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CEL-SCI Corporation (CVM - NYSE)

Any Day Now

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 (2/13/2020)	$14.50
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 recent catalysts related to favorable decision against a former CRO and the lifting of a clinical hold on Multikine, investors are anticipating a near term conclusion of the Phase 3 trial and readout on the head and neck cancer study.

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 2020 FDA approval of Multikine for head and neck cancer and a late 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	**15.42**
52-Week Low	**2.37**
One-Year Return (%)	**405**
Beta	**2.9**
Average Daily Volume (sh)	**772,362**
Shares Outstanding (mil)	**36.4**
Market Capitalization ($mil)	**528**
Short Interest Ratio (days)	**5.8**
Institutional Ownership (%)	**21.4**
Insider Ownership (%)	**4.9**
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	$0.1 E	$0.1 E	$0.1 E	$0.3 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	-$0.15 A	-$0.17 E	-$0.11 E	-$0.10 E	-$0.53 E
2021					-$0.12 E
2022					$3.14 E

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WHAT'S NEW

First Quarter Fiscal Year 2020 Operational and Financial Results

CEL-SCI Corporation (NYSE: CVM) reported first quarter fiscal year 2020 operational and financial results for the three month period ending December 31, 2019. The company provided an update of the Phase III Multikine trial, highlighting the second Independent Data Monitoring Committee (IDMC) meetings that occurred in October 2019. The IT-MATTERS trial has been running for nine years and the data related to the patient population enrolled in the trial suggests that we should be near its end. News has been sparse since the prior quarterly update; however, in December 2019 and January 2020, CEL-SCI raised gross proceeds of $6.3 million from a public offering of shares.

During the first quarter of fiscal year 2020, CEL-SCI recognized grant income of $36,000, which was related to the LEAPS platform and the development of a rheumatoid arthritis vaccine. This compares to $126,000 that was received in 1Q:19. Research and development expenses rose to $4.2 million in the quarter, compared to a restated $3.5 million in the prior year's quarter. General and administrative expenses were $2.6 million in the year, up from a restated $1.7 million in the prior year.[1] Increased expenses of $0.9 million are attributed to higher non-cash compensation expense. Research and development costs were also up in a number of categories including $0.7 million allocated towards manufacturing facility preparation, $0.5 million of stock option expense, and $0.2 million of depreciation expense attributable to the change in accounting rules related to a leasing standard. Trial expenses related to the Phase III Multikine trial fell by $0.7 million year over year. Other income was $1.6 million, largely comprised of gains from derivative instruments ($0.8 million) and other non-operating items ($0.8 million). After subtracting $251,000 in interest expense, CEL-SCI reported a net loss of ($5.5) million, or ($0.16) per share. Removing the gain on derivative instruments and other non-operating gains had a $1.6 million impact on net income and a $0.04 impact on EPS.

Cash balance as of December 31, 2019 stands at $9.4 million, a $1 million increase from year end 2019 levels. CEL-SCI benefitted from $5.1 million in financing cash flows partially offset by cash burn of ($4.2) million. CEL-SCI continues with no debt.

Infectious Disease

While most of the attention for CEL-SCI has been focused on the last events for the IT-MATTERS trial and Multikine, the company's second platform, Ligand Epitope Antigen Presentation System or LEAPS, has come into focus for its years-long work on pandemic flu. The coronavirus spreading across Asia, now designated COVID-19, has been dominating the news over the last month and attention on approaches and platforms that may eventually address viral outbreaks has escalated.

While antivirals can be used for severe cases of influenza, antiviral resistance emerges quickly; illustrating the need for novel therapeutic approaches that are more effective. 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 withdrawn blood from H1N1 and healthy patients in response to administration of 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."*

[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.

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.

Capital Raise

On December 23rd, CEL-SCI announced that the company would offer shares of common stock in a public offering. The effort was successful and closed its underwriting along with a full exercise of the over-allotment option. The transaction was completed January 7, 2020, with the announcement of the completion of the over-allotment and a total raise of $6.325 million in gross proceeds. 697,354 shares were issued at a price of $9.07 per share. Aegis Capital Corp. was the sole book-running manager for the offering. We note that the transaction was able to take place without any warrants being issued, a rarity in today's climate.

IT-MATTERS Phase III Trial

CEL-SCI announced its latest IDMC review for the IT MATTERS Phase III Multikine study for head and neck cancer in mid-October. We believe that the longer than expected duration of the trial combined with the IDMC recommendation to continue its progress have positive implications for the safety and efficacy of the investigational drug.

