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EQUITY RESEARCH
Company Report

March 4, 2015

Cel-Sci (CVM - $ 1.14)

Healthcare/Biotechnology

On Path to Realizing the Therapeutic and Commercial Potential of Multikine

Ticker:	**CVM**
Rating:	**Buy**
Price Target:	**$ 6.00**

We are transferring research coverage of CVM to Yale Jen on the departure of the covering analyst. We are re-initiating with a Buy rating and 12-month target price of $6.

- **Made from a defined mixture of human cytokines, Multikine is a patent protected immunotherapy.** Multikine is an immunotherapy comprised of multiple cytokines with composition of matter patent protection to last until 2024.
- **Promising potential of Phase III study for Multikine in head and neck (H&N) cancer is the major value driver.** CVM is conducting one of the largest Phase III studies (n=880) in H&N cancer to evaluate Multikine as a 1st line treatment in squamous cell carcinoma of the H&N. Prior encouraging Phase II study results demonstrate that Multikine + the standard of care (SOC) achieved 33% improvements (63% vs. 47%) in overall survival (OS) vs. SOC alone based on historical data. The Phase III study is an open-label randomized trial (Figure 1). The primary endpoint is to achieve 10% improvements in OS for Multikine + SOC vs. SOC alone. Secondary endpoints include PFS and local regional control (LRC). Measuring OS is an event-driven phenomenon (est. n=298) and we estimate the top-line results could be available in 2017. CVM indicated that patient recruitment could be completed by year-end 2015.
- **Multikine in anal warts in HIV/HPV co-infected patients Phase I study results are expected in late 2H15.** This study is funded by the U.S. Navy and a Phase IIb study could begin in 2H15.
- **Arbitration proceedings against InVentiv Health Clinical are ongoing.** CVM seeks at least $50MM in damage compensation for the alleged breach of contract. InVentiv is a CRO hired by CVM to conduct the Multikine in H&N cancer Phase III study. The trial date is scheduled for May 4, 2015. Although CVM could financially benefit from a favorable decision, we believe it is too difficult to speculate on the outcome.
- **Substantial upside remains.** We are reassuming our coverage of CVM with a Buy rating and $6.00 target price to reflect the advancements of Multikine in H&N cancer. Our valuation is based on peer comparable and probability-adjusted-NPV analyses.

Trading Data:

Last Price (03/03/2015)	$ 1.14
52–Week High (3/21/2014)	$ 1.90
52–Week Low (12/10/2014)	$ 0.54
Market Cap. (MM)	$ 104
Shares Out. (MM)	92

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.10	-0.10	-0.11	-0.12	-0.43	NM
FY-14A	-0.11	-0.24	-0.04	-0.09	-0.48	NM
FY-13A	-0.08	-0.02	-0.14	-0.06	-0.30	NM
FY-12A	NA	NA	NA	NA	-0.70	NM

Source: Laidlaw & Company estimates

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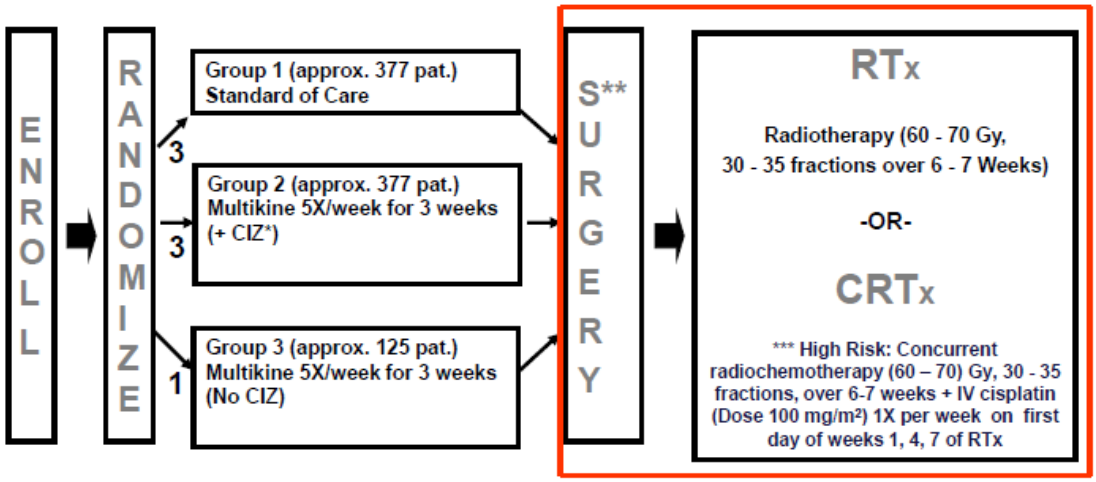
Our $6 price target is based on a blended measurement of probability-adjusted NPV and comparable analyses.

