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CEL-SCI Corporation (CVM: NYSE)

A New Year Ahead

Based on our DCF model and a 15% discount rate, CEL-SCI is valued at approximately $13.00 per share. Our model applies an 85% probability of ultimate approval and commercialization for Multikine in head and neck cancer in lower severity patients that do not need chemotherapy. The model includes contributions from the US, EU and rest of world.

Current Price (12/30/2022)	$2.35
Valuation	**$13.00**

OUTLOOK

CEL-SCI is developing two platforms, Multikine and LEAPS. Multikine has completed a Phase 3 trial for head and neck cancer while LEAPS is conducting preclinical studies for RA, Pandemic Flu and breast cancer. In June 2021, CEL-SCI reported selected data from its IT-MATTERS trial demonstrating a benefit in the non-chemotherapy population. CEL-SCI plans to submit a BLA to the FDA based on this data.

Multikine is an immuno-oncology biologic that contains human blood-derived cytokines that are thought to enhance the body's natural defenses against cancer. For the lead indication, SCCHN, it is used prior to and in conjunction with SoC, which includes surgery, radiation and chemotherapy. LEAPS is a peptide epitope delivery technology that can direct immune response. It is appropriate for diseases where antigenic epitope sequences have been identified.

Our valuation assumes a 2023 FDA approval of Multikine for head and neck cancer and a 2023 launch of the compound in the US, followed by a subsequent launch in the EU and global availability by 2023 that will be achieved through the efforts of partners.

SUMMARY DATA

52-Week High	**7.73**
52-Week Low	**1.88**
One-Year Return (%)	**-68.8**
Beta	**1.7**
Average Daily Volume (sh)	**180,482**
Shares Outstanding (mil)	**43.4**
Market Capitalization ($mil)	**181**
Short Interest Ratio (days)	**18.8**
Institutional Ownership (%)	**18.3**
Insider Ownership (%)	**3.9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of USD)

	Q1 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023					$40.8 E
2024					$129.1 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-$0.21 A	-$0.28 A	-$0.22 A	-$0.20 A	-$0.92 A
2022	-$0.20 A	-$0.23 A	-$0.23 A	-$0.21 A	-$0.87 A
2023					$0.29 E
2024					$1.89 E

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WHAT'S NEW

Fiscal Year 2022 Financial Results

On December 28, 2022, CEL-SCI Corporation (NYSE: CVM) submitted its fiscal year 2022 Form 10-K with the SEC concurrent with a press release announcing fiscal year 2022 results. Since our last update in August, CEL-SCI has participated in multiple scientific conferences and presented posters and abstracts on the Phase III IN-MATTERS clinical trial for Multikine. Beyond the additional data presented at ASCO and ESMO regarding the IT-MATTERS results, the highlight for fiscal year 2022 was the biologic license application (BLA) preparation efforts for Multikine in squamous cell carcinoma of the head and neck (SCCHN) which we expect to be submitted in 2023.

CEL-SCI updated investors on progress it has made with journal articles and biologics license application (BLA) press release including the observation that tumors in five patients in the Multikine arm of the IT-MATTERS trial had disappeared before surgery compared with no patients in the control arm. Company materials note that 8.5% of the patients in the intent to treat (ITT) Multikine arm showed a tumor response before surgery whereas no patients in the ITT control group demonstrated a tumor response prior to surgery. The p-value of the statistical significance between these two events was $< 1 \times 10^{-11}$.

CEL-SCI recognized no revenues for fiscal year 2022 and incurred operating expenses totaling $36.1 million during the year. This resulted in a net loss available to common shareholders of ($37.6) million, or ($0.87) per share.

For the fiscal year ending September 30, 2022 versus the same ending September 30, 2021:

- Expenses for research and development rose by 10% to $25.4 million from $23.1 million. The primary driver for the increase is preparation activity for the BLA related to the IT MATTERS trial;
- General and administrative expenses decreased by 18% to $10.7 million from $13.1 million on a reduction in employee stock compensation expense;
- Other non-operating gains were an expense of ($0.5) million compared to a $1.1 million gain largely related to gain on derivative instruments in the FY:22 period;
- Net interest expense was ($1.1) million compared with ($1.1) million;
- Net loss totaled ($37.6) million versus ($36.4) million or ($0.87) and ($0.89) per share, respectively.

