

CEL-SCI Corporation (CVM - \$ 0.85)

No Issues with Second Interim Review of Phase III Safety Data

CEL-SCI announced this morning that the second interim review of the safety data from its pivotal Phase III study of Multikine for head and neck cancer raised no safety concerns.

- No Safety Concerns from IDMC on Interim Data.** CEL-SCI announced this morning that the second interim review of the safety data by an Independent Data Monitoring Committee (IDMC) from its pivotal Phase III study of Multikine for head and neck cancer raised no safety concerns. The IDMC recommended that the Phase III study continue unmodified. The IDMC's safety findings from this interim review were similar to those reported by investigators during CEL-SCI's Phase I-II trials. We had not been expecting any safety issues but still view this news as a positive for the company.
- Enrollment Effort Accelerating.** Following the first safety review by the IDMC for this study, CEL-SCI doubled its efforts to expand the study to many more clinical sites in the U.S. and Europe in order to increase the accrual rate. CEL-SCI terminated its CRO, Inventiv Clinical, and in its place hired Aptiv Solutions, a U.S.-based CRO and Ergomed, a European-based CRO, to secure clinical sites and increase the number of subjects accrued to the study. CEL-SCI has three co-development deals with Ergomed for three different indications for Multikine, head & neck cancer, treatment of HIV/HPV co-infected men and women with peri-anal warts, and HIV/HPV co-infected women with cervical dysplasia. CEL-SCI recently filed an arbitration claim against Inventiv alleging: breach of contract, fraud in the inducement, and common law fraud. The company is seeking at least \$50 million in damages. On October 21st, CEL-SCI held an investigator meeting for the European clinical investigators participating in the Multikine Phase III trial. The meeting had 108 participants from 56 clinical centers in 13 countries that are or will be participating in the trial. The investigator meeting for the clinical centers in the U.S. and Canada is scheduled for November 2013.
- 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 indications, HIV/HPV co-infected patients with peri-anal warts and HIV/HPV co-infected women with cervical dysplasia. 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.

Healthcare / Biotechnology

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

Trading Data:

Last Price (11/05/2013)	\$ 0.85
52-Week High (11/7/2012)	\$ 3.80
52-Week Low (10/16/2013)	\$ 0.75
Market Cap. (MM)	\$ 41
Shares Out. (MM)	49

Earnings Estimates: (per share)

(Sept.)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	-0.51	NM
FY_14E	-0.13	-0.13	-0.14	-0.12	-0.52	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

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Source: Laidlaw & Company estimates

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Valuation

Our valuation for CEL-SCI is based on the NPV of our probability-adjusted forecasts for Multikine

Our risk-adjusted mean projections for total sales of Multikine are \$10 million in 2018 growing to \$502 million by 2023

Our 12-month price target for CEL-SCI is \$7.50

Our valuation for CEL-SCI is based on the NPV of our probability-adjusted forecasts for Multikine. We believe that Multikine has substantial blockbuster potential, which is currently undervalued by the market. A substantial majority of the value of CEL-SCI is hinged to the success of Multikine in head and neck cancer. Since the Multikine Phase III trial is an event-driven trial, it is difficult to definitively state when the trial will end and the drug will be submitted to regulatory authorities and approved. We do expect a rolling submission in the U.S. We have run two scenarios for the timing of approval, one of which we assume Multikine will be launched in 2018 and the other in 2020. It is possible that, assuming the drug is approved, that it could be on the market prior to our 2018 assumption. We believe there is a greater than 50% chance that the drug is approved. Our risk-adjusted mean (the mean of our best and worst case expectations) projections for total sales of Multikine are \$10 million in 2018 growing to \$502 million by 2023.

Our 12-month price target for CEL-SCI is \$7.50, which includes our risk-adjusted value for Multikine, a small value for the company's manufacturing plant and no value for the LEAPS program, due to its preclinical status. However, we believe the LEAPS program could potentially have substantial value in the future provided at least one drug candidate enters Phase I studies by the end of 2016. 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 indications, HIV/HPV co-infected patients with peri-anal warts and HIV/HPV co-infected women with cervical dysplasia. With the recent capital raise, we believe the company has enough cash to fund its operations for at least another year. With a market cap of \$41 million, an estimated over \$16 million in cash, a \$25 million manufacturing facility, a product in a large Phase III trial and potentially entering two new indications with faster paths to approval in our opinion, we believe CEL-SCI's stock is under-valued. We note that this recommendation is speculative in nature due to the company's current stock price (under \$1.00 per share) and our opinion that the 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.

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 Dec	Q2_12 Mar	Q3_12 Jun	Q4_12 Sept	Q1_13 Dec	Q2_13 Mar	Q3_13 Jun	Q4_13E Sept	Q1_14E Dec	Q2_14E Mar	Q3_14E Jun	Q4_14E Sept					
Product Sales, net	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant Income and Other	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>	<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>							
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 commonn 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)	(0.13)	(0.13)	(0.14)	(0.12)	(1.28)	(0.70)	(0.43)	(0.52)	(0.51)
Diluted EPS (non-GAAP)	(0.18)	(0.41)	(0.03)	(0.09)	(0.08)	(0.02)	(0.15)	(0.17)	(0.13)	(0.13)	(0.14)	(0.12)	(1.28)	(0.70)	(0.43)	(0.52)	(0.51)
Weighted Diluted Shares outstanding (000s)	22.9	24.7	25.8	27.3	28.3	30.9	30.9	33.5	51.3	51.3	51.3	54.0	20.8	25.2	30.9	52.0	58.0
Weighted Diluted Shares outstanding YOY change (%)	11.4%	19.5%	24.0%	27.9%	23.9%	24.9%	19.7%	22.7%	81.1%	66.0%	65.8%	61.2%	-57.9%	20.8%	22.7%	68.1%	11.6%

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	0.0	26.6	4.3	3.9	0.0	2.4	2.9
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	2.6	29.1	9.0	7.4	2.6	5.0	5.8
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	10.9	37.8	18.6	16.1	10.9	12.5	12.9
Liabilities & Shareholders' Equity:														
Accounts payable	0.6	0.7	0.7	0.6	0.4	0.5	1.2	-	1.5	0.7	0.6	-	-	-
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	1.8	3.3	7.2	1.9	1.8	1.8	1.8
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	5.8	10.0	9.5	9.0	5.8	5.8	5.8
Stockholders' Equity	8.1	6.2	9.0	7.0	11.6	11.5	7.8	5.2	27.9	9.1	7.0	5.2	6.8	7.1
Total Liabilities & Equity	16.7	18.4	19.9	16.1	22.0	18.5	14.8	10.9	37.8	18.6	16.1	10.9	12.5	12.9

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)	1.7	-	-
(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)	(13.6)	(23.5)	(26.5)
Operating Cash Flow per share	(\$0.26)	(\$1.08)	(\$0.48)	(\$0.44)	(\$0.45)	(\$0.46)
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	9.8	26.0	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	9.8	26.0	27.0
Net (decrease) increase in cash and cash equivalents	-	(7.0)	(0.3)	(3.9)	2.4	0.5
Cash and cash equivalents at beginning of the period	-	33.6	4.3	3.9	0.0	2.4
Cash and cash equivalents at end of period	-	26.6	4.3	3.9	2.4	2.9

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

DISCLOSURES:**ANALYST CERTIFICATION**

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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

** 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
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%	42.86%	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%

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