- **We are transferring research coverage of CVM to Yale Jen due to the departure of the covering analyst. We are re-initiating with Buy rating and 12-month target price of $6.** Cel-Sci Corporation is a mid/late-clinical stage biopharmaceutical company focusing on the development of Multikine as an immunotherapy for cancer and other indications. Multikine is in a Phase III trial in squamous cell carcinoma of H&N cancer. Patient recruitment completion is expected by year-end 2015 (or early 2016), with potential top-line results in 2017, based on our estimate.

The primary objective of using Multikine is to eradicate micro metastases located near the initial tumor mass and in the lymph nodes to reduce the recurrence rate.

- **The clinical uses of Multikine.** The results from most of the clinical studies suggest that the maximum potential benefit from Multikine treatment could be realized in cancer patients if it is administered before other therapies. The other therapies include surgery, radiation, and chemotherapy. Researchers postulate that during this early period, a cancer patient may still retain substantial immunity. Therefore at this stage the patient could generate the maximum anti-tumor immune response when treated with Multikine immunotherapy. The primary objective of using Multikine is to eradicate micro metastases located near the initial tumor masses and in the lymph nodes, to reduce the recurrence rate. One of the proposed mechanisms of the immunotherapeutic effect of Multikine is to change the tumor microenvironment by increasing the ratio between the CD4+ and CD8+ T cells.

Figure 1: Multikine in H&N Phase III study design



Source: Company presentation

CVM expects to complete patient recruitment by year-end 2015.

- **Accelerating patient recuritment for the Multikine Phase III study is a positive development.** After the very anemic pace of patient recruitment for the initial Phase III study, CVM replaced InVentiv Health Clinical in 2Q13 with two new CROs: Ergomed and Aptiv Solutions. The pace of patient recruitment has increased since then. As of February 2015, the study has recruited 377 patients, out of the total of 880. (Figure 2) CVM expects to complete patient recruitment by year-end 2015 (or in 1H16). CVM share value has risen since the concerns over completing patient recruitment have subsided.

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Figure 2: Multikine Phase III study patient recuritment pace

Source: Company presentation

Leukocyte interleukin is a broad collection of various interleukins and different cytokines.

- **Multikine (leukocyte interleukin, injection).** Leukocyte interleukin is a collection of various interleukins and different cytokines. The manufacturing process starts from selected human peripheral blood mononuclear cells. Subsequently, these cells are cultured with mitogen. The next step is to harvest the serum-free culture supernatant aseptically. This is followed by a commercial virus exclusion process, then concentration, and microfiltration. The product is then calibrated to a targeted IL-2 concentration. CVM has built a manufacturing facility for the production of Multikine. Multikine also received an Orphan drug designation for H&N cancer.

CVM expects to complete the study in mid-2015, with top-line results potentially available in late 2015 or early 2016.