As of September 30, 2022, cash and equivalents totaled $22.7 million. Cash burn for the 12-month period amounted to approximately ($18.9) million versus ($18.8) million in the prior year. CEL-SCI holds no debt on its balance sheet.

Highlights From November Shareholder Letter

CEL-SCI's CEO, Geert Kersten issued a shareholder letter on November 22, 2022 highlighting progress in the advancement of Multikine towards approval.

Several findings from the trial were summarized:

- Median overall survival improvement of 46.5 months - nearly four years;
- 62.7% of Multikine patients were alive after five years vs. 48.6% in the control;
- Nearly one out of every six patients had their tumors shrink by more than 30% in just 3 weeks;
- Five patients had their tumors completely disappear in just 3 weeks;
- Tumor shrinkage/disappearance cut the death rate by a factor of three.

CEL-SCI acknowledges that it is taking longer than precedent to prepare the BLA for submission and attributes this specificially to Multikine's status as a neoadjuvant therapy for SCCHN and the need for additional support for the biologic's efficacy. The company also argues that it lacks the resources of a large pharma or biotech company, and the workload is spread over fewer people requiring in a longer period to prepare the submission. Mr. Kersten concludes the missive noting that he has not sold any shares of CEL-SCI over the last 20 years and maintains confidence that the product confers survival advantages to patients.

ESMO Abstract and Poster

CEL-SCI presented data from its Phase III IT-MATTERS trial at the European Society for Medical Oncology (EMSO) annual Congress on September 10, 2022 in Paris, France. Dr. Philip Lavin, and Dr. Jósef Timár each presented a poster at the conference. Dr. Lavin, a biostatician by trade with experience obtaining a number of FDA approvals, presented the first poster entitled "*Early response to Neoadjuvant Leukocyte Interleukin Injection (LI) immunotherapy extends overall survival (OS) in locally advanced primary squamous cell carcinoma (SCC) of the head & neck (HN): the IT-MATTERS Study*." The second poster was introduced by Dr. Tímár under the title of "*Histopathology (HP) biomarkers confirm Leukocyte Interleukin Injection (LI) treatment (Tx) outcome in naïve locally advanced primary head & neck squamous cell carcinoma (SCCHN) the IT-MATTERS Study*."

Dr. Lavin's presentation summarized several conclusions:

- Early response to Multikine treatment occurs before surgery at a median of 5 weeks post-randomization;
- Early response provides a positive signal to both patients and care providers (early in the treatment course)
  - Early response was only noted in the Multikine treatment groups
  - Early response occurs in both the lower and higher risk groups for recurrence;
- Early response is prognostic and predictive for overall survival in overall and lower risk populations;
- Benefit was seen in Multikine-treated lower risk non-responders.

Conclusions from Dr. Timár's presentation:

- Pre-defined markers, ratios, and combinations contribute to Multikine efficacy for overall survival (OS), progression free survival (PFS) and loco-regional control (LRC);
- Broad representation of markers, ratios and combinations overall are associated with Multikine efficacy in lower risk patients relating to OS, PFS, LRC efficacy study endpoints;
- There were 61 (21.9%) favorable overall and 54 (19.4%) favorable low risk treatment group outcomes and only a total of five instances (1.9%) having unfavorable treatment group outcome, the latter of which were all high risk subjects;
- Results support the low risk treatment advantage significantly favoring Multikine + SOC vs SOC alone.

ASCO Abstract and Poster

In late April of this year, CEL-SCI emerged from its coccoon and announced that multiple abstracts had been accepted by American Society of Clinical Oncology (ASCO) for presentation during the organization's 2022 meeting from June 3 to 7 in Chicago, IL. On June sixth CEL-SCI presented the data as described in a press release. During the event, the presentations were accompanied by a poster entitled: Leukocyte Interleukin Injection (LI) immunotherapy extends overall survival (OS) in treatment naïve low risk (LR) locally advanced primary squamous cell carcinoma of the head & neck: the IT-MATTERS Study.

