

CEL-SCI Corporation

(CVM - NYSE)

First Quarter Fiscal Year 2022 Results

OUTLOOK

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.

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.

Current Price (2/15/2022) **\$5.83**
Valuation \$13.00

SUMMARY DATA

52-Week High **27.86**
 52-Week Low **5.11**
 One-Year Return (%) **-72.6**
 Beta **2.10**
 Average Daily Volume (sh) **880,046**

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

Shares Outstanding (mil) **43.3**
 Market Capitalization (\$mil) **252**
 Short Interest Ratio (days) **11.2**
 Institutional Ownership (%) **36.5**
 Insider Ownership (%) **3.88**

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 2021 Estimate **N/A**
 P/E using 2022 Estimate **N/A**

Zacks Rank **N/A**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Dec)	(Mar)	(Jun)	(Sep)	(Sep)
2021	\$0.0 A				
2022	\$0.0 A	\$0.0 E	\$0.0 E	\$0.0 E	\$0.0 E
2023					\$93.9 E
2024					\$174.1 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	-\$0.16 E	-\$0.15 E	-\$0.13 E	-\$0.49 E
2023					\$0.91 E
2024					\$2.61 E

WHAT'S NEW

First Quarter Fiscal Year 2022 Financial Results

On February 14, 2022, CEL-SCI Corporation (NYSE: CVM) issued a [press release](#) and filed Form [10-Q](#) with the SEC reporting first quarter fiscal year 2022 results. CEL-SCI recently announced in October 2021 that the commercial-scale buildout of the company's Multikine manufacturing facility was [completed](#). CEL-SCI intends to file a BLA for Multikine this year.

CEL-SCI recognized no revenues and incurred operating expenses totaling \$8.8 million for the quarter. This resulted in a net loss available to common shareholders of (\$8.8) million, or (\$0.20) per share.

For the first quarter ending December 31, 2021 versus the same ended December 31, 2020:

- Expenses for R&D increased by 12% to \$6.1 million from \$5.4 million. Major components of this increase include approximately \$0.6 million in employee stock compensation expense and \$0.3 million in depreciation of leasehold improvements to the manufacturing facility that were placed in service in October 2022. This increase is offset by overall reductions in expenses related to the Phase 3 clinical study and other research and development costs of approximately \$0.2 million;
- G&A expenses decreased by 17% to \$2.8 million from \$3.3 million. A major component of the decrease is an approximate \$0.6 million reduction in employee stock compensation costs resulting from a change in the requisite service period for the performance-based stock options;
- Gain on derivative instruments was \$0.4 million compared to \$0.9 million;
- Other non-operating gains were a loss of \$31,000 compared to a gain of \$122,000;
- Net interest expense was (\$0.3) million compared with (\$0.3) million;
- Net loss available to common shareholders totaled (\$8.8) million versus (\$8.0) million or (\$0.20) and (\$0.21) per share, respectively.

As of December 31, 2021, cash and equivalents totaled \$37.1 million. Cash burn for the quarter amounted to approximately (\$4.8) million versus (\$7.0) million in the prior year period, with the majority of the difference attributable to manufacturing facility-related capital expenditures that were recognized in the year prior period. CEL-SCI carries lease obligations, both financial and operating, valued at approximately \$12.9 million and \$2.0 million, respectively, excluding current portion. The amounts are related primarily for the manufacturing facility (San Tomas) lease as well as office headquarters and R&D laboratory. CEL-SCI holds no debt on its balance sheet.

Completion of Multikine Manufacturing Facility (San Tomas) Buildout

CEL-SCI [announced](#) on October 22, 2021 the completion of its commercial-scale buildout of its Multikine cGMP¹ manufacturing facility. The construction began in 2020, supported by a \$11 million investment, and expanded the facility, adding various upgrades to bring it in line with the FDA's cGMP regulations. The facility's production capacity has been doubled and renovations also have been made in anticipation of the additional personnel required for a second manufacturing shift. CEL-SCI staff recently returned to the renovated facility.

Immunotherapy Revenue Analysis

In order to update our pricing and revenue assumptions for Multikine and for other immunotherapies, we conducted an analysis on revenue data available through EvaluatePharma. The data were downloaded, scrubbed and analyzed. We recorded total IO revenues that were patent protected or approved under exclusivity, aligning them by year of first commercialization. The effort yielded revenue arcs over the life of a product, as well as summary statistics on their size.

Our data query sought all revenues for branded immuno-oncology drugs over the 2010 to 2021 period. We excluded products that had insufficient data and combined revenues for products that were marketed by multiple companies. The data were further refined so that immunotherapies with two or fewer years of revenues and 12 or greater years of revenues were excluded as the former did not contribute materially to the development of the

¹ Current Good Manufacturing Practice

revenue arc, and the latter contained data that do not reflect the current pricing environment. We excluded the first year of revenues as this in likely all cases did not represent a full year of product marketing.

