Zacks Small-Cap Research

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May 13, 2020

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CEL-SCI Corporation (CVM - NYSE)

Last Event Completed; On To Analysis

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 (5/12/2020)	$15.78
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	**3.70**
One-Year Return (%)	**188**
Beta	**2.5**
Average Daily Volume (sh)	**1,007,504**
Shares Outstanding (mil)	**37.6**
Market Capitalization ($mil)	**593**
Short Interest Ratio (days)	**5.5**
Institutional Ownership (%)	**21.4**
Insider Ownership (%)	**7.7**
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	$0.1 E	$0.1 E	$0.5 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	-$0.11 E	-$0.10 E	-$0.61 E
2021					-$0.13 E
2022					$3.13 E

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WHAT'S NEW

Second Quarter Fiscal Year 2020 Operational and Financial Results

CEL-SCI Corporation (NYSE: CVM) reported second quarter fiscal year 2020 operational and financial results for the three month period ending March 31, 2020. Following a near nine year duration of the IT-MATTERS trial evaluating Multikine in head and neck cancer, the company announced the final event has taken place. During the quarter, the final Independent Data Monitoring Committee (IDMC) review took place, additional capital was raised, and a global pandemic brought the LEAPS platform into the spotlight. Following the announcement of the final event, we anticipate the two contract research organizations (CROs) will follow the standard checklist to generate topline data over the next few months.

During the second quarter of fiscal year 2020, CEL-SCI recognized grant income of $300,000 funding the LEAPS platform and the development of a rheumatoid arthritis vaccine. This compares to $150,000 that was received in 2Q:19. Research and development expenses of $4.4 million in the second quarter rose 55% over prior year restated levels. General and administrative expenses were $2.6 million for the three month period, up from a restated $1.6 million the prior year, a 58% increase.[1] Increased R&D expenses are attributed to $0.6 million in greater cost from manufacturing facility preparation, $0.5 million higher stock compensation expense, a $0.3 million increase in depreciation from a new leasing standard and $0.2 million rise from other miscellaneous items. G&A expenses were up in 2Q:20 on account of a $0.7 million increase in stock compensation expense and a $0.2 million rise in unallocated expenditures. Other income totaled ($2.1) million, largely comprised of losses from derivative instruments ($3.0) million partially offset by $1.0 million from other non-operating items. After incurring $253,000 in interest expense, CEL-SCI reported a net loss of ($9.0) million, or ($0.25) per share. Removing derivative related changes and other non-operating gains had a $2.1 million impact on net income and a $0.06 impact on EPS.

Cash balance as of March 31, 2020 stands at $14.3 million, an almost $6 million increase from year end 2019 levels. CEL-SCI benefitted from a net $14.6 million positive financing cash flow partially offset by cash burn of ($4.6) million. CEL-SCI continues to hold no debt.

Final Event in IT-MATTERS Trial

After almost a decade of duration, the IT-MATTERS clinical trial experienced its final event, reported in a press release on May 4, 2020. 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 ultimately 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 (1) 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.

Now that the final event has taken place, there will be additional steps that occur over the next few months as data is validated and analyzed. CEL-SCI reported that the data is now being prepared for lock and analysis. The company's two contract research organizations (CROs), ICON and Ergomed, will generate remaining queries, verify data, complete the medical review and build the final database. ICON will perform the data analysis and control.

[1] Restatements were related to classification of operating expenses from general and administrative expenses to research and development expenses. ~$0.3 million of 1Q:19 G&A expenses were moved to R&D. Total operating expenses remained the same for 1Q:19.

Our experience with event-based trials suggests that it can take from two to three months[2] to complete the follow up steps after the last event is reported. 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. However, in our conversations with other management teams, no material delays have been noted for other trials and data analysis in our anecdotal review. We expect possible finalizing steps for the IT-MATTERS trial to include:

- Follow up safety visits
- Adjudication of events
- Follow up with discontinued patients
- Data base lock
- 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 the 2 to 3 month range that we expect. The CROs are fully responsbile 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 come 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 conference for CEL-SCI's Multikine results to be presented. The ESMO Immuno-Oncology Congress in the second week of December may also be appropriate.

We congratulate CEL-SCI on the completion of their nine-year trial for Multikine and eagerly await topline results. As we have explained in our research, we believe that Multikine will, more likely than not, be safe and effective. Our belief is based on earlier Phase II results where the longer-than-expected length of the trial and the IDMC's consistent recommendation to continue the trial suggest extended life when compared with historical precedents.

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 pandemic flu. 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 which is then used to activate dendritic cells that are injected into the host. In mice, LEAPS were 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.

[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.

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 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.

Since the publication of our previous report, CEL-SCI announced the initation of an immunotherapy March 9th to treat the coronavirus 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 succesful in reducing morbidity and mortality in animal models. The proposed peptides for the study are directed towards antigens within the nucleocapsid protein (NP) of the coronavirus 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.

Capital Raise

On March 26th, CEL-SCI closed its $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.

Summary

CEL-SCI has reported the final event in the IT-MATTERS trial and we believe topline data will be available in the next few months. 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. If Multikine is able to meet or surpass its primary endpoint of 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 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$0.5**	**$0.0**	**$0.3**	**$0.1**	**$0.1**	**$0.5**	**$9.7**	**$194.7**
YOY Growth	*-3%*	*-72%*	*98%*	*-8%*	*30%*	*15%*	*1712%*	
Research & Development	$12.7	$4.2	$4.4	$2.5	$2.0	$13.1	$6.0	$1.0
General & Administrative	$8.0	$2.6	$2.6	$1.7	$1.9	$8.8	$9.1	$9.3
Income from operations	($20.2)	($6.8)	($6.7)	($4.1)	($3.8)	($21.4)	($5.4)	$184.3
Other Income	($0.1)	$1.6	($2.1)	$0.0	$0.0	($0.5)	$0.0	
Interest Expense	($1.8)	($0.3)	($0.3)	($0.4)	($0.4)	($1.3)	($1.6)	($1.6)
Pre-Tax Income	($22.1)	($5.5)	($9.0)	($4.5)	($4.2)	($23.2)	($7.0)	$182.7
Provision for Income Tax	$0.0	$0.0	$0.0			$0.0	$0.0	$1.0
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)**	**($4.5)**	**($4.2)**	**($23.2)**	**($7.0)**	**$181.7**
Net Margin								
Reported EPS	**($0.71)**	**($0.16)**	**($0.25)**	**($0.11)**	**($0.10)**	**($0.61)**	**($0.13)**	**$3.13**
YOY Growth								
Basic Shares Outstanding	31.17	35.10	36.17	40.00	42.00	38.32	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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