The poster summarized the IT MATTERS Phase III clnical trial highlighting the key elements of the 923 subject study. It enrolled previously untreated advanced primary squamous cell carcinoma of the head and neck (SCCHN) patients having met inclusion/exclusion criteria as described in the study record (NCT01265849). Enrollees were then randomized 3:1:3 into one of the following treatment arms:

- Group 1 – LI Multikine (MK) + cyclophosphamide (CIZ) + standard of care (SOC); n=395
- Group 2 – LI (MK) + SOC; n=134
- Group 3 – SOC alone (Control); n=394

The primary goal of IT MATTERS was to assess OS superiority of LI (MK) + CIZ + SOC compared with SOC alone. Secondary objectives were to determine the rate of progression free survival (PFS) and local regional control (LRC) failure, quality of life, histopathological nature of cellular tumor infiltrate, and tumor response to Multikine.

The poster addressed elements of both safety and efficacy. Multikine features include relative ease of administration, localized treatment emergent adverse events (TEAEs), self-resolving TEAEs, and absence of TEAEs after surgery. The five serious adverse events (SAEs) observed included edema, bleeding, osteoradionecrosis, atrial fibrillation and delirium, with two cases in edema and pyrexia that led to discontinuation. Furthermore, Multikine did not delay or interfere with surgery, did not contribute to any differences in the observation of adverse events be-

tween the study groups after treatment and led to no deaths or withdrawals. The poster examined two groups for OS: the intent to treat (ITT) group which has an N of 923 and the lower risk population with an N of 380. The ITT group did not distinguish itself relative to control; however, in the low-risk population,[1] which includes patients receiving radiotherapy only, there was a statistically significant OS benefit from using Multikine. The low-risk group consisted of 380 subjects and demonstrated a 14.1% improvement in OS for the LI (MK) + CIZ + SOC group vs. the SOC group at 60 months.

Exhibit I – Low Risk Group (N=380) Alive at Each Time Point[2]

		Treatment Group			Delta
Population	Milestone	LI (MK)+CIZ+SOC ('1')	LI (MK)+SOC ('2')	SOC ('3')	'1' vs '3'
ITT (99.5%)	36 months	72.4% (64.4%, 78.9%)	78.8% (65.0%, 87.7%)	67.5% (59.7%, 74.1%)	4.9%
ITT (99.5%)	48 months	67.3% (59.0%, 74.3%)	62.3% (47.4%, 74.1%)	57.8% (49.7%, 65.0%)	9.5%
ITT (99.5%)	60 months	62.7% (54.0%, 70.2%)	55.5% (40.5%, 68.2%)	48.6% (40.4%, 56.4%)	14.1%

The hazard ratio[3] for the low-risk treatment vs. control group was favorable with a value of 0.68 and a confidence interval of 0.48 and 0.95. Median survival for the low-risk LI + CIZ + SOC group was 101.7 months vs. SOC at 55.2 months.

Exhibit II – Endpoint Values for OS, PFS & LRC in Low-Risk Group[4]

		Endpoint		
	Treatment Comparison	**OS (380; 166d)**	**PFS (380; 188p)**	**LRC (380; 104f)**
	Failures (Group '1', '2', '3')	(58, 24, 84)	(70, 27, 91)	(41, 16, 47)
ULR P-value	LI (MK)+CIZ+SOC vs SOC	0.0478	0.1797	0.6142
SLR P-value	LI (MK)+CIZ+SOC vs SOC	0.0137	0.0159	0.3024
Hazard Ratio	LI (MK)+CIZ+SOC vs SOC	0.68 (0.48-0.95)	0.76 (0.55-1.04)	0.84 (0.55-1.28)
	LI (MK)+SOC vs SOC	0.82 (0.52-1.29)	0.84 (0.54, 1.30)	0.93 (0.53-1.65)
Cox PH P-value	LI (MK)+CIZ+SOC vs SOC	0.0236	0.0896	0.4082
	LI (MK)+SOC vs SOC	0.3859	0.4376	0.8131
Medians (months)	LI (MK)+CIZ+SOC	101.7 months	66.4 months	Not reached
	LI (MK)+SOC	68.2 months	68.2 months	Not reached
	SOC	55.2 months	51.2 months	Not reached

[1] The high-risk population is defined as those that were prescribed both chemotherapy and radiotherapy.
[2] Source: CEL-SCI Poster: Leukocyte Interleukin Injection (LI) immunotherapy extends overall survival (OS) in treatment naïve low risk (LR) locally advanced primary squamous cell carcinoma of the head & neck: the IT-MATTERS Study.
[3] Hazard ratio (HR) is a measure of an effect of an intervention on an outcome of interest over time. Hazard ratio is reported most commonly in time-to-event analysis or survival analysis. Calculated as: hazard (risk of death) in the intervention group / hazard in the control group.
[4] Source: CEL-SCI Poster: Leukocyte Interleukin Injection (LI) immunotherapy extends overall survival (OS) in treatment naïve low risk (LR) locally advanced primary squamous cell carcinoma of the head & neck: the IT-MATTERS Study.

