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February 23, 2021

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CEL-SCI Corporation (CVM - NYSE)

1Q:21 Financial Update

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 (2/22/2021)	$19.00
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 2022 FDA approval of Multikine for head and neck cancer and a 2022 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	**40.91**
52-Week Low	**6.35**
One-Year Return (%)	**15.2**
Beta	**2.09**
Average Daily Volume (sh)	**1,102,506**
Shares Outstanding (mil)	**40.5**
Market Capitalization ($mil)	**770**
Short Interest Ratio (days)	**4.81**
Institutional Ownership (%)	**30.9**
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 (Dec)	Q2 (Mar)	Q3 (Jun)	Q4 (Sep)	Year (Sep)
2020	$0.0 A	$0.3 A	$0.2 A	$0.0 A	$0.6 A
2021	$0.0 A	$0.1 E	$0.1 E	$0.1 E	$0.3 E
2022					$99.6 E
2023					$199.8 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2020	-$0.16 A	-$0.25 A	-$0.27 A	-$0.14 A	-$0.82 A
2021	-$0.21 A	-$0.19 E	-$0.13 E	-$0.10 E	-$0.64 E
2022					$1.05 E
2023					$2.18 E

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WHAT'S NEW

First Quarter Fiscal Year 2021 Operational and Financial Results

CEL-SCI Corporation (NYSE: CVM) posted a press release and filed its 10-Q for its first quarter of fiscal year 2021 in mid-February 2021. Since our previous report update on January 6, CEL-SCI has continued to monitor its contract research organization's progress analyzing locked data for the IT-MATTERS trial. Management also participated in the Bioconnect Virtual Conference in early January. During the first quarter, ending December 31, 2020, CEL-SCI raised additional capital, provided an update on the IT-MATTERS trial and demonstrated a survival benefit in SARS-CoV-2 infected mice using its LEAPS platform.

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 continues to be conducted according to its initially approved plan. 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. In December 2020, CEL-SCI announced results from its SARS-CoV-2 virus challenge in mice transgenic for human ACE2. LEAPS COV-19 peptides achieved a 40% survival rate in the treated group compared to 0% survival in the two control groups.

Financial results were summarized in the earnings press release and in the Form 10-Q. No revenues were reported in 1Q:21 compared with $36,000 in the same quarter of the prior year. Total operating expenses rose 28% during the period to $8.7 million.

For the fiscal first quarter ending December 31, 2020, compared to the fiscal first quarter ended December 31, 2019:

- Expenses for R&D were $5.4 million, up 29% from $4.2 million, with the increase attributable to higher expenses related to the Phase III clinical study and greater stock compensation expense;
- G&A expenses were $3.3 million, up 26% from $2.6 million, on greater employee stock compensation costs;
- Gain on derivative instruments was $933,000 compared to $767,000, due to change in fair value of derivative liabilities based on CEL-SCI's stock price;
- Other non-operating gains were $122,000 compared with $791,000;
- Net interest expense was ($260,000) compared with ($251,000) million due to reduction in interest rate applied to CEL-SCI's finance leases, adjusted to reflect adoption of ASC 842;

As of December 31, 2020, cash was $21.9 million and cash burn for 1Q:21 was ($3.8) million, below the ($4.2) million recognized in the prior year period. Financing cash flows were $13.3 million reflecting proceeds from sale of common stock and a small amount from exercise of warrants and options. Following the end of the reporting period and up to February 5, 2021, CEL-SCI received $3.9 million from the exercise of warrants and options.

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 geographical breadth 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 December 11, 2020, CEL-SCI announced the closing of a capital raise that yielded $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 which was not exercised.

Letter to Shareholders

On January 4, 2021, CEL-SCI CEO, Geert Kersten, issued a Letter to Shareholders. The missive summarized CEL-SCI's Multikine cancer immunotherapy and the motives behind development and 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 and that 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 $13.3 million in cash from financing during 1Q:21 and another $3.9 million after the end of the quarter. 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

