

CEL-SCI Corporation (CVM - \$ 1.24)

CEL-SCI Announces Agreement with U.S. Navy for Multikine Phase I Trial

Today, CEL-SCI announced that it has signed an agreement with the Naval Medical Center, San Diego, under which, it will conduct a Phase I dose escalation study of CEL-SCI's investigational immunotherapy Multikine in HIV/HPV co-infected men and women with peri-anal warts. Multikine is currently in a Phase III clinical trial as a potential first-line treatment for advanced primary head and neck cancer.

Navy Agreement. The US Naval Medical Center, San Diego will conduct a Human Subjects Institutional Review Board approved Phase I dose escalation study of CEL-SCI's Multikine in HIV/HPV co-infected men and women with peri-anal warts. This indication is large unmet medical need. CEL-SCI will contribute Multikine and will retain all rights to any currently owned technology and will have the right to exclusively license any new technology developed from the collaboration. The purpose of this dose escalation study is to evaluate the safety and clinical impact of Multikine as a treatment of peri-anal warts and assess the effect on anal intraepithelial dysplasia (AIN) in HIV/HPV co-infected men and women. Five participants will be treated with Multikine injections around the peri-anal warts at the lower dose for 5 days/week for 2 weeks, off 2 weeks, then 5 days per week for two more 2 weeks. If no serious adverse events are noted, 10 more patients will receive the higher dose of Multikine in the same manner.

More Near-term Catalysts. The initiation of the Phase I trial for HIV/HPV co-infected patients with peri-anal warts will give CEL-SCI more near-term catalysts while we still wait for the primary driver for the valuation of the stock, the Phase III study in front-line head and neck cancer. While there will be no new data out from the Phase III Multikine trial for several years, the company did take action in April to speed the time of the trial when it fired its CRO and hired two new companies to run the trial, one of which has made a \$10 million co-development deal with CEL-SCI. CEL-SCI is adding over 40 clinical centers around the world, more than doubling the number of clinical trial sites that will enroll patients in the Phase III study. We continue to expect that Multikine, if approved by the FDA, could reach the market in the 2018 - 2020 timeframe. The size and the ultimate design of future trials for HIV/HPV patients with peri-anal warts could enable Multikine for this indication to reach the market first. We believe today's announcement is positive for the stock as CEL-SCI now has multiple and earlier chances for success in bringing Multikine to market.

Maintaining Buy-rating and Price Target. While there will be no new data out from the Phase III Multikine trial in head and neck cancer for several years, we expect nearer-term news flow to come from the new potential indication. Our 12-month price target for CEL-SCI is \$7.50, which 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
FY_15E	NA	NA	NA	NA	-0.68	NM
FY_14E	-0.18	-0.19	-0.19	-0.17	-0.72	NM
FY_13E	-0.08A	-0.02A	-0.15A	-0.17	-0.43	NM
FY_12A	-0.18	-0.41	-0.03	-0.09	-0.70	NM

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker:	CVM
Rating:	Buy
Price Target:	\$ 7.50

Trading Data:

Last Price (10/07/2013)	\$ 1.24
52-Week High (10/8/2012)	\$ 3.89
52-Week Low (10/4/2013)	\$ 1.01
Market Cap. (MM)	\$ 38
Shares Out. (MM)	31

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Phase I Dose Escalation Study for Multikine in HIV/HPV Co-infected Men and Women with Peri-anal Warts

Anal and genital warts are commonly associated with the Human Papilloma Virus (HPV), the most common sexually transmitted disease. Men and women with a history of anogenital warts have a 30 fold increased risk of anal cancer. Persistent HPV infection in the anal region is thought to be responsible for up to 80% of anal cancers. HPV is a significant health problem in the HIV infected population as individuals are living longer as a result of greatly improved HIV medications. The treatment regimen for the study of up to 15 HIV/HPV co-infected patient volunteers with peri-anal warts to be conducted by Naval Medical Center San Diego will be identical to the regimen that was used in the Multikine cervical study in HIV/HPV co-infected patient volunteers. As that cervical study had positive safety data, we have some confidence that this Phase I study will also have a successful safety finding.

