

CEL-SCI Corporation

(CVM - NYSE)

3Q:19 Results

Based on our DCF model and a 15% discount rate, CEL-SCI is valued at approximately \$14.00 per share. Our model applies a 50% 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 (8/16/2019) **\$8.15**
Valuation \$14.00

OUTLOOK

CEL-SCI is developing two platforms, Multikine and LEAPS. Multikine is in a Phase 3 trial for head and neck cancer and in Phase I for HPV 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 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 **8.99**
 52-Week Low **1.00**
 One-Year Return (%) **731.6**
 Beta **4.79**
 Average Daily Volume (sh) **890,092**

Shares Outstanding (mil) **34.8**
 Market Capitalization (\$mil) **284**
 Short Interest Ratio (days) **9.0**
 Institutional Ownership (%) **8.7**
 Insider Ownership (%) **5.4**

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 2018 Estimate **N/A**
 P/E using 2019 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)
2018	\$0.1 A	\$0.1 A	\$0.1 A	\$0.1 A	\$0.5 A
2019	\$0.1 A	\$0.2 A	\$0.1 A	\$0.1 E	\$0.5 E
2020					\$0.4 E
2021					\$35.6 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2018	-\$0.53 A	-\$0.31 A	-\$0.36 A	-\$0.61 A	-\$1.87 A
2019	\$0.04 A	-\$0.22 A	-\$0.37 A	-\$0.09 E	-\$0.64 E
2020					-\$0.30 E
2021					\$0.38 E

WHAT'S NEW

Third Quarter 2019 Results

CEL-SCI Corporation (NYSE: CVM) [reported](#) fiscal third quarter 2019 results for the three month period ending June 30, 2019. The company provided an update of the Phase III Multikine trial, noting that the last patients enrolled will be coming up on their three year anniversary next month. LEAPS jumped to the forefront of the news cycle in the quarter with several new data presentations related to rheumatoid arthritis and influenza. Strong share price performance led to CEL-SCI's selection as a member of the Russell 3000 index in July and warrants being exercised, filling the company's coffers. Prior to the start of the third quarter, the Independent Data Monitoring Committee (IDMC) [recommended](#) that the trial continue as we wait for IT MATTERS final events to occur, affirming the study's potential to meet the primary endpoint.

During its fiscal third quarter, CEL-SCI recognized grant income of \$109,000, which was related to the LEAPS platform and the development of a rheumatoid arthritis vaccine. This was similar to the amount recognized in the third quarter of 2018, but a sequential decline from the second quarter. Research and development expenses fell slightly to \$2.3 million, a 5% decline compared to the prior year's amount due to lower trial activity levels. General and administrative expenses were \$3.0 million in the quarter, up 73% relative to the \$1.7 million in the same period during the prior year due to the grant of stock based compensation. Other income was \$18,000, loss on derivative instruments was (\$7.9) million due to share price increases and other non operating gain of \$1.5 million was related to payments to Ergomed for CRO services. After subtracting \$443,000 in interest expense, CEL-SCI reported a net loss of (\$12.1) million, or (\$0.37) per share. Removing the gain on derivative instruments and other non-operating gains, provides adjusted net loss was (\$5.7) million or (\$0.17) per share. This compares to our estimated loss of (\$0.10) per share with the difference attributable to stock based compensation.

LEAPS Poster and Presentation

Dr. Daniel Zimmerman, CEL-SCI's Senior Vice President of Research, presented data on the LEAPS platform at the American Association of Immunologists in San Diego on May 11th. The presentation was called "Therapeutic vaccination by two DerG LEAPS conjugates incorporating different PG (aggrecan) epitopes protect by different immune mechanisms in the PG G1 domain induced mouse model of rheumatoid arthritis;" a title not distinguished by its brevity.

In the referenced study, a mouse model was used to compare two therapeutic vaccines alone and in combination that use distinct epitopes associated with arthritis. The goal is to approach RA with two LEAPS conjugates potentially addressing additional disease-related epitopes and resulting in greater efficacy. A combination vaccine that addresses these multiple targets could compensate for missing or mutated epitopes that distinguish the disease and allow T cells to maintain the ability to identify the protein. The LEAPS platform is being developed with a \$1.5 million NIH grant that was granted in 2017 to support the development of an Investigational New Drug (IND) application.

LEAPS data was also [presented](#) by Dr. Adrienn Markovitz at i-Chem2019 in San Francisco who presented the same topic as Dr. Zimmerman did at the San Diego conference. The conclusion of the presentation found that vaccination with DerG LEAPS conjugates of distinct PG epitopes either alone or together were effective in modulating the inflammatory response of arthritis and slowing its progression.

Dr. Zimmerman and colleagues authored and published a [July](#) review entitled "[Lessons From Next Generation Influenza Vaccines For Inflammatory Disease Therapies](#)" in the journal International Immunopharmacology. Treating autoimmune diseases using a T cell approach offers advantages compared to standard of care and antigen specific therapies need to be specific to each patient, depending on the antigen and T cell response involved. The review favors antigen specific therapy over an ablative approach as the latter approach blocks, inhibits or kills the pathways, cytokines or cells that promote inflammatory processes. Ablation also increases the risk of infection and other side effects. In contrast, T cell antigen therapy can increase the appropriate and decreasing the inappropriate immunopathogenic responses to antigens. CEL-SCI's LEAPS platform can be modified to provide an antigen specific approach to modifying disease and immune response in animal models.

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**
- **Multikine 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 historical survival rates. As of September, all patients will have been in the trial for a minimum of three years in the study and we anticipate a final IDMC meeting to take place that month. 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 \$14.00.