- **Multikine in peri-anal warts in HIV/HPV co-infected patients Phase I study.** In collaboration with the U.S. Naval Medical Center, San Diego, CVM is conducting a Phase I study evaluating Multikine in peri-anal warts in HIV/HPV co-infected patients. Anal and genital warts are commonly associated with the Human Papilloma Virus (HPV), which is the most common sexually transmitted disease. Patients with a history of anogenital warts have a 30 fold increased risk of anal cancer. The Phase I study is a dose escalating, 15-patient trial with the objective of assessing the safety and clinical impact on anal warts and anal intraepithelial neoplasia (AIN). The treatment duration is 6 weeks with approximately 6 months follow-up. CVM expects the study to be completed in mid-2015, with top-line results potentially available in late 2015 or early 2016. CVM expects the Navy to start a Phase IIb trial evaluating Multikine in anal warts in HIV/HPV co-infected patients in 2H15. Since the U.S. Navy is funding the study, CVM is not expected to incur any expenditure for these clinical advancements.

  Multikine has demonstrated positive results from an earlier Phase I clinical study. In that study the drug was used to treat cervical dysplasia in HIV/HPV co-infected women. The study exhibited visual and histological evidence of clearance of lesions.

- **Ligand Epitope Antigen Presentation System (LEAPS)** is CVM's proprietary technology that could facilitate the development of peptide treatments to generate a specific immune response to effectively combat infectious and non-infectious diseases.

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Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing
Multikine	Head and neck cancer	Potentially complete patient recuritment of Phase III trial	**YE15**
		Potentially complete Phase III trial	**2017**
	Human Papillomavirus (HPV) in HIV-infected patients	A KOL possibly join the study	**1H15**
		Complete Phase I trial	**2H16**
		Arbitration decision	**1H15**
		Scheduled date for trial start	**May 4, 2015**

Source: Laidlaw & Company estimates and company presentation.

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Financial projections and valuation

CVM reported holding cash of ~$9.4MM as of the end of 4Q14. Based on management's public comments, the company might need $27MM to complete the Multikine in H&N Phase III study. As such, we believe the cash should support the company's operations into 2H15, by our estimate.

Our probability-adjusted-NPV analysis suggests that the total NPV of Multikine in H&N cancer is $512MM with a conservative assumption of 40% of probability of success. By adding the manufacturing facility and LEAP technology, we estimate the total value of $542MM, or $6.30 per share.

We have chosen a group of oncology development stage companies for the peer comparable analysis. Based on these peer comparisons our analysis suggests a 12-month target price for CVM of $6.42.

Together, we derive a 12-month target price of **$6.00**

Oncology peer comparable analysis

Company	Ticker	Rating	Target Price ($)	Price ($) (3/2/15)	Shares Outstanding (MM)	Market Cap ($ MM)	Cash ($ MM)	Debt ($ MM)	Tech Value ($ MM)	Most Advanced Development Stage	Major Indication
TG Therapeutics	TGTX	NR	NA	14.59	44	641	67	0	574	Phase II	Hematological
Epizyme	EPZM	NR	NA	23.93	34	817	212	0	606	Phase I/II	Hematological
NewLink Genetics	NLNK	NR	NA	44.43	28	1242	51	0	1191	Phase III	Pancreatic
Inovio Pharmaceuticals	INO	NR	NA	7.17	61	434	101	0	334	Phase II	H&N
Northwest Biotherapeutics	NWBO	NR	NA	7.23	62	450	35	0	415	Phase III	Brain
Peregrine Pharmaceuticals	PPHM	NR	NA	1.40	182	255	64	0	190	Phase III	NSCLC
Xencor	XNCR	NR	NA	15.83	31	497	61	0	436	Phase II	Hematological
MacroGenics	MGNX	NR	NA	34.70	28	964	179	0	785	Phase II	Breast, solid tumor, AML
Karyopharm Therapeutics	KPTI	NR	NA	27.64	33	904	227	0	677	Phase III	Hematological
Average						586	*101*	*0*	579		
Cel-Sci	CVM	Buy	6.00	1.08	92	99	9	0	90	Phase III	H&N

CVM share fair value matching its Phase II/III oncology peers = $6.42

Potential upside = 494%

Source: Laidlaw & Company estimates

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Major risks

Risks of clinical study failure could have a significant impact on CVM share value. Although the prior studies have provided encouraging clinical outcomes, risks remain that some current trials might not meet study endpoints. As such, the value of the clinical assets could be significantly impaired and, therefore, CVM shareholder value could diminish. Such a negative impact could be more pronounced if the clinical program is in an advanced development stage, such as Multikine in head and neck cancer. Regulatory risks are part of the clinical risks. Even if a drug meets its endpoints in pivotal studies, regulatory agencies might not grant approval.

