

CEL-SCI Corporation

(CVM - NYSE)

Fiscal Year 2020 Results

Based on our DCF model and a 15% discount rate, CEL-SCI is valued at approximately \$19.00 per share. Our model applies a 70% probability of ultimate approval and commercialization for Multikine in head and neck cancer. The model includes contributions from the US, EU and rest of world.

Current Price (1/5/2021) **\$12.52**
Valuation \$19.00

OUTLOOK

CEL-SCI is developing two platforms, Multikine and LEAPS. Multikine is being used in a Phase 3 trial for head and neck cancer while LEAPS is conducting preclinical studies for RA, Pandemic Flu and breast cancer. After reporting the 298th and final event in its IT-MATTERS trial, we anticipate a top line readout for Multikine's Phase III trial in the near term.

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 2021 FDA approval of Multikine for head and neck cancer and a 2021 launch of the compound in the US, followed by a subsequent launch in the EU and global availability by 2022 that will be achieved through the efforts of partners.

SUMMARY DATA

52-Week High **18.00**
 52-Week Low **6.35**
 One-Year Return (%) **40.0**
 Beta **2.2**
 Average Daily Volume (sh) **554,839**

Shares Outstanding (mil) **39.8**
 Market Capitalization (\$mil) **498**
 Short Interest Ratio (days) **18.3**
 Institutional Ownership (%) **30.8**
 Insider Ownership (%) **4.20**

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 2020 Estimate **N/A**
 P/E using 2021 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	Q2	Q3	Q4	Year
	(Dec)	(Mar)	(Jun)	(Sep)	(Sep)
2019	\$0.1 A	\$0.2 A	\$0.1 A	\$0.1 A	\$0.5 A
2020	\$0.0 A	\$0.3 A	\$0.2 A	\$0.0 A	\$0.6 A
2021					\$9.7 E
2022					\$194.7 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	\$0.04 A	-\$0.22 A	-\$0.37 A	-\$0.14 A	-\$0.71 A
2020	-\$0.16 A	-\$0.25 A	-\$0.27 A	-\$0.14 A	-\$0.82 A
2021					-\$0.11 E
2022					\$3.15 E

WHAT'S NEW

Fiscal Year 2020 Operational and Financial Results

On December 30, 2020 CEL-SCI Corporation (NYSE: CVM) [reported](#) its fiscal year 2020 operational and financial results for the year ending September 30, 2020 and filed its companion [10-K](#).

Following a near decade-long duration of the IT-MATTERS trial that evaluated biologic Multikine in head and neck cancer, the company announced the trial had reached the targeted 298 event threshold on May 4, 2020. Reaching this milestone signalled the company's contract research organization (CRO) to begin data evaluation. The study is now undergoing database lock and analysis. In [December 2020](#), CEL-SCI provided an update on the study data analysis highlighting that it was being conducted according to a plan that was approved prior to data lock. The effort has been complicated by both the geographical diversity of trial sites and delays related to the pandemic. CEL-SCI will publicize the results once the full analysis has been finalized and results are presented to the firm.

CEL-SCI has initiated the development of an immunotherapy targeting SARS-CoV-2 using the company's patented Ligand Epitope Antigen Presentation System (LEAPS) peptide technology. Initial *in vivo* experiments demonstrated that after a single injection, LEAPS COVID-19 conjugates induced antibody response faster and in higher titers than expected against a highly conserved region of SARS-CoV-2, paving the way for challenge studies using live virus at the University of Georgia Vaccine Center. Following the end of the fiscal year, in [December 2020](#), CEL-SCI announced results from its SARS-CoV-2 virus challenge in human ACE2 transgenic mouse models. LEAPS COVID-19 peptides achieved a 40% survival rate in the treated group compared to 0% survival in the two control groups.

In September, CEL-SCI was [issued](#) the patent entitled "Method of Preparation and Composition of Peptide Constructs for Treatment of Rheumatoid Arthritis," by the European Patent Office related to its LEAPS platform.

