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CEL-SCI Corporation (CVM - NYSE)

Fiscal 3Q:20 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 (8/14/2020)	$12.71
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 by late summer.

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	**6.00**
One-Year Return (%)	**50.6**
Beta	**2.3**
Average Daily Volume (sh)	**663,439**
Shares Outstanding (mil)	**38.6**
Market Capitalization ($mil)	**490.1**
Short Interest Ratio (days)	**16.48**
Institutional Ownership (%)	**21.8**
Insider Ownership (%)	**4.5**
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)
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	$0.1 E	$0.6 E
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	-$0.10 E	-$0.77 E
2021					-$0.11 E
2022					$3.15 E

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WHAT'S NEW

Third Quarter Fiscal Year 2020 Operational and Financial Results

CEL-SCI Corporation (NYSE: CVM) reported its fiscal third quarter 2020 operational and financial results for the three month period ending June 30, 2020 and filed the companion 10-Q. Following a near nine year duration of the IT-MATTERS trial that evaluated biologic Multikine in head and neck cancer, the company announced the trial had reached the targeted threshold of 298 events on May 4th of this year. The completion of required events enables the company's contract research organization (CRO) to begin data evaluation. The study is undergoing database lock and analysis. CEL-SCI will publicize the results once analysis has been finalized and results are made available to the firm.

Shifting to the LEAPS platform, 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 conserved region of SARS-CoV-2, paving the way for challenge studies using live virus at the University of Georgia Vaccine Center.

CEL-SCI and the University of Georgia's Center for Vaccines and Immunology entered into a collaboration agreement to develop the LEAPS COVID-19 immunotherapy. Initial studies performed through the collaboration will attempt to replicate experiments done with LEAPS against H1N1 flu virus in mice which demonstrated improvement in the animals' morbidity and mortality. The aim for the therapy is to improve outcomes for those already infected. The LEAPS COVID-19 leverages a highly conserved region of the virus and has both anti-viral and anti-inflammatory attributes, distinguishing it from other potential therapies.

During the third quarter of CEL-SCI's fiscal year 2020 and compared with the same quarter last year, R&D expense increased by $1.0 million (32%)[1] to $3.9 million, driven by a $0.7 million manufacturing facility preparation for commercial production of Multikine, a $0.8 million increase in employee stock compensation, and a $0.3 million increase in depreciation expense offset partially by a decrease of $1.0 million related to the completion of the clinical phase of IT-MATTERS. General and administrative expenses increased approximately $0.8 million (36%) to $3.2 million, driven primarily by higher employee stock compensation. Quarterly net loss amounted to $10.2 million, equivalent to loss per share of ($0.27).

CEL-SCI's cash increased to $20.1 million from $14.3 million at the end of the prior quarter. Cash burn for the three month period was approximately $4.5 million. This was more than offset by net cash from financing of $10.3 million reflecting proceeds from exercise of warrants and options.

Final Event in IT-MATTERS Trial

After almost a decade of duration, the IT-MATTERS clinical trial had its final event, reported in a press release on May 4, 2020 and is now in the database lock and analysis phase. The event-driven trial for head and neck cancer enrolled its first patients in 2011 in the US, Canada, UK, France and 20 other countries. 928 patients were enrolled, with the final individual added in September 2016. The primary endpoint for the study is an overall survival benefit of 10% over standard of care alone in defined areas of the head and neck. Based on timelines for other trials we have seen, we think CEL-SCI will present findings at a conference before the end of the year.

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 near nine year duration, 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. Next steps are for CRO ICON to perform the data analysis and submit results to management.

[1] Note that this compares 3Q:20 with restated numbers for the prior year that do not match the historical data in our model as some expenses were reclassified from G&A to R&D.

Our experience with event-based trials finds that period from final event to topline readout can take from two to three months[2] to complete the follow up steps after the last event is reported. We are already at approximately 3.5 months from the final event announcement. Management did not provide any guidance on expected timeline and we caution investors that coronavirus-related disruptions could extend the period of analysis relative to our estimate. After database lock and analysis, we expect near term future events to include:

- 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 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 a report of topline data will become public within a few days of it being available to the company.

We believe that one of the major oncology conferences in the last months of 2020 will be targeted for presenting data. While the pandemic has forced the cancellation of many conferences, by fall, we believe that the major annual conferences will be held virtually if not in person. The mid-September European Society for Medical Oncology Congress (ESMO) may be an appropriate venue for CEL-SCI's Multikine results to be presented. The ESMO Immuno-Oncology Congress in the second week of December may also be suitable.

Infectious Disease Review

While most of the attention for CEL-SCI has been focused on the final events for the IT-MATTERS trial and Multikine, the company's second platform, Ligand Epitope Antigen Presentation System or LEAPS, has come into focus after its years-long work on H1N1 influenza. The coronavirus' spread across the globe has dominated the news over the last several months and media focus on potential solutions that may eventually address viral outbreaks has intensified.