Commercial risk that even with approval, sales could be substantially below expectations. Even it is approved, the commercial sales of any drug could below expectations, resulting in diminished CVM shareholder value. Factors that could impact the commercial outlook of a drug include execution of marketing and sales, competition from other drugs, potential change of the treatment paradigm, and unrealistic expectations or projections.

Future capital raises could potentially dilute value of current shareholders. CVM is still in the product development stage and additional financial resources will likely be needed for further advancement of their product pipeline. The company may need to raise capital from financial markets to support its operations. This may be necessary even if the company already has partners to provide milestone and other types of payments and/or product revenue. The company might not always be able to raise capital from financial markets at favorable terms. Share dilution under this scenario could reduce the value of the investment to current shareholders of the company.

Limited product diversity could increase overall risk. Given the concentrated product development of the company, the value of the product pipeline mainly resides on Multikine in H&N cancer development. The remaining part of the pipeline, such as Multikine in genital warts and LEAPS technology remain in a very early development stage. As such, we believe the company at the current stage has very limited diversification potential in its product pipeline.

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Figure 1: Income Statement

CEL-SCI Corp. – Income Statement

($MM)	2013	1Q14	2Q14	3Q14	4Q14	2014	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Revenue												
Product Sales, net	0.0	-	-	-	-	0.0	-	-	-	-	-	-
Grant Income and Other	0.2	0.1	0.1	0.0	0.1	0.3	0.1	0.1	0.1	0.1	0.2	0.2
Total revenue	0.2	0.1	0.1	0.0	0.1	0.3	0.1	0.1	0.1	0.1	0.2	0.2
Costs of goods	0.0	-	-	-	-	0.0	-	-	-	-	-	0.0
Gross sales	0.2	0.1	0.1	0.0	0.1	0.3	0.1	0.1	0.1	0.1	0.2	0.2
Selling, general and administrative	7.0	2.0	2.1	2.4	4.1	10.6	4.2	4.4	5.4	5.7	19.7	21.7
Research and development	12.7	4.0	4.2	4.5	4.4	17.0	4.7	5.1	5.6	6.5	21.9	21.9
Depreciation and amortization	0.4	0.1	0.1	0.1	0.1	0.2	0.1	0.1	0.1	0.1	0.2	0.2
Total Operating Expenses	20.0	6.0	6.3	6.9	8.6	27.8	8.9	9.6	11.1	12.2	41.8	43.8
Operating Incomes (losses)	(19.9)	(5.9)	(6.2)	(6.9)	(8.5)	(27.6)	(8.9)	(9.6)	(11.0)	(12.1)	(41.6)	(43.5)
2 Gain on derivative instruments	10.8	1.6	(7.1)	4.5	1.3	0.2	1.6	2.0	2.0	2.0	7.6	7.6