As expected, dispersion among revenue amounts increased as the time series progressed. A majority of revenues are clustered beneath \$500 million per year while there are only a few drugs that generated over \$1 billion per year.

Exhibit I - Summary Data, Immunotherapy Revenue Over Time (\$MM)²

Full Year	1	2	3	4	5	6	7	8	9	10
Mean	\$375	\$894	\$1,447	\$2,181	\$3,571	\$4,088	\$6,837	\$748	\$845	\$994
Median	\$286	\$455	\$576	\$724	\$1,055	\$869	\$5,088	\$748	\$845	\$994
N	14	13	12	11	7	6	4	2	2	2

Our estimates for Multikine in global revenues for the first full year of revenues is \$360 million and a peak in year eight of \$1.7 billion. In the early stages of our estimates, we were closer to the mean, but as the products matured, our estimates fell behind both the mean and the median of this group. We attribute a material proportion of the difference to several high revenue products in the checkpoint inhibitor class which over time have been approved in multiple indications. This compares with our addressable market which is a subset of the head and neck cancer market. We use the results from this analysis to check the reasonableness of our estimates. While we appear to be close to the average in the early years, our model falls well behind both the mean and the median as the time series progresses. If Multikine is approved in a wider set of indications, we see further upside in the later years of our forecast. Another factor that should be considered when comparing our future estimates and the revenues provided above is inflation. There is an approximate 10 year difference between the average revenues above and the timing for our Multikine revenue estimate. Even at a 3% annualized inflation rate, this would generate a 34% difference over a 10 year time period.

Data Readout Refresher From the IT MATTERS Trial

On June 28, 2021, CEL-SCI [reported](#) selected data from the IT-MATTERS trial. While details for the primary endpoint were not provided, an important subset of the population in the Multikine arm produced a statistically significant 14.1% improvement in overall survival (OS) relative to standard of care (SoC). The p-value for the 5-year result was 0.0236 and the Hazard Ratio (HR) was 0.683 in a population representing about 40% of all advanced primary squamous cell carcinoma of the head and neck (SCCHN) patients. No safety issues were reported in the study population. We summarize below the key data provided by the company:

Exhibit II – Summary of Subset Data⁴

Survival Advantage	MK + CIZ RT	MK + CIZ RT+Chemo	MK no CIZ	SOC	p-value	Hazard Ratio	Delta
N = 923							
3 year	72.4%	N/A	78.8%	67.5%			4.9%
5 year	62.7%	N/A	55.5%	48.6%	0.0236	0.68	14.1%

Additional detail provided by the company in a [discussion](#) following the July 1st Annual Shareholder Meeting identified a total of 923 patients in the intent to treat (ITT) group which were broken down into three divisions: **Low risk**, which did not receive chemotherapy, **high risk**, which did receive chemotherapy and **exclusions**, which captured patients who had been randomized, received Multikine, but did not elect to move on to SoC. Group sizes were 380 (41.2%) for the low risk (no chemo) group, 467 (50.6%) for the high risk (administered chemo) group and 76 in the exclusion group.

The cancer patient population exhibiting the response in the trial was at the advanced (stage III and IV) primary (not yet treated) SCCHN. Safety for the trial population which was treated with Multikine, did not raise any safety concerns and matched the favorable results demonstrated in earlier trials. No safety issues were found related to drug administration with no detection of late adverse effects.

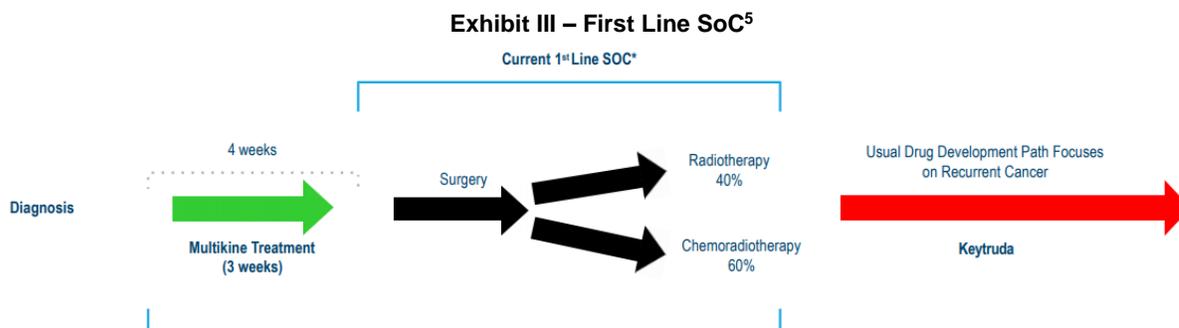
² Compiled by Zacks Analyst, EvaluatePharma. Comparator immuno-oncology drugs include Bavencio, Blincyto, Emplicit, Imfinzi, Keytruda, Klymriah, Libtayo, Opdivo, Provenge, Tecartus, Tecentriq, Tyvyt, Yervoy and Yescarta.