The purpose of this dose escalation study is to evaluate the safety and clinical impact of Multikine as a treatment of peri-anal warts and assess the effect on anal intraepithelial dysplasia (AIN) in HIV/HPV co-infected men and women. Anal intraepithelial neoplasia (AIN) is an anal cancer precursor lesion with grades of 1 (low-grade) to 3 (high-grade). At present, AIN has limited effective treatment options and a high recurrence rate. According to a recent study of the efficacy and side-effects of available AIN treatments published in April 2013 in *The Lancet Oncology*, anal cancer incidence is increasing in HIV infected individuals. The study showed progression from high grade AIN to anal cancer was reported to be approximately 15% among HIV positive men who have sex with men (MSM) during median follow up periods of 2 years to 5 years. CEL-SCI estimates the range of prevalence of high-grade AIN in HIV/HPV infected adults in the U.S. to be between 94,594 and 372,086 men and women, with a range of 25% – 52% of those infected being MSM. Current treatment for AIN is electrocautery, imiquimod and/or fluorouracil. Studies have shown that electrocautery is better than imiquimod and fluorouracil in the treatment of AIN, but recurrence rates for all treatments are substantial.

The Naval Medical Center San Diego, a referral center of excellence for HIV/AIDS care of active duty, family members, and retired individuals since the start of the HIV epidemic in the 1980s, has conducted over 30 HIV/AIDS human subjects approved clinical research protocols to advance clinical patient care. The Principle Investigator on this Phase I study is John D. Malone MD, MPH, Infectious Diseases Staff Physician, Naval Medical Center San Diego.