Interest income	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.1	0.1
Interest expense	(0.2)	(0.0)	(0.0)	(0.0)	(0.0)	(0.2)	(0.0)	(0.0)	(0.0)	(0.0)	(0.2)	(0.2)
Other expenses	0.0	(1.1)	-	-	1.1	(0.0)	0.0	0.0	0.0	0.0	0.1	0.1
Total Other Income (Expense)	10.7	0.5	(7.1)	4.5	2.4	0.2	1.6	2.0	2.0	2.0	7.6	7.6
Net loss before tax	(9.2)	(5.5)	(13.4)	(2.4)	(6.1)	(27.4)	(7.3)	(7.6)	(9.0)	(10.1)	(33.9)	(35.9)
Tax	0.0	-	-	-	-	0.0	-	-	-	-	-	-
Net Income (Loss)	(9.2)	(5.5)	(13.4)	(2.4)	(6.1)	(28.5)	(7.3)	(7.6)	(9.0)	(10.1)	(33.9)	(35.9)
Net Income (Loss) Applicable to Common Shareholders	(9.2)	(5.5)	(13.4)	(2.4)	(6.1)	(28.5)	(7.3)	(7.6)	(9.0)	(10.1)	(33.9)	(35.9)
Net Earnings (Losses) Per Share	($0.30)	($0.11)	($0.24)	($0.04)	($0.09)	($0.48)	($0.10)	($0.10)	($0.11)	($0.12)	($0.43)	($0.36)
Shares outstanding—basic	30.28	48.2	56.2	64.7	66.1	58.80	71.1	76.1	81.1	86.1	78.6	98.6
Shares outstanding—diluted	30.28	48.2	56.2	64.7	66.1	58.80	71.1	76.1	81.1	86.1	78.6	98.6
Margin Analysis (% of Sales/Revenue)												
Costs of goods	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Gross margin	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
R&D	7946%	3553%	6186%	27986%	6448%	6439%	7798%	8578%	9350%	10753%	9120%	9120%
SG&A	4376%	1742%	3109%	15071%	6117%	4017%	7018%	7369%	8990%	9439%	8204%	9024%
Operating Income (loss)	-12450%	-5245%	-9271%	-43366%	-12551%	-10443%	-14814%	-15944%	-18337%	-20189%	-17321%	-18142%
Net Income	-5747%	-4819%	-19902%	-15361%	-9027%	-10788%	-12134%	-12598%	-14991%	-16843%	-14142%	-14957%
Financial Indicator Growth Analysis (YoY%)												
Contract revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Product revenue	-37%	654%	336%	-86%	339%	65%	-47%	-11%	277%	-12%	-9%	0%
Total Revenue	-37%	654%	336%	-86%	339%	65%	-47%	-11%	277%	-12%	-9%	0%
R&D	22%	37%	65%	18%	26%	34%	16%	24%	26%	48%	29%	0%
SG&A	6%	-2%	27%	35%	167%	52%	114%	112%	125%	37%	86%	10%
Operating Income (Losses)	15%	18%	47%	25%	68%	39%	50%	54%	59%	42%	51%	5%
Net Income	-48%	136%	1774%	-45%	260%	211%	34%	-43%	268%	65%	19%	6%
EPS	-57%	39%	929%	-74%	65%	60%	-9%	-58%	193%	27%	-11%	-16%

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

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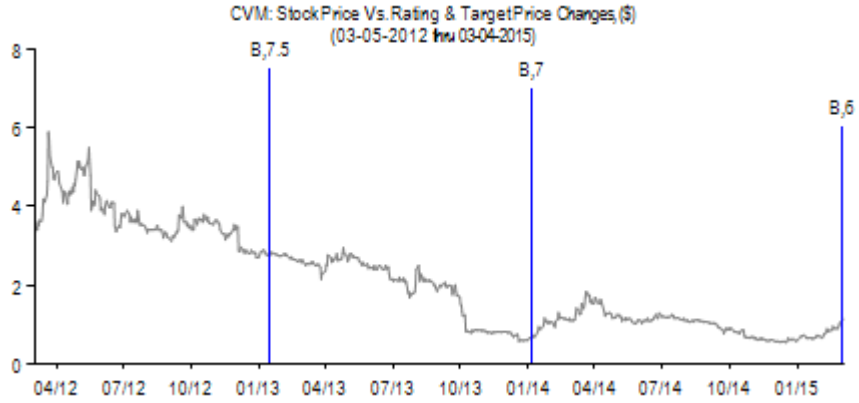
Rating and Price Target Change History



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
03/04/2015	6.00	1.14*

** Previous Close3/3/2015*
*** Split Adjusted*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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