Zacks Small-Cap Research
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CEL-SCI Corporation (CVM: NYSE)

CVM: Health Canada Conditional Approval

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 (5/15/2023)	$2.60
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	**5.42**
52-Week Low	**1.86**
One-Year Return (%)	**-11.0**
Beta	**1.7**
Average Daily Volume (sh)	**199,198**
Shares Outstanding (mil)	**44.7**
Market Capitalization ($mil)	**116.2**
Short Interest Ratio (days)	**24.4**
Institutional Ownership (%)	**13.8**
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 A	$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	-$0.18 E	-$0.17 E	-$0.16 E	-$0.69 E
2024					-$0.48 E
2025					$0.06 E

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WHAT'S NEW

Second Quarter Fiscal Year 2023 Update

CEL-SCI Corporation (NYSE: CVM) reported second quarter fiscal year 2023 results on May 15, 2023 and filed its Form 10-Q with the SEC. Since our previous update in February, the company has continued to compile the clinical documentation necessary to support a Biologic License Application (BLA) with the FDA, presented new data at two European conferences, announced its pursuit of marketing approval in Canada and raised $1.35 million in a public offering.

Financial Review

CEL-SCI recognized no revenues for its fiscal second quarter ending March 31, 2023 and incurred operating expenses totaling $8.2 million during the three-month period. This resulted in a net loss available to common shareholders of ($8.3) million, or ($0.18) per share.

For the quarter ending March 31, 2023 versus the same ending March 31, 2022:

- Expenses for research and development fell 7% to $6.1 million from $6.5 million. The primary contributors to the decline are 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 31% to $2.1 million from $3.0 million predominantly due to lower stock compensation expense;
- Other non-operating items were nil million compared to a $2,195 gain with the difference due to the absence of a derivative gain in 2Q:23 that was present in 2Q:22;
- Net interest expense, which is related to lease liabilities was ($0.2) million compared with ($0.3) million;
- Net loss totaled ($8.3) million versus ($9.8) million or ($0.18) and ($0.23) per share, respectively.

As of March 31, 2023, cash and equivalents totaled $10.0 million. Cash burn for the three-month period amounted to approximately ($7.6) million versus ($3.3) million in the prior year period. After the end of the quarter, CEL-SCI executed a $1.35 million public offering. CEL-SCI holds no debt on its balance sheet.

Further highlights from the press release and filing include the engagement of a regulatory consultancy with expertise in European regulatory matters to help prepare the documents for a European Medicines Agency (EMA) submission. CEL-SCI is close to receiving validation from the FDA for its manufacturing facility and the process is moving toward completion. The process had previously been delayed as COVID-related regulations gave preference to facilities manufacturing COVID products.

Pursuing Conditional Approval from Health Canada

In an April 19th press release CEL-SCI announced its intent to pursue a conditional approval pathway for Multikine in advanced primary head and neck cancer. Conditional pathways are justified by limiting eligibility to drugs intended for serious and life-threatening diseases or where there is unmet need. It is an appropriate pathway for an indication that is considered a rare disease that lacks effective treatment.

Conditional approval is a regulatory mechanism used by Health Canada to provide approval for marketing in Canada and is based on a less rigorous submission than is required for a full approval. It is intended for serious conditions that have few if any other treatments available and allows patients earlier access. If Health Canada grants conditional approval it is usually for a limited period while additional studies are conducted to support the product's safety and effectiveness.

CEL-SCI reported that it held a productive pre-submission meeting with Health Canada. The conversation with the agency explored how patients at lower risk for recurrence could be targeted for treatment and which post-market commitments could help ensure that only the most suitable patients would be treated with Multikine.

Poster Presentation at European Society for Radiotherapy and Oncology (ESTRO) 2023 Congress

CEL-SCI presented data from its Phase III IT-MATTERS trial in a poster presented at the European Society for Radiotherapy and Oncology (ESTRO) 2023 Congress in Vienna, Austria. Its title is "Histopathology population (HPP) confirms Multikine [Leukocyte Interleukin Injection (LI)] treatment (Tx) outcome in naïve locally advanced primary head & neck squamous cell carcinoma SCCHN)." The poster was presented during the Head & Neck Cancer Session on Saturday, May 13, 2023. Details of the event were provided in a May 15th press release.

