Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive
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CEL-SCI Corporation (CVM: NYSE)

BLA Filing Still on the Horizon

We use a DCF model and apply a 15% discount rate to CEL-SCI's forecasted cash flows to generate our valuation. 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 (2/24/2023)	$2.61
Valuation	**$11.00**

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 2024 FDA approval of Multikine for head and neck cancer and a 2025 launch of the compound in the US, followed by a subsequent launch in the EU and global availability by 2026 that will be achieved through the efforts of partners.

SUMMARY DATA

52-Week High	**6.14**
52-Week Low	**1.88**
One-Year Return (%)	**-56.1**
Beta	**1.7**
Average Daily Volume (sh)	**170,482**
Shares Outstanding (mil)	**43.7**
Market Capitalization ($mil)	**114.1**
Short Interest Ratio (days)	**44.9**
Institutional Ownership (%)	**13.5**
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 2023 Estimate	**N/A**
P/E using 2024 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)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2024					$0.0 E
2025					$26.6 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2022	-$0.20 A	-$0.23 A	-$0.23 A	-$0.21 A	-$0.87 A
2023	-$0.18 A	-$0.17 E	-$0.17 E	-$0.16 E	-$0.67 E
2024					-$0.48 E
2025					$0.06 E

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WHAT'S NEW

First Quarter Fiscal Year 2023 Update

CEL-SCI Corporation (NYSE: CVM) reported first quarter fiscal year 2023 results on February 15, 2023 and filed its Form 10-Q with the SEC. The company has continued to compile the clinical documentation necessary to support a Biologic License Application (BLA), which will be submitted in order to receive marketing approval.

During the first quarter, which ended December 31, 2022, CEL-SCI announced that Dr. Lavin's presentation from the European Society for Medical Oncology (ESMO) Annual Congress was made available to investors in October. In November, CEO Geert Kersten issued a letter to shareholders highlighting progress in the Multikine trial.

Financial Review

CEL-SCI recognized no revenues for its fiscal first quarter ending December 31, 2022 and incurred operating expenses totaling $7.7 million during the three-month period. This resulted in a net loss available to common shareholders of ($8.0) million, or ($0.18) per share.

For the quarter ending December 31, 2022 versus the same ending December 31, 2021:

- Expenses for research and development fell by 11% to $5.4 million from $6.1 million. The primary contributor to the decline is lower employee stock compensation expense, and lower costs related to the IT MATTERS trial. These expenses were partially offset by the recognition of costs to prepare for the potential commercial sale of Multikine;
- General and administrative expenses decreased by 18% to $2.3 million from $2.8 million on lower stock compensation expense partially offset by an increase in other expenses;
- Other non-operating items were an expense of ($0.2) million compared to a $0.3 million gain related to the modification of warrants and other expense;
- Net interest expense, which is related to lease liabilities was ($0.2) million compared with ($0.3) million;
- Net loss totaled ($8.0) million versus ($8.8) million or ($0.18) and ($0.20) per share, respectively.

As of December 31, 2022, cash and equivalents totaled $18.0 million. Cash burn for the three-month period amounted to approximately ($4.7) million versus ($4.8) million in the prior year period. After the turn of the year, the company deposited $2.3 million with its San Tomas landlord, which is equivalent to one year's rent. It will be carried as a current asset. CEL-SCI holds no debt on its balance sheet.

Further highlights from the press release and filing include an expected submission to a peer-reviewed scientific journal that will include important data and additional efforts to prepare the company's Multikine manufacturing facility for inspection by the FDA.

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's presentation was later made available to stakeholders. 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.

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;
- Tumors in five patients completely disappeared 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 being a neoadjuvant therapy for SCCHN and the need for additional support for the proof that the biologic works. The company also argues that it lacks the resources of a large pharma or biotech company, and the workload is spread over fewer people thereby taking longer to move forward. 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.

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.

Valuation

We adjust our discounted cash flow model and move first sales back by one year to reflect our best estimate on timing for commercialization of Multikine absent any management guidance. We also adjust for existing cash and share balances. This changes our valuation to $11 per share.

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 – 2023
- Development of paper(s) for publication in peer reviewed journal – 2023
- 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. During the first quarter and period to date, CEL-SCI continues to direct its efforts towards compiling and analyzing data. Efforts now are centered on developing journal articles and presentations and preparing the manufacturing facility for inspection. 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 and our attention turns to FDA response to interactions with CEL-SCI. 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

