Zacks Small-Cap Research

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CEL-SCI Corporation (CVM: NYSE)

CVM: Model Revisions

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 75% 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 EU UK and Canada.

Current Price (7/28/2023)	$1.66
Valuation	**$7.00**

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 applications in the EU, UK and Canada.

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	**1.52**
One-Year Return (%)	**-55.9**
Beta	**1.6**
Average Daily Volume (sh)	**263,053**
Shares Outstanding (mil)	**47.2**
Market Capitalization ($mil)	**78.4**
Short Interest Ratio (days)	**29.6**
Institutional Ownership (%)	**11.9**
Insider Ownership (%)	**3.6**
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					$0.0 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 A	-$0.17 E	-$0.16 E	-$0.69 E
2024					-$0.48 E
2025					-$0.38 E

WHAT'S NEW

CEL-SCI Corporation (NYSE: CVM) provided several updates in recent weeks. This includes details from its pre-submission meeting with the FDA, a poster presentation related to Multikine performance in subjects with low PD-L1 expression and the announcement of a small capital raise. We update our model to reflect the need for additional studies to support either conditional for full approval in the United States, and modify our probability adjusted conditional or full approval in other geographies including Canada, the United Kingdom and Europe.

Capital Raise

CEL-SCI announced that it intended to raise additional capital to support continued funding of Multikine development and general corporate purposes in a July 17th press release. Pricing was subsequently determined and 2.5 million shares were offered at $2.00 per share yielding gross proceeds of $5.0 million. ThinkEquity is acting as sole book-running manager for the offering. The deal was closed on July 20th.

FDA Meeting

CEL-SCI updated investors on its interactions with the FDA in a July 14th, 2023 press release. While the FDA suggested that the company submit a biologic license application (BLA) based on available data, it also requested additional information which will be provided in a subsequent meeting with the agency. Few details were provided regarding the next steps; however, we anticipate another study will be required before the company may successfully file a BLA with the FDA.

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 for Boston Biostatistics Research Foundation, Inc.

CEL-SCI's statistical consultant, Philip Lavin, PhD, presented new data examining the survival advantage of Multikine in the IT-MATTERS study. The July 10th presentation was announced in a press release and held at the American Head and Neck Cancer Society's (AHNS) 11th Annual International Conference on Head and Neck Cancer on July 10, 2023 in Montreal, Canada. The presentation, which was entitled "Tumor cell PD-L1 biomarker confirms Leukocyte Interleukin Injection (LI) treatment (Tx) survival outcome advantage in naïve locally advanced primary head & neck squamous cell carcinoma (SCCHN), the IT-MATTERS Study" highlighted the performance of Multikine in patients with low levels of PD-L1 expression.

The data demonstrated a relationship between low PD-L1 expression and efficacy of Multikine. The proportion of responders in the low PD-L1 group was 91.7%; this compares with low PD-L1 expression in the non-responders group which was 73.8%. High PD-L1 expressers had a lower level of responders in the Multikine group (8.3%) compared with the non-responder group (17.7%).

Conclusions from the presentation are that Multikine is more effective in patients with low levels of tumor cell PD-L1. This contrasts with the effectiveness of PD-L1 and PD-1 inhibitors that work well in patients with high levels of this marker. This is a positive for patients with tumors that have low levels of PD-L1 expression, offering them an alternative when PD-L1/PD-1 inhibitors have a low likelihood of working.