The histopathology of tumor samples from patients in the IT-MATTERS trial showed a different tumor and tumor microenvironment cellular profile at surgery than that exhibited by standard of care treated subjects at surgery. This suggests that Multikine brought about a change in the three weeks following its administration. Low-risk histopathology subjects that were treated with Multikine compared with low-risk histopathology subjects treated with standard of care demonstrated:

- Overall Survival of 63.9% vs 44.4% (hazard ratio: 0.64 [95% confidence interval {CI} 0.41, 1.01])
- Progression Free Survival of 56.9% vs 41.1% (hazard ratio 0.67 [95% CI 0.44, 1.02])
- Local Regional Control of 73.1% vs 63.6% (hazard ratio 0.62 [95% CI 0.35,1.09])
- Multikine-treated subjects had a significantly lower (39.1% [45/115]) death rate versus a 53.7% (51/95) death rate for standard of care alone (two-sided Fisher Exact Test p=0.038)

European Congress on Head & Neck Oncology

CEL-SCI presented new data at the 10th European Congress on Head & Neck Oncology held in Lisbon, Portugal. The March 8th presentation was followed by a publication of a summary of the findings in a poster entitled "Leukocyte Interleukin Injection (LI) immunotherapy followed by radiotherapy extends overall survival (OS) in treatment naïve locally advanced primary squamous cell carcinoma of the head & neck: the IT-MATTERS Study." Eyal Talor, CEL-SCI's Chief Scientific Officer traveled to Lisbon to present the data demonstrating the survival and death rate advantages of the patients treated with Multikine over control in the population with a lower risk of recurrence who received only radiotherapy following surgery.

Significant findings inlcude:

- The overall survival advantage accelerated and increased over time, with the benefit of adding Multikine + CIZ to the treatment regimen as compared to Standard of Care (SOC) alone increasing from 2.8% at three years, to 8.3% at four years, to 15.6% at five years, with a 49.7% survival for control vs. 65.3% for the Multikine treated group at five years;
- The hazard ratio was 0.70 (95% CI: [0.49 - 1.00]) which represents a 43% survival extension:
- Progression free survival was 8.4% higher at five years for patients treated with Multikine + CIZ + SOC as compared to patients treated with SOC control alone;
- 16.5% of IT-MATTERS subjects were early tumor responders, including complete tumor responders (confirmed by pathology at surgery), following the three-week treatment with Multikine as compared to 0% who were treated with SOC alone;
- Multikine patients who had an early tumor response had significantly improved survival. Their death rate was only 15.6% vs. 48.7% death rate for the control patients;
- Even the patients who did not have an early tumor response had a better survival than did the control group patients, with a 43.8% death rate vs. 48.7% death rate for control.

Regulatory Submission

Now that the company has completed the IT-MATTERS trial and reported details of the trial outcome at several major conferences, attention turns to the next steps in the regulatory process and submission of a BLA. Efforts are being made not only with the FDA in the United States, but also with Health Canada and in Europe through the hiring of a consultancy to help prepare a potential filing in the trade union. 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

- Presentation of poster at ECHNO – March 2023
- Pre-submission meeting with Health Canada – April 2023
- Public offering of common stock – April 2023
- Presentation of poster at ESTRO – May 2023
- 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 has made advances on the regulatory side meeting with Canadian regulators and electing to pursue the conditional approval pathway in that country. The company has also hired a consultant that will assist in the process to gain marketing approval in Europe. Other efforts include participation at several more scientific conferences where Multikine's features were presented both in terms of survival advantage and histopathology. CEL-SCI continues to direct its efforts towards compiling and analyzing data. 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