³ The 0.68 Hazard Ratio was better than and below the pre-specified cutoff of 0.721

⁴ Compiled by Zacks' analysts from company press release.

Few details were released regarding the primary endpoint except that the press release noted that the study did not achieve the 10% improvement in OS in the combined study groups. We anticipate that this information will be made available later.

CEL-SCI, while blinded to the study, developed several prospective statistical analyses for the population prior to data lock. The company believes that the early identification of the Multikine neoadjuvant population exhibiting a 14.1% OS advantage at five years will be amenable to the FDA's reviews of the data. In an area of unmet need, such as head and neck cancer, the bar is lower for determined endpoints and we anticipate a meeting with the FDA will provide additional clarity. Safety is a strong point with Multikine, which raised no concerns in the Phase III trial nor in previous studies compared with SoC and with other immunotherapies that are associated with cytokine storm and other negative side effects. We think it is likely that the agency will look favorably upon a new treatment for an unmet need that is safe. To this point, we highlight the case of aducanumab, which demonstrated minimal, if any, efficacy, but was approved by the FDA given the substantial unmet need. We discuss the FDA's thinking on this matter in a recent article [here](#) which may apply to CEL-SCI's application.



Now that the company has made its announcement, key drivers for valuation include the FDA's willingness to accept the data available for a Biologic License Application (BLA) consideration. Additional data and information may be 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. We will update investors on these meetings, their outcomes and impact on valuation when details are made available.

Multikine Near Term Milestones

- Release of subset data for IT MATTERS – June 28, 2021
- Establish internal SCCHN KOL advisory committee – 2021
- Development of clinical study report – 2022
- Request meeting with FDA to determine path forward – 2022
- Development of paper for publication in peer reviewed journal – 2022
- Presentation of data package to review with FDA – 2022
- Address FDA Comments – 2022
- Submission of BLA to FDA – 2022

⁵ Source: CEL-SCI July 2021 Corporate Presentation

Summary

On February 14, 2022, CEL-SCI filed Form [10-Q](#) with the SEC, reporting first quarter fiscal year 2022 results. CEL-SCI recognized no revenues and incurred operating expenses totaling \$8.8 million for the quarter. This resulted in a net loss available to common shareholders of (\$8.8) million, or (\$0.20) per share. As of December 31, 2021, cash and equivalents totaled \$37.1 million. Cash burn for the quarter amounted to approximately (\$4.8) million versus (\$7.0) million in the prior year period.

During the first quarter, CEL-SCI announced the completion of the renovations of the Multikine manufacturing facility. Upgrades were made to not only bring the facility into compliance with the FDA's cGMP regulations, but also to double capacity and make accommodations for a second manufacturing shift. CEL-SCI staff recently returned to the newly-renovated facility.

In our previous report, we conducted an [analysis](#) on immuno-oncology revenues based on data sourced from EvaluatePharma. Our processing of the data selected immuno-oncology drugs that have sufficient history to provide a guide for follow on products in this category. We aggregated each drug's revenue, time-aligning them to generate a mean and median for the group as a reasonableness check on our estimates. We observed that our estimates for global Multikine sales were slightly below the mean in the first full year of sales, but increased at a slower rate to peak as we do not add forecasted revenues for multiple indications as is the case with many of the other products.

CEL-SCI reached the final event in the IT-MATTERS trial in May 2020 and released selected data for a key treatment arm in June 2021. The data demonstrated a 14.1% 5-year survival advantage for patients in the Multikine, surgery and radiotherapy treatment arm. Efforts now are centered on further analysis of the data, scheduling a pre-BLA meeting with the FDA and preparing a manuscript for publication of the study in a journal. There are a number of favorable factors that support the approval of Multikine, which we have listed above. Other cancer drugs have been approved on weaker data such as overall response rate and with less statistical significance than now presented by Multikine. 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. We maintain our price target of \$13 per share.

