company reports; Laidlaw &amp; Company estimates

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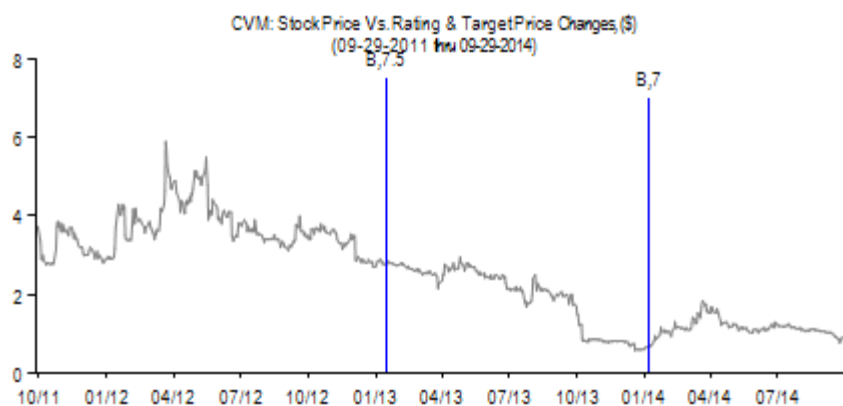
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### Rating and Price Target Change History



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
01/15/2013	Buy (B)	2.82

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
01/15/2013	7.50**	2.82
01/06/2014	7.00	0.69

\*\* Split Adjusted

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	95.00%	30.00%	10.00%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	5.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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