Valuation

We update our valuation based on CEL-SCI's anticipated strategy for the United States and other geographies. In the United States, we model costs for an additional study and extend anticipated approval to 2028. We adjust our penetration estimate to be able to address a third of low risk SCCHN patients in the United State by the fifth year of commercialization. This is just over 5,000 treatments by 2032 and 2033. We anticipate that new competition will arise in 2034, and individuals treated will slowly decline in the following years. Based on the positive statements from CEL-SCI management, we anticipate an application for conditional approval in Canada. While timing was not provided, we expect that a submission could take place in the next twelve months, followed by approval in 2025 and first sales in 2026. Canada has about 1,800 cases of SCCHN per year that fall into the low risk category and we see penetration into this addressable market to rise to 30% in the fifth year of commercialization. In 2032 and beyond, we see competition reducing the market share of Multikine. The EU is one of the more attractive markets given its size. We believe that CEL-SCI is in contact with EMA regulators and is strategizing on a plan to make a submission. An additional study may or may not be required and we elect to take a more conservative route and forecast a submission in the next twelve months, followed by approval in 2025, then a period of pricing negotiations and eventually sales in 2026. Similar to other regions, penetration into the near 22,000 low risk SCCHN cases is expected to start at 3% and rise to 30% by year six then market share stabilization and declines in 2033 and 2034. The final geography that we include in our DCF model is the UK. According to Cancer Research UK, there are about 12,400 head and neck cancers. As we work down to the addressable market for Multikine, we have a population of about 3,000 that are appropriate for treatment. Similar to other regions, we anticipate a regulatory submission and approval with first sales in 2026. By year six, we see Multikine providing treatments to about 30% of the addressable market which is about 928 individuals in 2031.

Pricing for immunotherapy, especially immuno-oncology products is strong. The United States has the most favorable pricing that is in the mid-$100,000 range. With anticipated inflation of 3% per annum, we expect revenues per treatment of $162 thousand in the US by the first year of sales in 2028. Other regions are forecasted with inflation rates at 2%. We continue to anticipate that an approved product will be commercialized by a partner and that upfronts, milestones and royalties will be paid to CEL-SCI or that an acquisition will take place recognizing a similar valuation approach. In our model, for simplicity, we incorporate all economic value received by CEL-SCI in our royalty. Royalty rates will range from 25% to 30% which in the early years reflect a proportion passed through to ERGOMED related to the co-development agreement.

We estimate research and development costs running at about $20 million per year over the 2024 to 2026 period, when they fall to $15 million and $8 million as final regulatory submissions are made. By 2029, R&D will fall to zero as Multikine is commercialized. In all, R&D estimates include an additional $81 million in expense for future studies required to obtain full approval in Canada and to receive consideration in the United States. General and administrative costs are forecasted at $10 million per year then rising at a 3% rate in 2026 and beyond. Cash taxes are calculated at 29.7%.

Our discounted cash flow (DCF) model uses a net present value (NPV) of future cash flows to determine our valuation. The discount rate used is 15%, terminal growth after year 20 is -10%. We also apply a probability of success factor based on historical precedent and CEL-SCI specific factors of 60%.

The product of our forecasts and estimates produces a valuation of approximately $7.00 per share.

CEL-SCI Milestones

- Presentation of poster at ECHNO – March 2023
- Pre-submission meeting with Health Canada – April 2023
- Presentation of poster at ESTRO – May 2023
- Presentation at AHNS – June 2022
- Public offering of common stock – July 2023
- Development of clinical study report – 2023
- Development of paper(s) for publication in peer reviewed journal – 2023
- Submission of license application to various agencies – 2024+

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 held a meeting with the FDA which is requesting additional information. We anticipate that an additional study will be required before full approval will be granted. We do see the option for provisional approval in multiple jurisdictions and anticipate that regulatory meetings and efforts to make these applications will take place over the next quarters. CEL-SCI has continued to present new data from its IT-MATTERS clinical trial and most recently highlighted Multikine's efficacy in subjects with varying levels of PD-L1 expression. We update our model with information from the latest press releases and filings to generate our valuation and price target of $7.00 per share.