The 10-K reported FY:20 grant revenues of \$559,000, up 21% from \$463,000 in FY:19 due to a Phase 2 Small Business Innovation Research grant of \$1.5 million that was disbursed over multiple years. Total operating expense rose 43% for the year to \$29.5 million versus \$20.7 million in FY:19.

For the fiscal year ended September 30, 2020, compared to the fiscal year ended September 30, 2019:

- Expenses for R&D were \$17.8 million up 41% from \$12.7 million, primarily driven by \$2.1 million in expenses to prepare for the potential filing of a BLA and commercial manufacture of Multikine and \$2.7 million in employee stock compensation expense partially offset by a decrease of approximately \$1.2 million related to the Phase III trial;
- G&A expenses were \$11.7 million, up 46% from \$8.0 million, on a \$3 million increase in employee stock compensation costs;
- Loss on derivative instruments was (\$349,000) compared to (\$761,000), due to change in fair value of derivative liabilities based on CEL-SCI's stock price;
- FY:20 saw warrant inducement expense of (\$806,000), absent in the prior year;
- Other non-operating gain of \$888,000 was up 63% from \$546,000 relating to a Securities Purchase Agreement with Ergomed;
- Net interest expense was (\$1.0) million compared to (\$1.8) million due to reduction in interest rate applied to CEL-SCI's finance leases, adjusted to reflect adoption of ASC 842;

As of September 30, 2020, cash was \$15.5 million and cash burn for FY:20 was (\$18.0) million for the year, almost flat with (\$16.5) million recognized in the prior year period. Financing cash flows were \$25.0 million reflecting proceeds from sale of common stock and exercise of warrants and options. Following the reporting period for FY:20, CEL-SCI [raised](#) an additional \$14.7 million announced December 11, 2020.

Final Event in IT-MATTERS Trial

After almost a decade, the IT-MATTERS clinical trial experienced its final event, reported in a [press release](#) on May 4, 2020. The study is now in the database lock and analysis phase. The event-driven trial for head and neck cancer added its first patients in 2011 in the US, Canada, UK, France and 20 other countries. 928 patients were enrolled, with the final individual treated in September 2016. The primary endpoint for the study was an overall

survival benefit of 10% over standard of care alone in defined areas of the head and neck. With data in lock and analysis, once the results are made available to CEL-SCI, it will present findings at a conference.

The trial had three arms including:

- 1) Multikine plus CIZ followed by SOC
- 2) Multikine (CIZ-exclusion) followed by SOC
- 3) SOC therapy as the active comparator

Only the M+CIZ and SOC groups were used to contribute to the event total for the trial. Over the duration of the trial, an independent data monitoring committee (IDMC) provided periodic checks approximately every 6 months to ensure patient interests were met and the trial was conducted ethically. In [December 2020](#), the study entered its final stage of statistical analysis of all study data.

The analysis of data has taken much longer than we expected in an extended process that management has attributed to the broad geographical extent of the trial and impacts from the pandemic. During the data analysis we expect the following to take place:

- Analysis of primary and secondary endpoints
- Full review of dataset and safety results
- Presentation of results at major oncology conferences
- Publication of results in journals

Once the full dataset is available, CEL-SCI will meet with the FDA and other regulatory authorities to develop a plan for the submission of a biologics license application (BLA). Management did not provide any guidance regarding a timeline but we caution investors that unexpected delays due to the global pandemic may extend the final stage thus, the timing of any reporting of data could differ from our initial expectations. The CROs are fully responsible for the timing for the development of the data analysis and CEL-SCI management is required to disclose material information once available. Therefore, we expect CEL-SCI will share selected data with investors from the full analysis within a few days of it being available to the company.

