

## CEL-SCI Corporation (CVM - \$ 1.12)

### First U.S. Clinical Site Opens for Phase III Head & Neck Study

On March 4, 2014 CVM announced its first U.S. Phase III Multikine trial at 21<sup>st</sup> Century Oncology in Greenville, NC. Management now expects to reach 10 – 15 U.S. sites by mid-2014.

- First U.S. Clinical Trial Center.** CEL-SCI announced that it has activated its first U.S. clinical trial center for the Phase III study of Multikine in patients with head and neck cancer at 21<sup>st</sup> Century Oncology in Greenville, NC. 21<sup>st</sup> Century is a provider of integrated cancer care services with 133 centers in 16 states. CEL-SCI projects it will reach 10 - 15 U.S. trial centers by the summer of 2014. This announcement follows an enrollment update for the Phase III trial, which has reached 146 patients with 84 patients dosed in 44 centers. Prior reported enrollment was 117 patients in 39 centers in April 2013. Enrollment was exceedingly slow, in our opinion, with the company's former Clinical Research Organization (CRO), which it replaced with two new CROs in 2013. CEL-SCI, along with its current CROs, Ergomed and Aptiv Solutions, continues to add clinical sites in order to accelerate patient enrollment. CEL-SCI projects the Phase III study will reach the full enrollment of 880 patients by the end of 2015.
- Other Indications.** In addition to the ongoing Phase III head and neck cancer study, CEL-SCI is exploring two other indications for Multikine including cervical dysplasia in HIV/HPV co-infected women and peri-anal warts in HIV/HPV co-infected patients. These indications both represent critical unmet medical needs and we believe any success in treating these diseases with Multikine could translate into significant market opportunities. Of note, the perianal warts study is being run with the U.S. Navy, which will incur most of the costs of the study. The Naval Medical Center San Diego has approved the start of a Phase I dose escalation study and we expect the first patient to be enrolled in the near-term. The company projects Phase I data will be available by the end of 2014. Ergomed has also signed a co-development agreement to work on this indication in support of the Navy, if required, and it will also assume 50% (up to \$3 million) of the clinical and regulatory costs. Ergomed 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. This study is expected to begin following the completion of the Phase I peri-anal warts trial.
- Maintain BUY Rating and Price Target.** We are maintaining our BUY rating and long term price target of \$7.00. Our target is based on the NPV of our probability-adjusted forecasts for Multikine and a small value for the company's manufacturing plant.

#### Earnings Estimates: (per share)

(Sept.)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY_15E</b>	NA	NA	NA	NA	-0.49	NM
<b>FY_14E</b>	-0.09A	-0.12	-0.13	-0.13	-0.47	NM
<b>FY_13A</b>	-0.08	-0.02	-0.15	-0.06	-0.30	NM
<b>FY_12A</b>	-0.18	-0.41	-0.03	-0.09	-0.70	NM

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker:	<b>CVM</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 7.00</b>

#### Trading Data:

Last Price (03/04/2014)	\$ 1.12
52-Week High (4/25/2013)	\$ 3.09
52-Week Low (12/19/2013)	\$ 0.53
Market Cap. (MM)	\$ 63
Shares Out. (MM)	56

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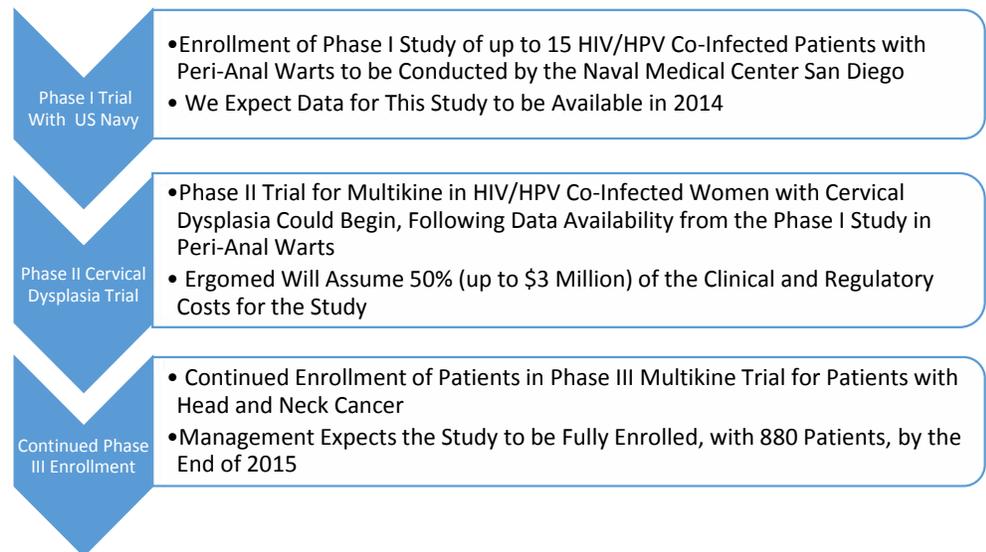
**Figure 1: Multikine Phase III Trial Clinical Center Updates**

CEL-SCI's lead investigational therapy, Multikine, is currently enrolling patients for a Phase III clinical trial in advanced primary head and neck cancer. As of February 2014, the study has enrolled 146 patients with an estimated 84 patients dosed with Multikine in 44 Centers. The company expects to reach full enrollment of 880 patients by 2015 as approved centers finalize logistics and approximately 50-60 centers are added worldwide. The following is a summary of recent clinical center announcements:

March 4 2014	First U.S. clinical site announced at 21st Century Oncology in Greenville, North Carolina. Management expects to reach 10 - 15 U.S. clinical centers by mid-2014.
January 23 2014	Serbia becomes the 11th country providing approval to participate in the Phase III Mutlikine trial. Management projects 72 of the worldwide total of 880 patients for the study could be enrolled in Serbia.
December 05 2013	Bosnia and Herzegovina, the 10th and 11th countries in which the Phase III trial received approval, marked expansion into one-half of the target 20 countries conducting the trial. CVM expects to enroll approximately 30 patients in Bosnia and Herzegovina through 3 clinical centers.
November 20 2013	North American meeting including 14 US and Canadian clinical center participants held. Focus, as at the earlier European meeting, was on the critical discussion of protocols, regulatory issues, enrollment criteria, study procedures and safety issues.
November 12 2013	Croatian Republic approves enrollment of patients in Phase III trial, becomes the 9th country into which CVM expects to enroll approximately 40 patients in Croatia through 4 clinical centers.
October 21 2013	Successful clinical investigator meeting held in Europe. CVM will continue to have a focus on European expansion. The Phase III trial will be conducted at 56 clinical centers in 13 European Countries.
February 25 2013	Taiwanese partner, Orient Europharma, announces 2 new centers: China Medical University Hospital which is located in Taichung, Taiwan, and the the Buddhist Tzu Chi General Hospital which is located in Hualian, Taiwan.

Source: Company reports

**Figure 2: Upcoming Expected Catalysts**



Source: Company reports

## 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.

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*Additional information available upon request.*

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### RATINGS INFORMATION

#### 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.	84.62%	30.77%	15.38%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	7.69%	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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