While antivirals can be used for severe cases of influenza, antiviral resistance can emerge quickly, illustrating the need for novel, more effective therapeutic approaches. LEAPS has been used by attaching influenza proteins to an immune-binding ligand that is then used to activate dendritic cells that are injected into the host. In mice, LEAPS was effective in treating infection with an antiviral drug-resistant influenza virus.

In 2009, CEL-SCI conducted its first clinical study comparing blood sampled from H1N1 and healthy patients who had been administered the LEAPS-H1N1 treatment. In a 2009 clinical trial of H1N1 patients, LEAPS was used and targeted a conserved region of H1N1 Pandemic Flu, Avian Flu (H5N1), and the Spanish Flu, a region that was not associated with exacerbating cytokine storm. The study drew blood from hospitalized H1N1 patients and activated their cells with the LEAPS H1N1 investigational therapy to assess the cell's response for future treatment.

In 2013, CEL-SCI published data showing LEAPS was effective in stopping three different influenza strains, including a drug resistant and a pandemic strain. The journal article that summarized the findings of the research noted that:

> *"Our data demonstrate that Influenza-J-LEAPS-pulsed DCs reduce virus replication in the lungs, enhance survival, and modulate the protective immune responses that eliminate the virus while preventing excessive cytokines that could injure the host. This approach shows promise as an adjunct to antiviral treatment of influenza virus infections."*

The effectiveness of the treatment was evidenced by the mouse animal model not losing weight, reduced virus production in treated mice and less inflammatory immune response. Dr. Daniel Zimmerman, the inventor of LEAPS and SVP of research at CEL-SCI, believes that this approach could address a future influenza pandemic. While

[2] We reviewed six recent Phase III trials and measured the number of days between the report of the last event and when topline was announced. We found an average length of 82 days (just under 3 months) with a range of 48 days to 110 days. Companies included all reported their last event in 2018 or 2019 and included Intec Pharma, Amarin Corp, MedDay, Acasti Pharma, Ritter Pharma and Resverlogix.

CEL-SCI is not actively advancing this program, a viral epidemic or pandemic could provide both the funding and motivation to pick up where they left off. We discuss the LEAPS program in further detail in a September article.

CEL-SCI announced the initiation of an immunotherapy on March 9th to treat COVID-19 using the LEAPS peptide technology. The approach has shown promise in influenza and Dr. Zimmerman, CEL-SCI's senior VP of Research, believes that a LEAPS-based peptide for the coronavirus peptide will slow or stop the progression of the viral infection and prevent tissue damage from inflammation.

On March 23rd, the corporation further revealed a collaboration with the University of Georgia's Center for Vaccines and Immunology to develop an immunotherapy treatment for the coronavirus using LEAPS. The two entities will start pre-clinical studies based on previous work done with H1N1 after the 2009 flu pandemic. The 2009 approach was successful in reducing morbidity and mortality in animal models. The proposed peptides for the study are directed towards antigens within the nucleocapsid protein (NP) of SARS-CoV-2 that elicit cytolytic T cell responses. The approach avoids the spike antigens which have been targeted by other antibody-based vaccines, and instead targets NP antigens which are less variable between viral strains and less likely to change in response to antibodies produced by infection or vaccines.

On July 24th, the firm announced that it had concluded animal experiments using LEAPS COVID-19, providing the basis to move forward into animal challenge studies with live SARS-CoV-2 virus. The LEAPS COVID-19 conjugates induced faster and much higher antibody responses than expected against a conserved region of SARS-CoV-2 after only one injection. IgG antibody response was generated within 10 days after a single immunization.

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. Similar to the capital raise in December, the transaction was able to take place without any warrants being issued, a rarity in today's climate. Exercise of warrants has also contributed substantial funds to CEL-SCI's coffers, as the steadily rising stock price has incentivized their actions. A June 30 press release highlighted that $10 million in proceeds were received through warrant exercises and CEL-SCI stated that $27.0 million in gross proceeds from warrants had been received for the first nine months of 2020.

Summary

CEL-SCI has reported the final event in the IT-MATTERS trial, which is now in the database lock and analysis phase. We believe topline data will be available shortly. During periods absent coronavirus related delays, duration from final event to topline readout has ranged from 48 to 110 days based on our review of other Phase III trial timelines. We have outlined many of the normal steps that are required following the completion of a trial and also reviewed other recent trials to give a sense of how long it takes from the last trial event to topline report. CEL-SCI management has noted the extended duration and geographical diversity of the study which may also contribute to a longer than expected period of analysis. 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 E	2020 E	2021 E	2022 E
Total Revenues	**$0.5**	**$0.0**	**$0.3**	**$0.2**	**$0.1**	**$0.6**	**$9.7**	**$194.7**
YOY Growth	*-3%*	*-72%*	*98%*	*80%*	*30%*	*36%*	*1436%*	*1911%*
Research & Development	$12.7	$4.2	$4.4	$3.9	$2.0	$14.5	$5.0	$1.0
General & Administrative	$8.0	$2.6	$2.6	$3.2	$1.9	$10.3	$9.1	$9.4
Income from operations	($20.2)	($6.8)	($6.7)	($6.9)	($3.8)	($24.2)	($4.4)	$184.3
Other Income	($0.1)	$1.6	($2.1)	($3.0)	$0.0	($3.6)	$0.0	$0.0
Interest Expense	($1.8)	($0.3)	($0.3)	($0.3)	($0.4)	($1.2)	($1.6)	($1.6)
Pre-Tax Income	($22.1)	($5.5)	($9.0)	($10.2)	($4.2)	($28.9)	($6.0)	$182.7
Provision for Income Tax	$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%*	*0.0%*	*0.0%*	*100.0%*
Net Income	**($22.1)**	**($5.5)**	**($9.0)**	**($10.2)**	**($4.2)**	**($28.9)**	**($6.0)**	**$182.7**
Reported EPS	**($0.71)**	**($0.16)**	**($0.25)**	**($0.27)**	**($0.10)**	**($0.77)**	**($0.11)**	**$3.15**
Basic Shares Outstanding	31.17	35.10	36.17	37.45	42.00	37.68	55.00	58.00