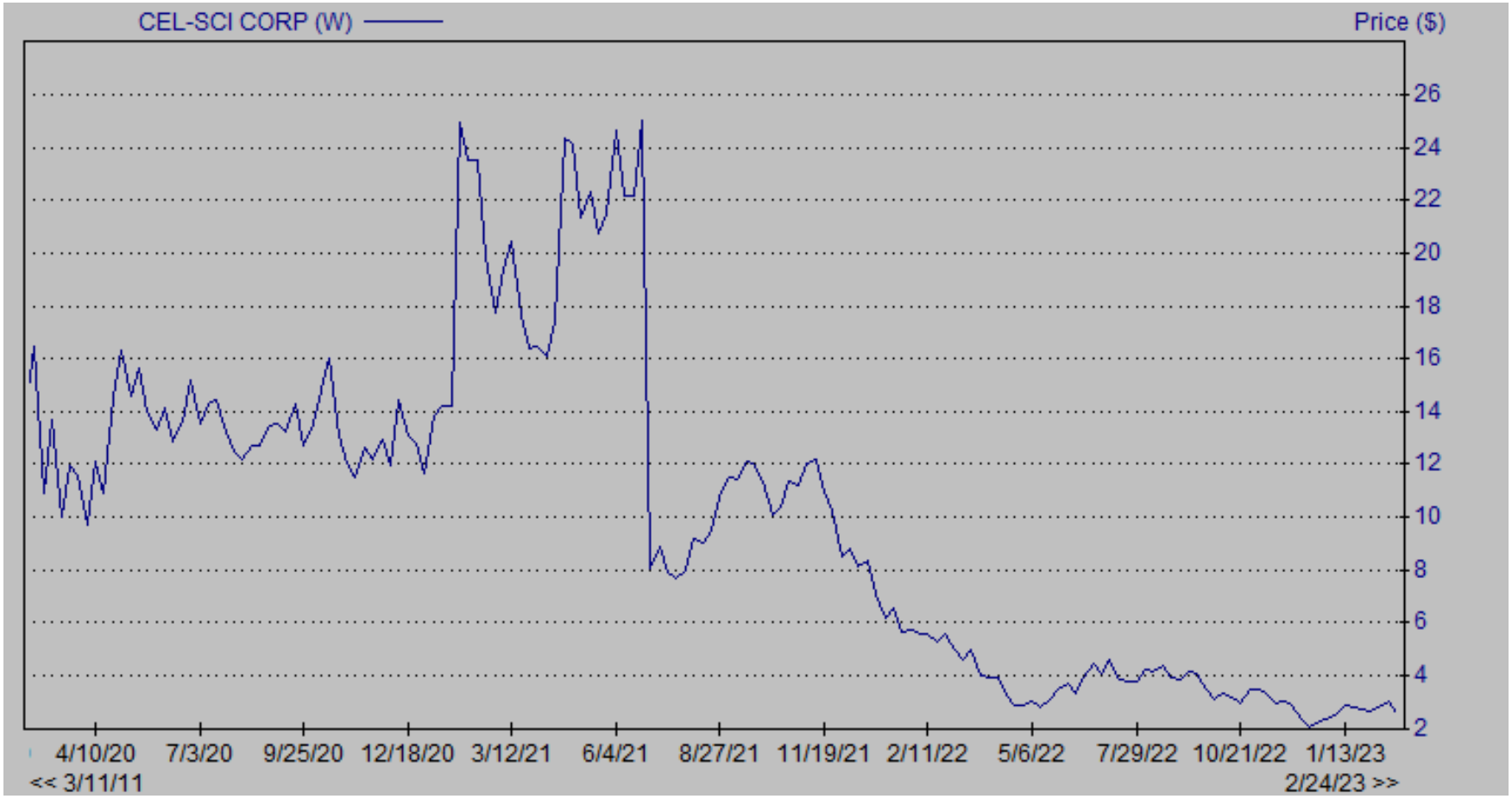
CEL SCI Corporation	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$26.6**
Research & Development	$25.4	$5.4	$5.0	$5.0	$5.0	$20.4	$18.0	$12.0
General & Administrative	$10.7	$2.3	$2.4	$2.6	$2.5	$9.8	$10.0	$10.0
Income from operations	($36.1)	($7.7)	($7.4)	($7.6)	($7.5)	($30.2)	($28.0)	$4.6
Other Income	($0.5)	($0.2)	$0.0	$0.0	$0.0	($0.2)	$0.0	$0.0
Interest Expense	($1.1)	($0.2)	($0.2)	($0.2)	($0.2)	($0.8)	($0.8)	($0.8)
Pre-Tax Income	($37.6)	($8.0)	($7.6)	($7.8)	($7.7)	($31.1)	($28.8)	$3.8
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	29.0%	29.0%	29.0%
Net Income	**($37.6)**	**($8.0)**	**($7.6)**	**($7.8)**	**($7.7)**	**($31.1)**	**($28.8)**	**$3.8**
Reported EPS	**($0.87)**	**($0.18)**	**($0.17)**	**($0.17)**	**($0.16)**	**($0.67)**	**($0.48)**	**$0.06**
Basic Shares Outstanding	43.15	44.44	45.00	47.00	49.00	46.36	60.00	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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