Risks to Owning the Stock

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 2012				FY 2013E				FY 2014E				FY_11 Sept	FY_12 Sept	FY_13E Sept	FY_14E Sept	FY_15E Sept
	Q1_12	Q2_12	Q3_12	Q4_12	Q1_13	Q2_13	Q3_13	Q4_13E	Q1_14E	Q2_14E	Q3_14E	Q4_14E					
	Dec	Mar	Jun	Sept	Dec	Mar	Jun	Sept	Dec	Mar	Jun	Sept					
Product Sales, net	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant Income and Other Revenue	0.01	0.11	0.04	0.11	0.02	0.02	0.11	0.02	0.02	0.02	0.02	0.02	0.96	0.25	0.16	0.07	0.07
Revenue	0.01	0.11	0.04	0.11	0.02	0.02	0.11	0.02	0.02	0.02	0.02	0.02	0.96	0.25	0.16	0.07	0.07
Cost of sales	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	0.01	0.11	0.04	0.11	0.02	0.02	0.11	0.02	0.02	0.02	0.02	0.02	0.96	0.25	0.16	0.07	0.07
<i>Operating expenses:</i>																	
Selling, general and administrative	1.85	1.63	1.67	1.44	2.00	1.65	1.78	1.47	2.05	1.69	1.82	1.51	6.66	6.60	6.90	7.06	7.24
Research and development	2.46	2.59	2.47	2.85	2.92	2.52	3.77	4.07	4.48	4.93	5.07	5.12	11.75	10.37	13.28	19.59	22.13
Depreciation and amortization	0.14	0.14	0.11	0.14	0.13	0.09	0.08	0.08	0.08	0.08	0.08	0.08	0.53	0.53	0.38	0.32	0.32
Total Operating Expenses	4.45	4.37	4.25	4.43	5.06	4.26	5.63	5.62	6.60	6.69	6.96	6.70	18.94	17.50	20.57	26.96	29.69
Total Operating Expenses (non-GAAP)	4.45	4.37	4.25	4.43	5.06	4.26	5.63	5.62	6.60	6.69	6.96	6.70	18.94	17.50	20.57	26.96	29.69
Operating Income/(loss)	(4.44)	(4.26)	(4.21)	(4.32)	(5.04)	(4.24)	(5.51)	(5.60)	(6.59)	(6.68)	(6.94)	(6.68)	(17.99)	(17.24)	(20.40)	(26.89)	(29.62)
Operating Income/(loss) non-GAAP	(4.44)	(4.26)	(4.21)	(4.32)	(5.04)	(4.24)	(5.51)	(5.60)	(6.59)	(6.68)	(6.94)	(6.68)	(17.99)	(17.24)	(20.40)	(26.89)	(29.62)
<i>Other Income:</i>																	
Gain on derivative instruments	0.96	(4.20)	3.39	1.77	2.75	3.54	1.08	0.00	0.00	0.00	0.00	0.00	4.43	1.91	7.36	0.00	0.00
Interest income	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.02	0.03	0.03	0.03	0.02	0.16	0.12	0.11	0.11	0.11
Interest expense	(0.12)	(0.06)	(0.04)	(0.04)	(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)
Other expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	(12.00)	0.00	0.00	0.00	0.00
Income (loss) before provision for income taxes (GAAP)	(3.58)	(8.49)	(0.84)	(2.57)	(2.31)	(0.71)	(4.45)	(5.62)	(6.60)	(6.69)	(6.95)	(6.70)	(25.71)	(15.48)	(13.10)	(26.95)	(29.67)
Income (loss) before provision for income taxes (non-GAAP)	(3.58)	(8.49)	(0.84)	(2.57)	(2.31)	(0.71)	(4.45)	(5.62)	(6.60)	(6.69)	(6.95)	(6.70)	(25.71)	(15.48)	(13.10)	(26.95)	(29.67)
<i>Tax: (%) non-GAAP</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Income tax provision GAAP	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) GAAP	(3.58)	(8.49)	(0.84)	(2.57)	(2.31)	(0.71)	(4.45)	(5.62)	(6.60)	(6.69)	(6.95)	(6.70)	(25.71)	(15.48)	(13.10)	(26.95)	(29.67)
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Modifications of Warrants/Inducement Warrants	(0.6)	(1.6)	0.0	0.0	0.0	0.0	(0.1)	0.0	0.0	0.0	0.0	0.0	(1.07)	(2.17)	(0.06)	0.00	0.00
Net income (loss) available to common shareholders GAAP	(4.16)	(10.09)	(0.84)	(2.57)	(2.31)	(0.71)	(4.51)	(5.62)	(6.60)	(6.69)	(6.95)	(6.70)	(26.78)	(17.65)	(13.16)	(26.95)	(29.67)
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Diluted EPS (GAAP)	(0.18)	(0.41)	(0.03)	(0.09)	(0.08)	(0.02)	(0.15)	(0.17)	(0.18)	(0.19)	(0.19)	(0.17)	(1.28)	(0.70)	(0.43)	(0.72)	(0.68)
Diluted EPS (non-GAAP)	(0.18)	(0.41)	(0.03)	(0.09)	(0.08)	(0.02)	(0.15)	(0.17)	(0.18)	(0.19)	(0.19)	(0.17)	(1.28)	(0.70)	(0.43)	(0.72)	(0.68)
Weighted Diluted Shares outstanding (000s)	22.9	24.7	25.8	27.3	28.3	30.9	30.9	33.5	35.9	35.9	37.4	40.0	20.8	25.2	30.9	37.5	43.4
Weighted Diluted Shares outstanding YOY change (%)	11.4%	19.5%	24.0%	27.9%	23.9%	24.9%	19.7%	22.7%	26.8%	16.1%	20.9%	19.5%	-57.9%	20.8%	22.7%	21.4%	15.6%