The presentation identified an incidence of approximately 890,000 head and neck cancer diagnoses per year with about 60,000 in the United States and 105,000 in Europe. 90% of SCCHN are squamous cell carcinomas, two-thirds are advanced primary and of this group, about 40% receive radiotherapy following surgery.

In summary, safety results did not differ significantly between treatment groups; however, there was a statistically significant survival benefit in the low-risk treatment group. The ITT lower risk LI + CIZ + SOC arm achieved a 14.1% advantage for OS compared with SOC at five years. The 0.68 hazard ratio corresponds to a 47% improvement in median survival for the treatment group compared to SOC alone.

Summary of key efficacy results:

- 14.1% absolute overall survival benefit in the lower-risk treatment cohort;
- 101.7 months median overall survival in the lower risk Multikine treatment cohort vs. 55.2 months for standard of care;
- 16.0% early response rate for Multikine vs. 0% for standard of care;
- 17.6% death rate for early responders in the lower-risk treatment cohort vs. 42.7% for non-responders;
- Progression free survival presents a 0.76 hazard ratio;
- Overall survival presents a 0.68 hazard ratio.

Regulatory Submission

Now that the company has completed the IT-MATTERS trial and reported details of the trial outcome at a major conference, attention turns to the next steps in the regulatory process and submission of a BLA. Key drivers for valuation include the FDA's willingness to accept the data available for a BLA and whether or not additional data and information is required prior to acceptance. The company has reached out to the FDA and contacted representatives from both the offices of oncology products and rare disease; however, it has not shared the agency's response if indeed the meetings have yet taken place. We will update investors on these meetings, their outcomes and impact on valuation when details are made available.

CEL-SCI Milestones

- Submission of data of clinicaltrials.gov – May 2022
- Presentation of abstract at ASCO – June 2022
- Appointment of Gail Naughton to Board of Directors – August 2022
- Development of clinical study report – 2022
- Development of paper(s) for publication in peer reviewed journal – 2022
- ClinicalTrials.gov results posted – August 2022
- ESMO presentation – September 2022
- Submission of BLA to FDA – 2023

Summary

CEL-SCI presented results from its IT MATTERS trial at ASCO and ESMO providing additional data related to the IT-MATTERS trial expanding into histology of tumors that respond to Multikine. Fiscal year 2022 results were filed, as CEL-SCI continues to compile and analyze data. Efforts now are centered on developing journal articles and presentations, interactions with the FDA and further preparation of the BLA. There are a number of favorable factors that support the approval of Multikine. Other cancer drugs have been approved on weaker data such as overall response rate and with less statistical significance than now presented by Multikine. However, to achieve ultimate approval, the FDA must accept the subgroup data. In a disease where a majority of the treatments are toxic or are associated with serious side effects, CEL-SCI's candidate provides a favorable safety profile with no serious side effects, a must in a space where the first goal is to do no harm.