We note a number of precedents of IDMC reviews being followed by the halt of a trial due to futility. Bioigen's (NASDAQ: BIIB) aducanumab, NuCana's (NASDAQ: NCNA) Acelarin and the Transgene/SillaJen's Pexa-Vec Phase III trials were all halted in 2019. These terminations show the willingness of monitoring committees to shut down a study if it fails to show results. While many examples can be found for trials ending early for futility, it is difficult to find examples of a trial being stopped early for exceptional efficacy.

We see the latest IDMC meeting as a favorable milestone and believe the results justified an increase in our probability of success estimate, although there could be other unexpected factors that are delaying the report of the target number of events. The delay in reported events could be attributed to higher than expected dropouts, a greater mix of Stage III vs. Stage IVa patients enrolled, or a higher proportion of a less fatal subtype of head and neck cancer among other unknown and unexpected factors.

A slip by Ergomed in a September 25th slide deck suggested that the IT MATTERS trial was 96% complete, and by extension lacks only an additional 11 or 12 events in the active and comparitor arm to achieve completion. While the statistic disappeared in a revised version of Ergomend's slide deck, we anticipate the 298th event to be just around the corner.

CEL-SCI provided some data in a September 10th slide presentation which updated data specific to the study population enrolled in CEL-SCI's Phase III trial. In its original study filing with the U.S. National Library of Medicine eight years ago, CEL-SCI cited median 3-year overall survival (OS) for their patient population as between 52 and 55% and five year OS as 43%. These statistics are somewhat out of date, especially considering the advances that have been made in immuno-oncology since the trial began.

The updated data was sourced from the Surveillance, Epidemiology and End Results (SEER) program, which is part of the National Institute of Health (NIH) National Cancer Institute (NCI). The group collects and publishes cancer incidence and survival data that represents over a third of the US population. CEL-SCI commissioned an external statistical group to analyze the data and determine an OS estimate for the specific population Multikine is addressing. Below we provide a summary of the data as provided by CEL-SCI:

Exhibit I – Overall Survival (OS) Estimates for Multikine Study Population[2]

Year	OS Estimate	95% Confidence Bound
1	71.42%	(69.84%, 72.92%)
2	53.86%	(52.09%, 55.59%)
3	**46.59%**	(44.74%, 48.42%)
4	41.98%	(40.02%, 43.93%)
5	**36.75%**	(34.475%, 39.03%)

Compared to the initial data cited by CEL-SCI, OS is lower in the updated population, which seems to be at odds with the OS trend for cancer types in general. As mentioned above, the three year OS was from 52 to 55%, while the updated SEER[3] data demonstrated an OS of 45 to 48%. At the five year mark, OS was cited as 43% in the U.S. National Library of Medicine filing, as compared to the updated data which indicates a 37% five-year OS. While it is difficult to say why head and neck cancer mortality rates have worsened over time, some ideas have crossed our collective mind. One may be the dramatic decrease in smoking over the last decades, which is highly correlated with head and neck cancer. Changing the prevalence of this risk factor could have impacted the characteristics of the head and neck population. Other factors could include changes in underlying behaviors and disease such as alcohol use, Epstein-Barr Virus (EBV) and Human Papilloma Virus (HPV). In any case, as the population was randomized, both the active and comparitor arms should reflect the same characteristics and not impact the measurement of benefit from Multikine. Our goal with this updated SEER data analysis was to estimate how many deaths should have occurred if the Multikine trial population matched the control arm.

If one assumes the median OS as indicated in the SEER data,[4] for the ~797 patients in the SOC and Multikine + ciz + SOC arms,[5] this suggests that there should be over 460 events so far. If we assume median OS in the SOC arm and a 10% improvement in OS in the Multikine arm, this suggests about 437 events in September 2019. Even under our conservative assumptions of patients in each cohort being enrolled at the end of the cohort period and at the highest bound of the 95% confidence interval for OS and a 30% improved efficacy, there should have already been over 60 events more than required to complete the IT MATTERS trial. While the longer than expected trial duration does increase the likelihood that Multikine is extending OS, it also suggests that there may be other factors also reducing the number of events as compared to what is expected based on the SEER dataset.

We place a lot of confidence in the IDMC team and their focus on safety and efficacy for the patient. The goal of any IDMC is to ensure that the interests of the patients are well served, the risk benefit ratio is appropriate and the scientific integrity of the trial is maintained. They have the responsibility to recommend early termination for a trial if interim data is sufficiently compelling for the medicine is either notably effective or harmful to the patients.