Capital Raise

On March 26th, CEL-SCI [closed](#) a \$7.7 million capital raise offering 630,500 shares at \$12.22 per share. An option to issue an additional 94,575 shares was exercised raising an additional \$1.15 million. Aegis Capital executed the deal. Exercise of warrants has also contributed substantial funds to CEL-SCI's coffers, as the steadily rising stock price has spurred the action. During fiscal year 2020, a net \$25.0 million in financing cash flows were received, comprised of \$14.0 million in common stock, \$12.1 million from warrants and a small additional amount from option exercise and officer and director purchases. This was partially offset by financing issuance costs and payments related to leases.

After the end of the FY:20 reporting period, on December 11, 2020, CEL-SCI [announced](#) the closing of \$14.7 million in proceeds, issuing 1 million common shares at \$14.65 per share. The underwriter was granted 30-day option to purchase up to 15,000 additional shares to cover over-allotments.

Letter to Shareholders

On January 4, 2021, CEL-SCI CEO, Geert Kersten, [issued](#) a Letter to Shareholders. The letter summarized CEL-SCI's Multikine cancer immunotherapy and the motives behind development, including primary head and neck cancer. The missive noted that 3-year survival rates for this indication have not improved in decades. Mr. Kersten highlighted the unique feature of Multikine's administration *before* surgical intervention. Some Multikine-treated patients in Phase II experienced complete tumor elimination in the three weeks leading up to surgery. Furthermore, the lack of Multikine toxicity enables it to be added to current standard of care without further patient burden. The Phase III trial's 298 required events were met later than originally anticipated due to improved patient survival. With the near decade-long trial concluded, data is now under lock and analysis, awaiting results.

Summary

CEL-SCI reached the final event in the IT-MATTERS trial in early May 2020 and we expect the final analysis to be available shortly. The company added \$25.0 million in cash from financing over FY:20 and another \$14.7 million in December 2020. We eagerly await results while CEL-SCI readies itself for potential BLA submission. The duration of the analysis period had exceeded our expectations and management has responded that the large scope of the trial and impacts from COVID have slowed the data analysis process. If Multikine is able to meet or surpass its primary endpoint of a 10% increase in overall survival as compared to standard of care alone, we see substantial upside to current levels. We maintain our target price of \$19.00.