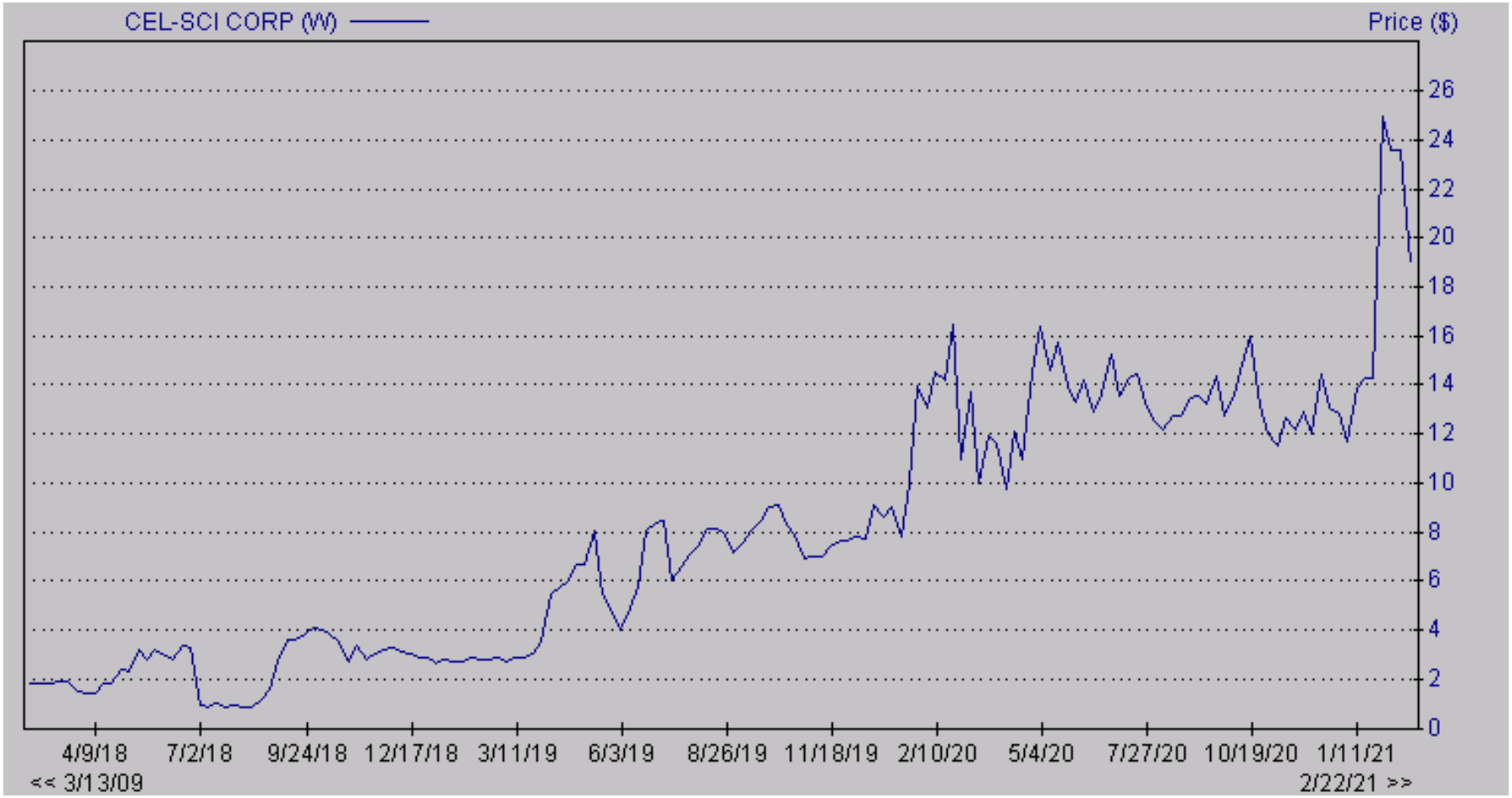
CEL SCI Corporation	2020 A	Q1 A	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues	**$0.6**	**$0.0**	**$0.1**	**$0.1**	**$0.1**	**$0.3**	**$99.6**	**$199.8**
YOY Growth	21%	-100%	-67%	-49%	250%	-46%	33091%	101%
Research & Development	$17.8	$5.4	$4.2	$3.1	$2.0	$14.7	$4.0	$4.0
General & Administrative	$11.7	$3.3	$3.2	$3.1	$3.2	$12.8	$12.4	$12.8
Income from operations	($29.0)	($8.7)	($7.3)	($6.1)	($5.1)	($27.2)	$83.2	$183.0
Other Income	($0.2)	$1.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest Expense	($1.0)	($0.3)	($0.3)	($0.3)	($0.3)	($1.2)	($1.6)	($1.6)
Pre-Tax Income	($30.3)	($8.0)	($7.6)	($6.4)	($5.4)	($28.4)	$81.6	$181.4
Provision for Income Tax	$0.0	$0.0				$0.0	$20.4	$52.6
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	29.0%
Net Income	**($30.3)**	**($8.0)**	**($7.6)**	**($6.4)**	**($5.4)**	**($28.4)**	**$61.2**	**$128.8**
Reported EPS	**($0.82)**	**($0.21)**	**($0.19)**	**($0.13)**	**($0.10)**	**($0.64)**	**$1.05**	**$2.18**
Basic Shares Outstanding	36.76	38.67	40.10	48.00	52.00	44.69	58.00	59.00

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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