PROJECTED FINANCIALS

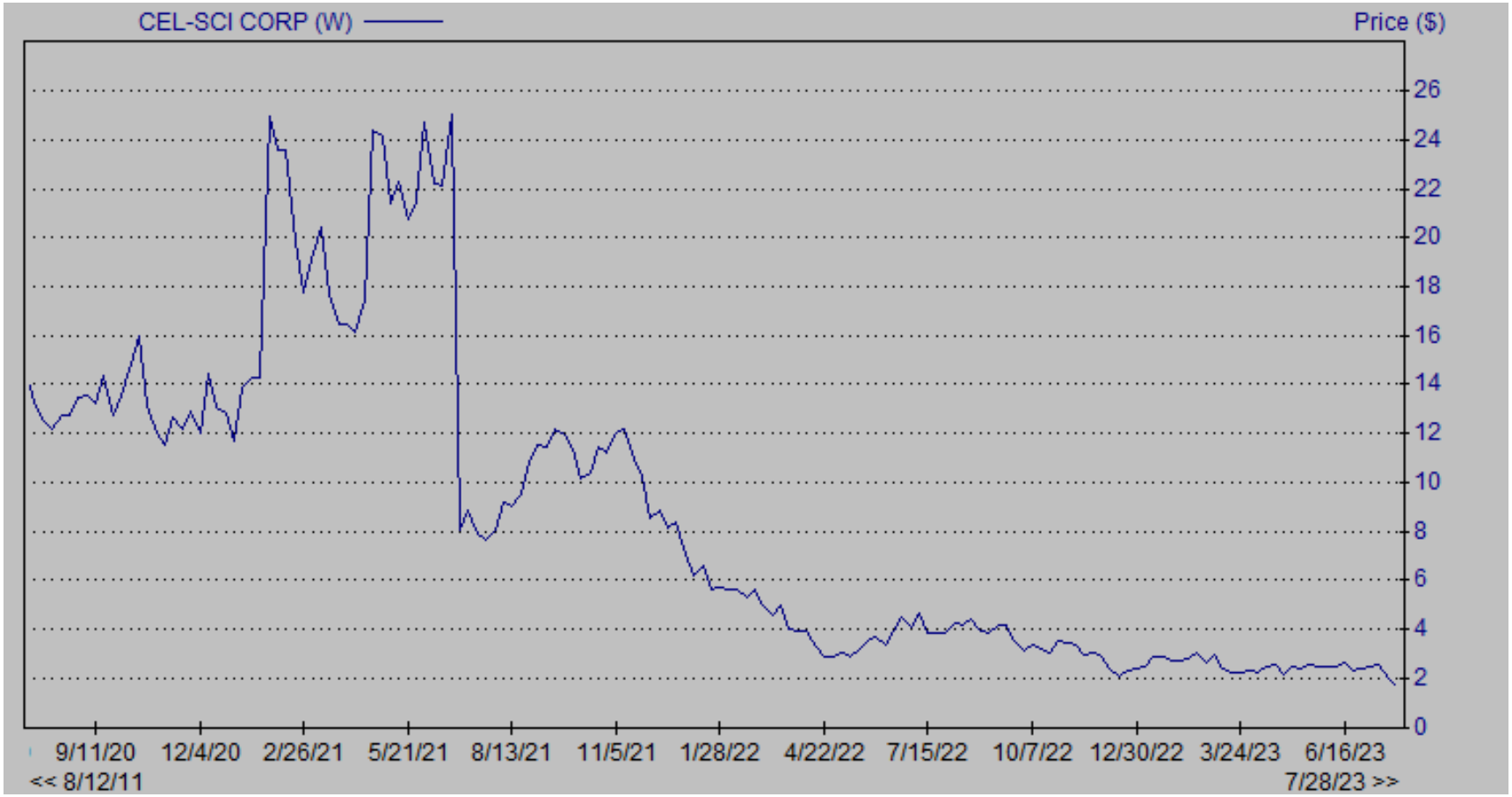
CEL-SCI Corporation - Income Statement

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**	**$0.0**
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)	($22.0)
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)	($22.8)
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)**	**($22.8)**
Reported EPS	**($0.87)**	**($0.18)**	**($0.18)**	**($0.17)**	**($0.16)**	**($0.69)**	**($0.48)**	**($0.38)**
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

HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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