PROJECTED FINANCIALS

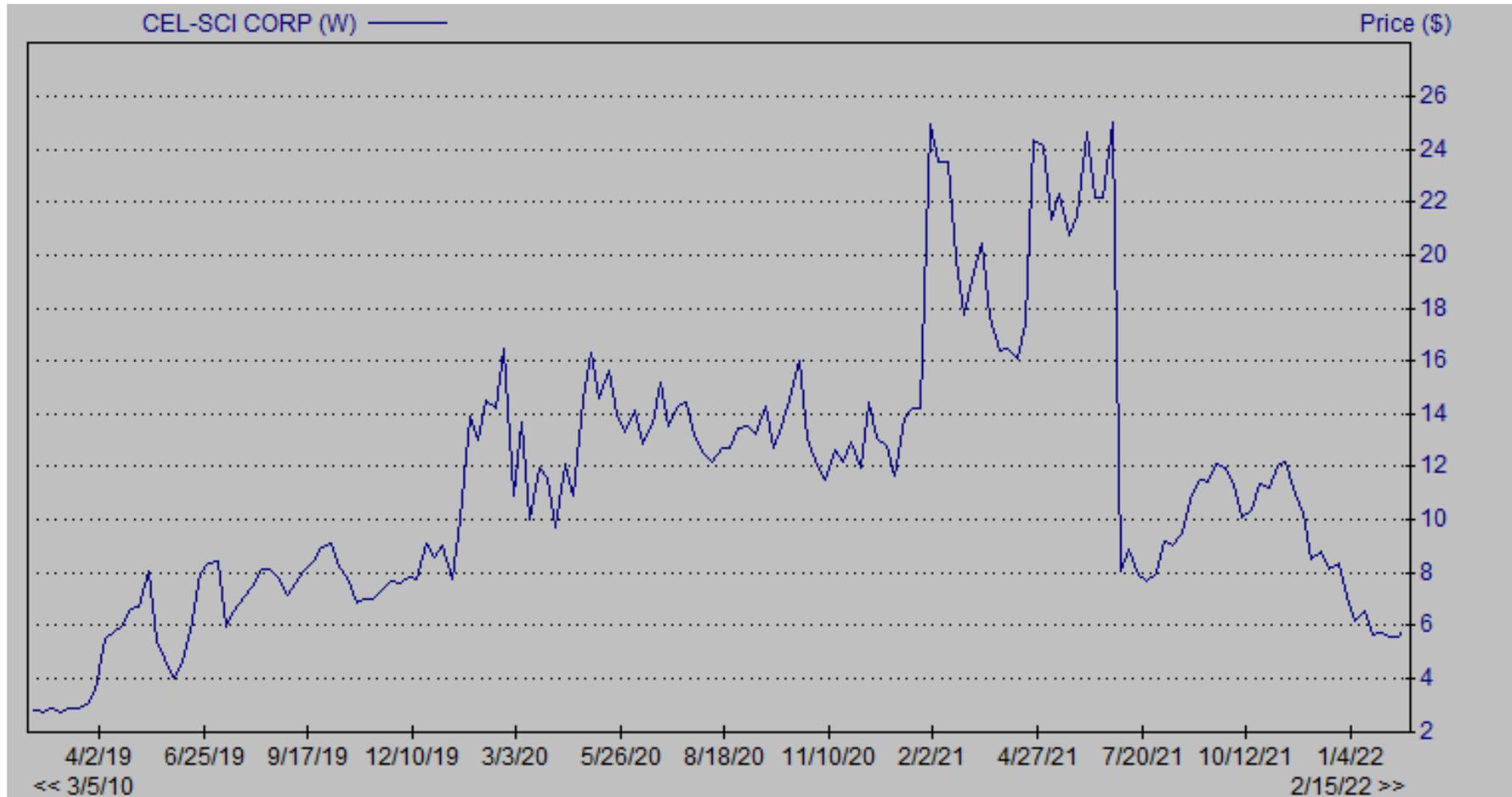
CEL-SCI Corporation - Income Statement

CEL SCI Corporation	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$93.9	\$174.1
Research & Development	\$23.1	\$6.1	\$3.3	\$3.0	\$2.2	\$14.6	\$4.0	\$3.0
General & Administrative	\$13.1	\$2.8	\$3.2	\$3.1	\$3.2	\$12.3	\$12.6	\$13.0
Income from operations	(\$36.2)	(\$8.8)	(\$6.5)	(\$6.1)	(\$5.4)	(\$26.8)	\$77.3	\$158.1
Other Income	\$0.0	\$0.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Interest Expense	(\$1.2)	(\$0.3)	(\$0.3)	(\$0.3)	(\$0.3)	(\$1.2)	(\$1.6)	(\$1.6)
Pre-Tax Income	(\$37.4)	(\$8.8)	(\$6.8)	(\$6.4)	(\$5.7)	(\$28.0)	\$75.7	\$156.5
Provision for Income Tax	\$0.0	\$0.0				(\$7.0)	\$21.9	\$0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	29.0%	29.0%
Net Income	(\$37.4)	(\$8.8)	(\$6.8)	(\$6.4)	(\$5.7)	(\$21.0)	\$53.7	\$156.5
Reported EPS	(\$0.92)	(\$0.20)	(\$0.16)	(\$0.15)	(\$0.13)	(\$0.49)	\$0.91	\$2.61
Basic Shares Outstanding	40.69	43.08	43.11	43.25	43.30	43.19	59.00	60.00

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

HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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