We believe the threshold required to recommend stopping the trial early for efficacy is extremely high, even when data are supportive. According to a study published by Pak, et al.[6], about 0.5% of trials that are terminated early are done so for success. When interim analyses suggest that patient health is at risk or the medicine under investigation is not working, the threshold is lower for recommending early termination as demonstrated in the examples above for Biogen, NuCana and Transgene/SillaJen. Therefore we see an asymmetric relationship between trials halted for superior efficacy and those halted for futility.

[2] Source: CEL-SCI Corporate Presentation, September 10, 2019.
[3] The SEER database estimates includes the same population enrolled in the IT MATTERS trial who received SOC. This includes oral cavity (anterior tongue [not base of tongue], cheek, floor of the mouth and soft palate. Over 3,000 patients were included in the study population to calculate 5 year survival.
[4] We employ a whole host of simplifying, conservative assumptions. Numbers for year cohorts provided by company are all assumed to occur at the end of the period. Five year survival is applied to all patients who have been in the trial for five or more years
[5] This assumes median OS for both arms and zero additional benefit from Multikine.
[6] Pak, TR; Rodriguez, MD; Roth, FP; Why Clinical Trials Are Terminated. bioRxiv. July 2, 2015. https://www.biorxiv.org/content/10.1101/021543v1

Using the SEER data analysis and some conservative assumptions,[7] we estimated the number of events that should have occurred assuming the control arm matches the SEER analysis and the Multikine arm demonstrates a 30% improvement in OS. We apply this to the upper bound (fewer deaths) of the confidence interval in Exhibit I and calculate a result of over 360 deaths as of September 2019.

The IT MATTERS trial has not yet ended, indicating that the 298 required events have not yet occurred. The events required for trial completion seems to be outside the confidence interval bounds suggested by the SEER data analysis, our own research cited in our initiation and other analyst research. It appears most likely to us that the group enrolled in the trial may be an outlier in terms of OS ***and*** Multikine is improving OS. Applying standard logic to the longer than expected trial and noting that that IDMC has allowed the trial to continue, it stands to reason that the longer the trial lasts, the more likely it is that Multikine is increasing OS. Combined with the IDMC's recommendation that the trial continue until the appropriate number of events have occurred, we maintain our optimism on the success of the IT MATTERS trial.

Investment Thesis

We remind investors of the key tenets that support ownership in CEL-SCI which are discussed in detail in our initiation:

- **Compelling preclinical and clinical data supportive of Multikine's effective mechanism of action**
- **Multkine is complementary to first line "intent to cure" SOC, in contrast to other monotherapies**
- **Multikine is administered prior to SOC, synchronizing with the preparation period prior to surgery**
- **Differentiated approach that employs multiple proteins for cancer cell identification & destruction**
- **Proprietary manufacturing process, patent protection and anticipated biologics exclusivity**
- **CEL-SCI maintains operation and control of its Multikine manufacturing facility**
- **Multikine source material is abundant human PBMCs**
- **Favorable drug safety profile with no reported drug-related adverse events**
- **Biologic eligible for 12 years of exclusivity in United States**
- **Global rights to intellectual property**
- **Pipeline includes LEAPS platform with additional indications**
    - **Rheumatoid Arthritis**
    - **Pandemic Flu**
    - **Breast Cancer**

Summary

CEL-SCI is in the final stages of the Multikine IT-MATTERS trial and we believe final events will occur in the next months, based on publically available information and our analysis of survival data for head and neck cancer patients. We are eagerly awaiting an announcement that the final event has occurred and hope to see a topline analysis shortly after. 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.

[7] We assume that all enrollees enrolled between 2011 and 2014 have been in the trial for five years, patients enrolled in 2015 have been enrolled for four years, and patients enrolled in 2016 have been enrolled for three years.

PROJECTED FINANCIALS

CEL-SCI Corporation - Income Statement

CEL SCI Corporation	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$0.5**	**$0.0**	**$0.1**	**$0.1**	**$0.1**	**$0.3**	**$9.7**	**$194.7**
YOY Growth	*-3%*	*-72%*	*-34%*	*-8%*	*30%*	*-27%*	*2786%*	
Research & Development	$12.7	$4.2	$3.8	$2.5	$2.0	$12.5	$6.0	$1.0
General & Administrative	$8.0	$2.6	$2.0	$1.7	$1.9	$8.2	$8.5	$8.7
Income from operations	($20.2)	($6.8)	($5.7)	($4.1)	($3.8)	($20.4)	($4.8)	$184.9
Other Income	($0.1)	$1.6	$0.0	$0.0	$0.0	$1.6	$0.0	
Interest Expense	($1.8)	($0.3)	($0.4)	($0.4)	($0.4)	($1.5)	($1.6)	($1.6)
Pre-Tax Income	($22.1)	($5.5)	($6.1)	($4.5)	($4.2)	($20.3)	($6.4)	$183.3
Provision for Income Tax	$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)**	**($6.1)**	**($4.5)**	**($4.2)**	**($20.3)**	**($6.4)**	**$182.3**
Net Margin								
Reported EPS	**($0.71)**	**($0.16)**	**($0.17)**	**($0.11)**	**($0.10)**	**($0.53)**	**($0.12)**	**$3.14**
YOY Growth								
Basic Shares Outstanding	31.17	35.10	36.40	40.00	42.00	38.37	55.00	58.00