PROJECTED FINANCIALS

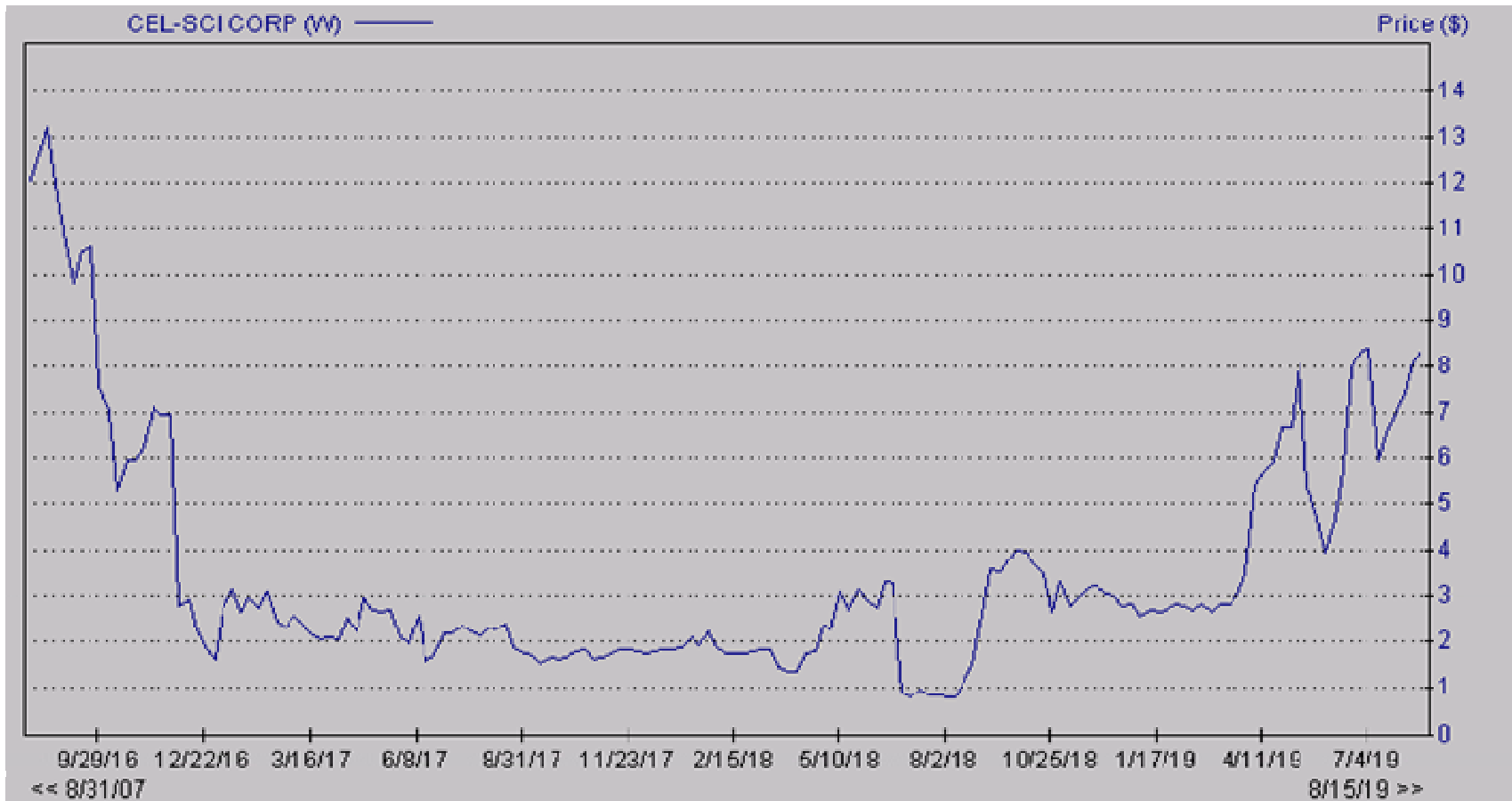
CEL-SCI Corporation - Income Statement

CELSCI Corporation	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
Total Revenues	\$0.5	\$0.1	\$0.2	\$0.1	\$0.1	\$0.5	\$0.4	\$35.6
<i>YOY Growth</i>	<i>590%</i>	<i>11%</i>	<i>14%</i>	<i>5%</i>	<i>-21%</i>	<i>2%</i>	<i>-18%</i>	<i>8790%</i>
Research & Development	\$9.4	\$3.1	\$2.5	\$2.3	\$1.5	\$9.5	\$6.0	\$5.0
General & Administrative	\$7.8	\$2.0	\$1.9	\$3.0	\$1.9	\$8.9	\$7.8	\$8.0
Income from operations	(\$16.8)	(\$5.0)	(\$4.3)	(\$5.2)	(\$3.3)	(\$17.9)	(\$13.4)	\$22.5
Other Income	(\$8.6)	\$6.7	(\$1.7)	(\$6.4)	\$0.0	(\$1.4)	\$0.0	\$0.0
Interest Expense	(\$6.5)	(\$0.4)	(\$0.5)	(\$0.4)	(\$0.4)	(\$1.8)	(\$1.6)	(\$1.6)
Pre-Tax Income	(\$31.8)	\$1.2	(\$6.4)	(\$12.1)	(\$3.7)	(\$21.0)	(\$15.0)	\$20.9
Provision for Income Tax	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>
Net Income	(\$31.8)	\$1.2	(\$6.4)	(\$12.1)	(\$3.7)	(\$21.0)	(\$15.0)	\$20.9
<i>Net Margin</i>								
Reported EPS	(\$1.87)	\$0.04	(\$0.22)	(\$0.37)	(\$0.09)	(\$0.64)	(\$0.30)	\$0.38
<i>YOY Growth</i>								
Basic Shares Outstanding	17.00	27.99	29.11	33.05	41.00	32.79	50.00	55.00

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

HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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