PROJECTED FINANCIALS

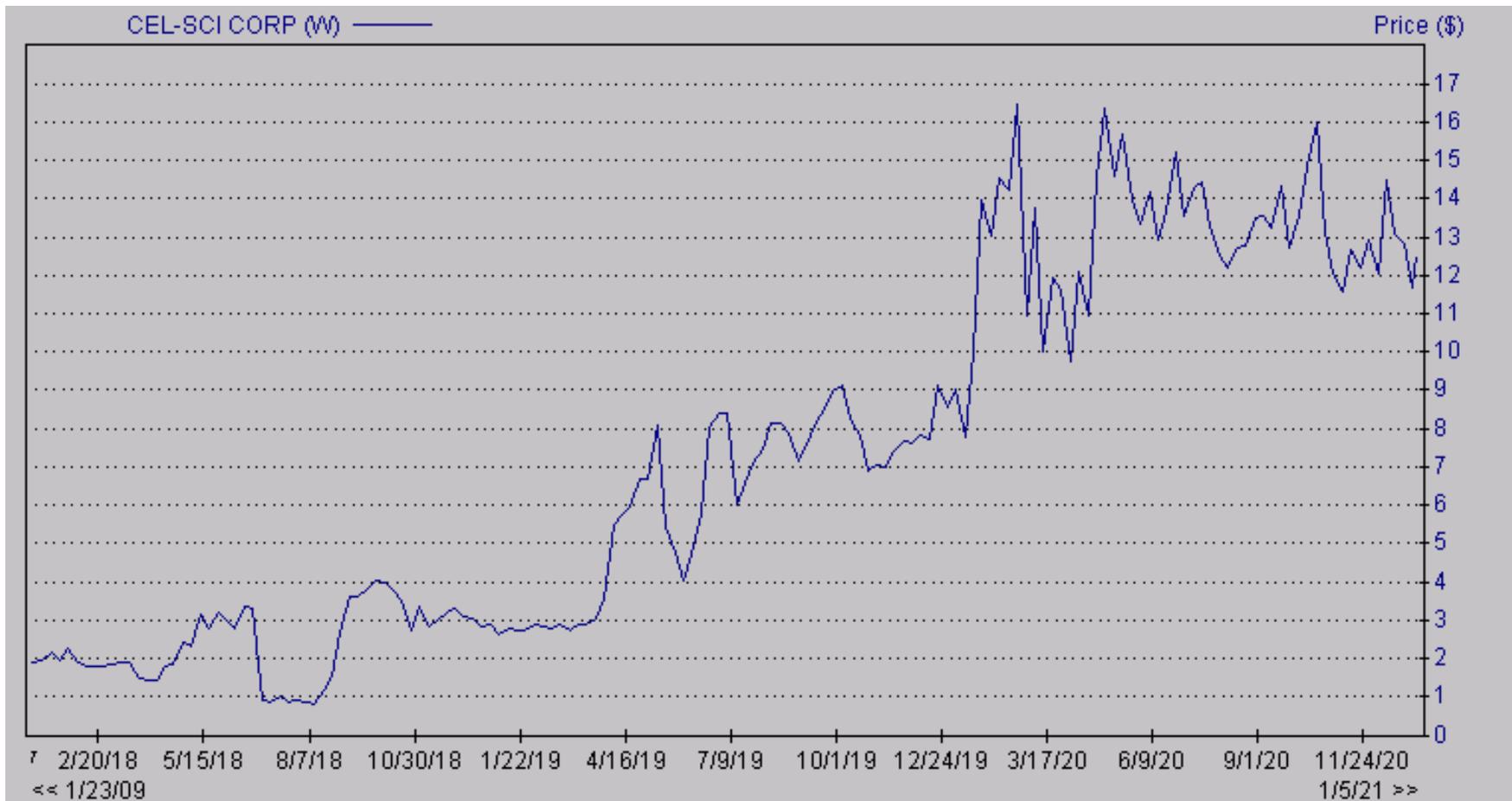
CEL-SCI Corporation - Income Statement

CEL SCI Corporation	2019 A	Q1 A	Q2 A	Q3 A	Q4 A	2020 A	2021 E	2022 E
Total Revenues	\$0.5	\$0.0	\$0.3	\$0.2	\$0.0	\$0.6	\$9.7	\$194.7
<i>YOY Growth</i>	-3%	-72%	98%	80%	-63%	21%	1633%	1911%
Research & Development	\$12.7	\$4.2	\$4.4	\$3.9	\$5.3	\$17.8	\$5.0	\$1.0
General & Administrative	\$8.0	\$2.6	\$2.6	\$3.2	\$3.3	\$11.7	\$9.1	\$9.4
Income from operations	(\$20.2)	(\$6.8)	(\$6.7)	(\$6.9)	(\$8.6)	(\$29.0)	(\$4.4)	\$184.3
Other Income	(\$0.1)	\$1.6	(\$2.1)	(\$3.0)	\$3.4	(\$0.2)	\$0.0	\$0.0
Interest Expense	(\$1.8)	(\$0.3)	(\$0.3)	(\$0.3)	(\$0.3)	(\$1.0)	(\$1.6)	(\$1.6)
Pre-Tax Income	(\$22.1)	(\$5.5)	(\$9.0)	(\$10.2)	(\$5.5)	(\$30.3)	(\$6.0)	\$182.7
Provision for Income Tax	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%
Net Income	(\$22.1)	(\$5.5)	(\$9.0)	(\$10.2)	(\$5.5)	(\$30.3)	(\$6.0)	\$182.7
Reported EPS	(\$0.71)	(\$0.16)	(\$0.25)	(\$0.27)	(\$0.14)	(\$0.82)	(\$0.11)	\$3.15
Basic Shares Outstanding	31.17	35.10	36.17	37.45	38.32	36.76	55.00	58.00

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

HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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