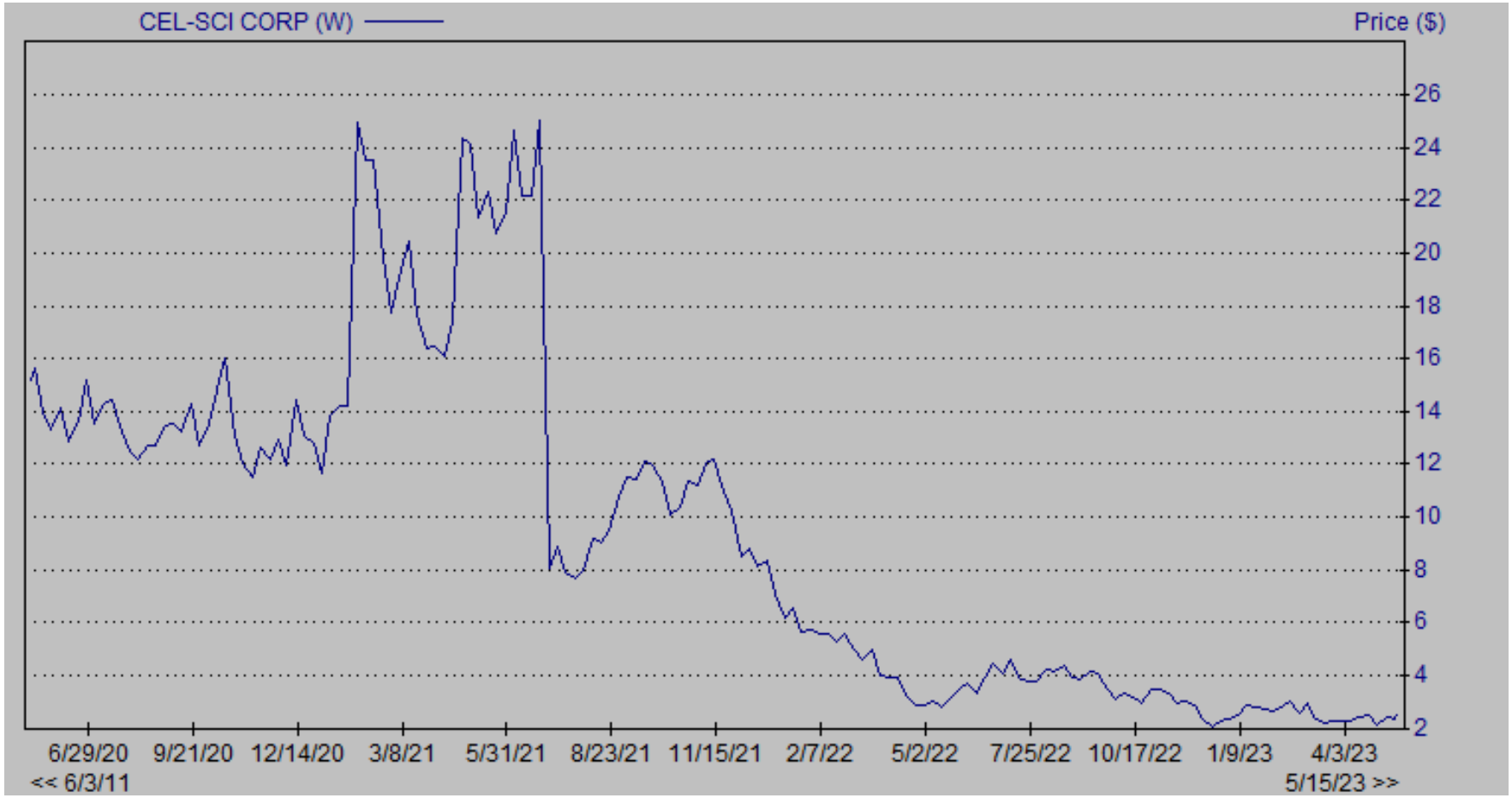
CEL SCI Corporation	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$26.6**
Research & Development	$25.4	$5.4	$6.1	$5.0	$5.0	$21.5	$18.0	$12.0
General & Administrative	$10.7	$2.3	$2.1	$2.6	$2.5	$9.5	$10.0	$10.0
Income from operations	($36.1)	($7.7)	($8.2)	($7.6)	($7.5)	($30.9)	($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)	($0.7)	($0.8)	($0.8)
Pre-Tax Income	($37.6)	($8.0)	($8.3)	($7.8)	($7.7)	($31.9)	($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)**	**($8.3)**	**($7.8)**	**($7.7)**	**($31.9)**	**($28.8)**	**$3.8**
Reported EPS	**($0.87)**	**($0.18)**	**($0.18)**	**($0.17)**	**($0.16)**	**($0.69)**	**($0.48)**	**$0.06**
Basic Shares Outstanding	43.15	44.44	45.59	47.00	49.00	46.51	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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