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

Figure 2: Balance Sheet

CEL-SCI Corp. <i>Balance Sheet (\$ millions, except per share data)</i>	FY 2012				FY 2013E				FY_10 Sept	FY_11 Sept	FY_12 Sept	FY_13E Sept	FY_14E Sept	FY_15E Sept
	Q1_12 Dec	Q2_12 Mar	Q3_12 Jun	Q4_12 Sept	Q1_13 Dec	Q2_13 Mar	Q3_13 Jun	Q4_13E Sept						
Assets:														
Cash and cash equivalents	3.5	5.3	7.2	3.9	10.7	7.0	3.5	5.8	26.6	4.3	3.9	5.8	1.2	1.7
Receivables	0.0	0.1	0.0	0.2	0.0	0.0	0.2	0.0	-	0.5	0.2	0.0	0.0	0.0
Prepaid expenses	1.8	1.9	1.8	1.3	1.1	1.3	0.8	0.8	0.3	2.0	1.3	0.8	0.8	0.8
Inventories used for R&D and manufacturing	1.4	1.4	1.4	1.4	1.1	1.3	1.1	1.1	1.5	1.6	1.4	1.1	1.1	1.4
Deferred rent- current portion	0.7	0.7	0.7	0.7	0.6	0.6	0.6	0.6	0.8	0.7	0.7	0.6	0.6	0.6
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Current Assets	7.3	9.3	11.0	7.4	13.6	10.2	6.2	8.4	29.1	9.0	7.4	8.4	3.8	4.6
Research and Office equipment and leasehold improvements	0.9	0.8	0.7	0.6	0.6	0.6	0.5	0.4	1.3	1.0	0.6	0.4	0.1	0.1
Patent costs	0.4	0.4	0.4	0.4	0.4	0.3	0.3	0.3	0.4	0.4	0.4	0.3	0.3	0.3
Deferred Rent	6.3	6.2	6.1	5.9	5.8	5.7	5.6	5.5	7.1	6.5	5.9	5.5	5.1	4.7
Deposits	1.7	1.7	1.7	1.7	1.7	1.7	2.1	2.1	-	1.7	1.7	2.1	2.1	2.1
Other assets	-	-	-	-	-	-	-	-	0.0	-	-	-	-	-
Total Assets	16.7	18.4	19.9	16.1	22.0	18.5	14.8	16.7	37.8	18.6	16.1	16.7	11.3	11.7
Liabilities & Shareholders' Equity:														
Accounts payable	0.6	0.7	0.7	0.6	0.4	0.5	1.2	0.2	1.5	0.7	0.6	0.2	0.2	0.2
Accrued expenses	0.2	0.2	0.2	0.2	0.2	0.2	0.6	0.6	0.2	0.3	0.2	0.6	0.6	0.6
Due to employees	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.0	0.0	0.0	0.1	0.1	0.1
Related party loan	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
Deferred rent - current portion	-	0.0	-	0.0	0.0	0.0	0.0	0.0	-	-	0.0	0.0	0.0	0.0
Lease obligations - current portion	-	-	-	-	0.0	0.0	0.0	0.0	-	-	-	0.0	0.0	0.0
Convertible note	3.0	-	-	-	-	-	-	-	-	5.0	-	-	-	-
Derivative instruments - current portion	0.0	-	-	-	-	-	-	-	0.4	0.1	-	-	-	-
Total Current Liabilities	4.9	2.0	2.0	1.9	1.8	1.9	3.0	2.0	3.3	7.2	1.9	2.0	2.0	2.0
Derivative instruments - net of current portino	3.5	10.0	8.8	7.0	8.4	4.9	3.8	3.8	6.5	2.2	7.0	3.8	3.8	3.8
Deferred revenue	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Deposits held	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-	-	0.0	0.0	0.0	0.0
Deferred rent - net of current portion	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Lease obligations - net of current portion	-	-	-	-	0.0	0.0	0.0	0.0	-	-	-	0.0	0.0	0.0
Other long-term obligations	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Liabilities	8.6	12.1	10.9	9.0	10.4	6.9	7.0	6.0	10.0	9.5	9.0	6.0	6.0	6.0
Stockholders' Equity	8.1	6.2	9.0	7.0	11.6	11.5	7.8	10.7	27.9	9.1	7.0	10.7	5.4	5.7
Total Liabilities & Equity	16.7	18.4	19.9	16.1	22.0	18.5	14.8	16.7	37.8	18.6	16.1	16.7	11.3	11.7