PROJECTED FINANCIALS

CEL-SCI Corporation - Income Statement

CEL SCI Corporation	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$40.8**	**$129.1**
Research & Development	$23.1	$6.1	$6.5	$6.3	$6.5	$25.4	$4.0	$3.0
General & Administrative	$13.1	$2.8	$3.0	$2.4	$2.5	$10.7	$11.0	$11.4
Income from operations	($36.2)	($8.8)	($9.6)	($8.7)	($8.9)	($36.1)	$25.8	$114.7
Other Income	$1.0	$0.3	$0.0	($0.3)	$0.0	($0.5)	$0.0	$0.0
Interest Expense	($1.1)	($0.3)	($0.3)	($0.9)	($0.3)	($1.1)	($1.6)	($1.6)
Pre-Tax Income	($36.4)	($8.8)	($9.8)	($9.9)	($9.2)	($37.6)	$24.2	$113.1
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$7.0	$0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	29.0%	29.0%
Net Income	**($36.4)**	**($8.8)**	**($9.8)**	**($9.9)**	**($9.2)**	**($37.6)**	**$17.1**	**$113.1**
Reported EPS	**($0.89)**	**($0.20)**	**($0.23)**	**($0.23)**	**($0.21)**	**($0.87)**	**$0.29**	**$1.89**
Basic Shares Outstanding	40.69	43.08	43.12	43.17	43.40	43.15	59.00	60.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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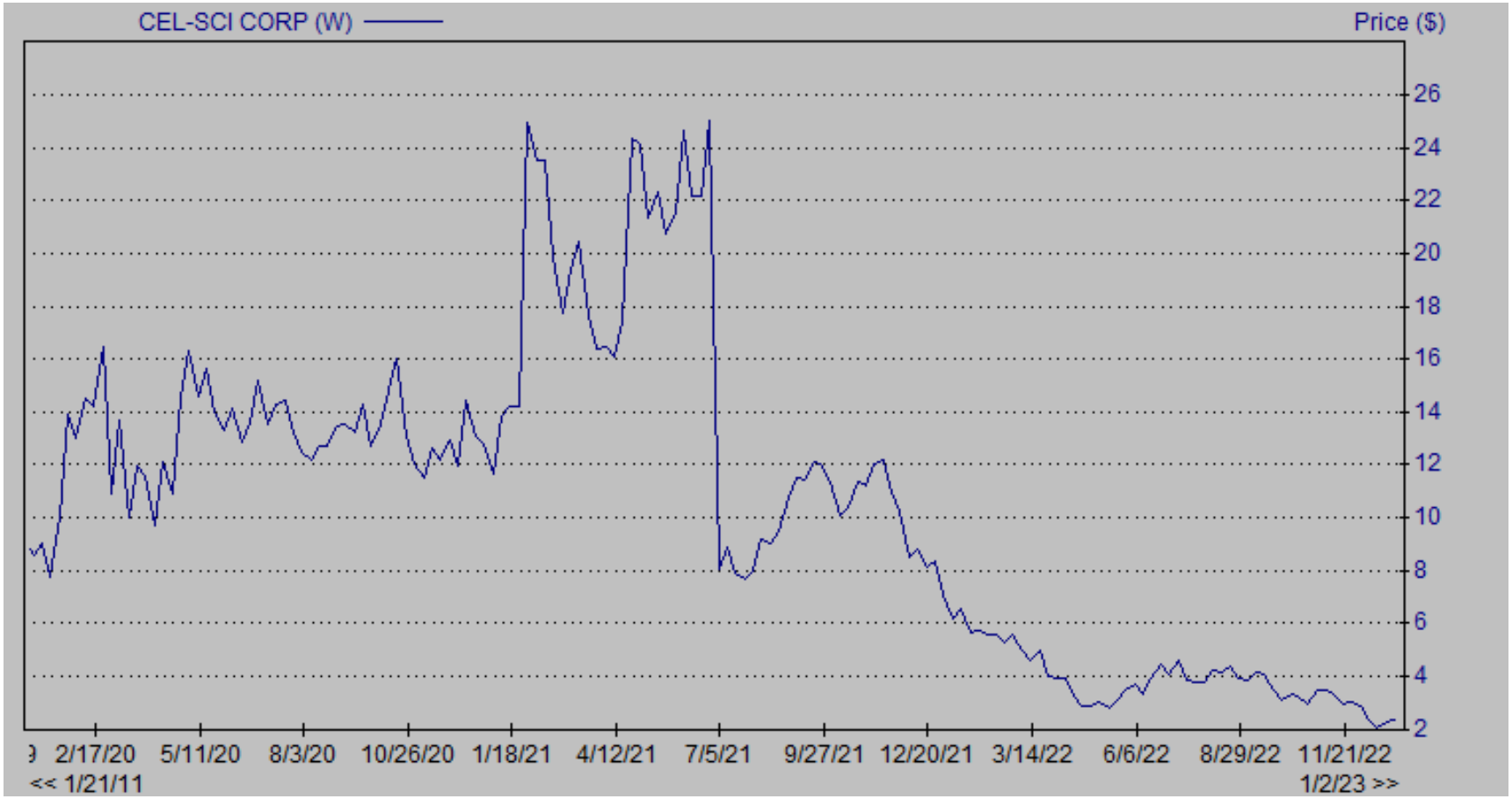
HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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