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

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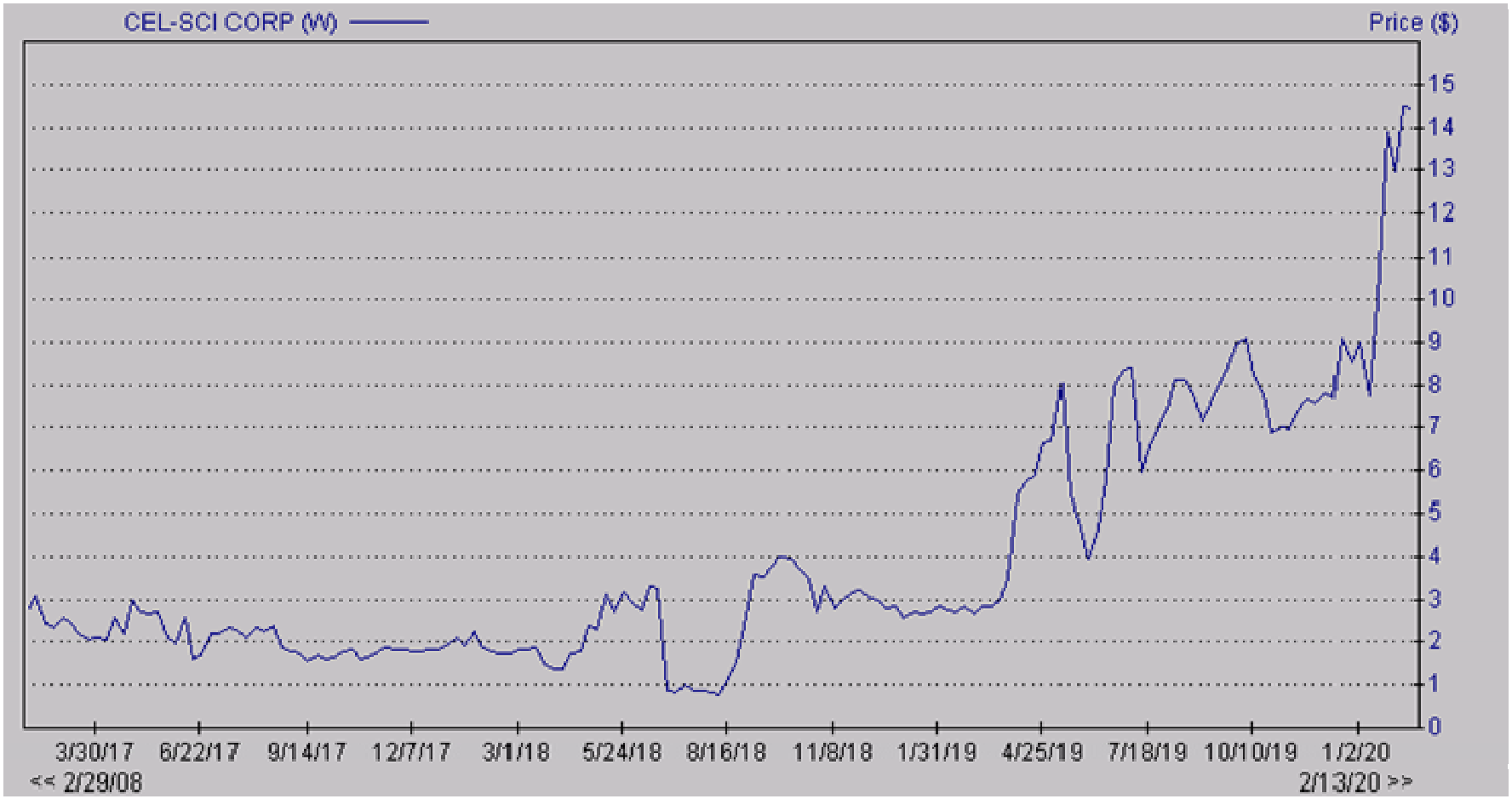
HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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