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

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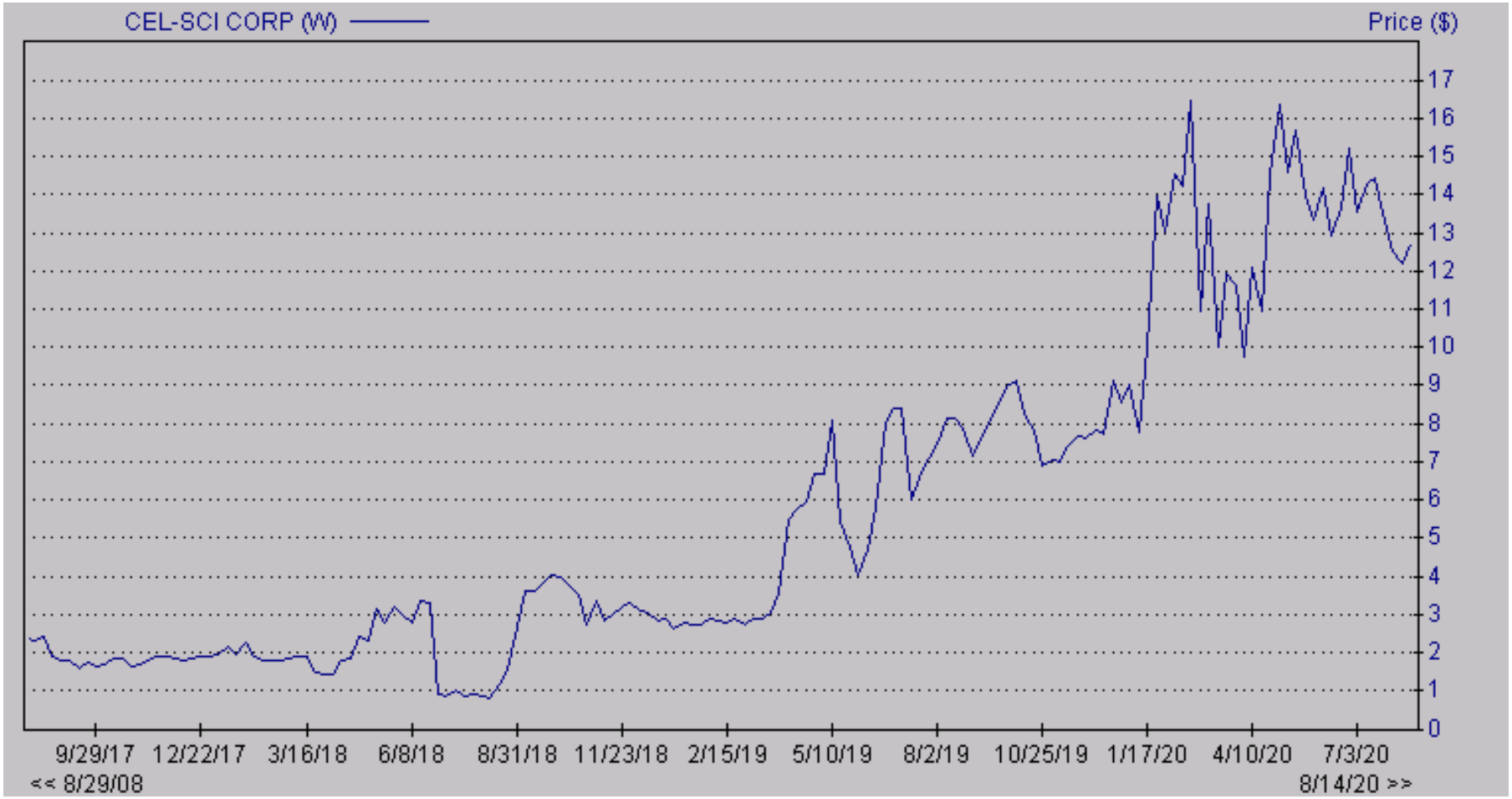
HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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