Source: Bloomberg LP; Company reports; Laidlaw & Company estimate

Figure 3: Cash flow Statement

CEL-SCI Corp. <i>Non-GAAP Cash Flow Cont. Ops. (\$ millions, except per share data)</i>	FY_10 Sept	FY_11 Sept	FY_12 Sept	FY_13E Sept	FY_14E Sept	FY_15E Sept
Cash flows from operating activities:						
Net income (loss)	10.5	(25.7)	(15.5)	(13.1)	(26.9)	(29.7)
<i>Adjustments to reconcile net income to net cash provided by operating activities:</i>						
Depreciation and amortization	0.5	0.5	0.5	0.4	0.4	0.4
Issuance of convertible notes and preferred stock in legal settlement	1.2	0.2	-	-	-	-
Issuance of common stock, warrants and options for services	-	9.0	0.5	0.4	-	-
Amortization of loan premium	(0.0)	-	-	-	-	-
Extension of options issued to consultants	0.0	0.0	0.1	-	-	-
Extension of options issued to employees	0.2	0.1	0.0	-	-	-
Employee option cost	1.3	1.5	2.2	2.7	2.3	2.3
Common stock contributed to 401 (k) plan	0.1	0.2	0.2	0.1	-	-
Impairment loss on abandonment of patents	0.0	0.0	0.0	0.0	-	-
Loss on retired equipment	0.0	0.0	0.0	0.0	-	-
Deferred rent	(0.0)	(0.0)	-	0.1	0.4	0.4
Gain on derivative instruments	(28.8)	(4.4)	(1.9)	(7.4)	-	-
Other	-	-	-	-	-	-
Changes in assets and liabilities:						
Decrease (increase) in deposits	1.6	(1.7)	-	(0.4)	-	-
Decrease (increase) in receivables	-	(0.5)	0.3	0.1	-	-
Decrease in deferred rent asset	1.0	0.6	0.6	0.5	0.4	0.4
Decrease (increase) in prepaid expenses	(0.3)	(1.7)	0.8	0.5	-	-
Decrease (increase) in inventory for R&D and manufacturing	(1.1)	(0.1)	0.2	0.2	(0.0)	(0.3)
Decrease in accounts payable	0.7	(0.8)	(0.2)	1.5	-	-
(Decrease) increase in accrued expenses	0.1	0.1	(0.1)	0.4	-	-
Increase in deferred revenue	0.1	-	0.0	0.0	-	-
Increase (decrease) in due to employees	(0.0)	(0.0)	(0.0)	0.1	-	-
Increase in deposits held	-	-	0.0	-	-	-
Decrease in deferred rent liability	(0.0)	-	0.0	0.0	-	-
Net cash provided by (used in) operating activities	(12.8)	(22.6)	(12.2)	(13.8)	(23.5)	(26.5)
Operating Cash Flow per share	(\$0.26)	(\$1.08)	(\$0.48)	(\$0.45)	(\$0.63)	(\$0.61)
Cash flow from investing activities:						
Additional investment in manufacturing facility	(0.0)	-	-	-	-	-
Decrease in restricted cash	0.0	0.0	-	-	-	-
Purchases of equipment	(0.5)	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)
Expenditures for patent costs	(0.0)	(0.1)	(0.1)	(0.0)	(0.0)	(0.0)
Cash provided by investing activities	(0.5)	(0.3)	(0.1)	(0.1)	(0.1)	(0.1)
Cash flows from financing activities:						
Proceeds from issuance of common stock	-	3.9	14.3	15.8	19.0	27.0
Payments on obligations under capital leases	-	-	-	(0.0)	(0.0)	(0.0)
Proceeds from exercise of warrants and stock options	6.3	0.7	2.7	-	-	-
Payments for repurchase of preferred stock	-	(4.1)	-	-	-	-
Payments on convertible debt	-	-	(5.0)	-	-	-
Cash (used in) provided by financing activities	6.3	0.6	12.0	15.8	19.0	27.0
Net (decrease) increase in cash and cash equivalents	-	(7.0)	(0.3)	1.9	(4.6)	0.5
Cash and cash equivalents at beginning of the period	-	33.6	4.3	3.9	5.8	1.2
Cash and cash equivalents at end of period	-	26.6	4.3	3.9	1.2	1.7

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

DISCLOSURES:

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Additional information available upon request.

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

** Split Adjusted

Source: Laidlaw & Company

Created by: <http://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
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	85.71%	28.57%	0.00%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	14.29%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

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