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CEL-SCI Corporation (CVM - NYSE)

Data Has Been Released

Based on our DCF model and a 15% discount rate, CEL-SCI is valued at approximately $12.00 per share. Our model applies a 85% probability of ultimate approval and commercialization for Multikine in head and neck cancer in lower severity patients that do not need chemotherapy. The model includes contributions from the US, EU and rest of world.

Current Price (6/28/2021)	$13.69
Valuation	**$12.00**

OUTLOOK

CEL-SCI is developing two platforms, Multikine and LEAPS. Multikine has completed a Phase 3 trial for head and neck cancer while LEAPS is conducting preclinical studies for RA, Pandemic Flu and breast cancer. In June 2021, CEL-SCI reported selected data from its IT-MATTERS trial demonstrating a benefit in the non-chemotherapy population. CEL-SCI plans to submit a BLA to the FDA based on this data.

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 2023 FDA approval of Multikine for head and neck cancer and a 2023 launch of the compound in the US, followed by a subsequent launch in the EU and global availability by 2023 that will be achieved through the efforts of partners.

SUMMARY DATA

52-Week High	**40.91**
52-Week Low	**9.00**
One-Year Return (%)	**-13.0**
Beta	**2.26**
Average Daily Volume (sh)	**974,844**
Shares Outstanding (mil)	**42.5**
Market Capitalization ($mil)	**582**
Short Interest Ratio (days)	**13.23**
Institutional Ownership (%)	**33.2**
Insider Ownership (%)	**3.90**
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 2021 Estimate	**N/A**
P/E using 2022 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	$0.0 A	$0.1 E	$0.1 E	$0.2 E
2022					$40.1 E
2023					$80.1 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	-$0.28 A	-$0.13 E	-$0.10 E	-$0.66 E
2022					-$0.23 E
2023					$0.74 E

WHAT'S NEW

Data Readout From the IT MATTERS Trial

After a long wait, CEL-SCI Corporation (NYSE: CVM) reported selected data from the IT-MATTERS trial. While details for the primary endpoint were not released, an important subset of the population in the Multikine arm produced a statistically significant 14.1% improvement in overall survival (OS) relative to standard of care (SoC). The p-value for the result was 0.0236 and the Hazard Ratio was 0.68 in a population representing about 40% of all advanced primary squamous cell carcinoma of the head and neck (SCCHN) patients. We summarize below the key data provided by the company:

Exhibit I – Summary of Subset Data[1]

Survival Advantage	MK + CIZ RT	MK + CIZ RT+Chemo	MK no CIZ	SOC	p-value	HR	Delta
N=923							
3 year	72.4%	N/A	78.8%	67.5%			4.9%
5 year	62.7%	N/A	55.5%	48.6%	0.0236	0.68	14.1%

The cancer patient population exhibiting the response in the trial was at the advanced (stage III and IV) primary (not yet treated) SCCHN. Safety for the trial population who were treated with Multikine, did not exhibit safety concerns and matched the favorable results in earlier trials. No safety issues were found related to drug administration with no identification of late adverse effects were detected.

Few details were released regarding the primary endpoint except that the press release noted that the study did not achieve the 10% improvement in OS in the combined study groups. We anticipate that this information will be made available later.

CEL-SCI, while blinded to the study, developed prospective several statistical analyses for the population prior to data lock which examined multiple groups likely to benefit from Multikine. The company believes that the early identification of the Multikine neoadjuvant population exhibiting a 14.1% OS advantage at five years will be amenable to the FDA as it reviews the data. In an area of unmet need, such as head and neck cancer, the bar is lower for determined endpoints and we anticipate a near-term meeting with the FDA will provide additional clarity. Safety is a strong point with Multikine, which showed no safety issues in the Phase III trial nor in previous studies compared with SoC and with other immunotherapies that are associated with cytokine storm and other negative side effects. We think it is likely that the agency will look favorably upon a new treatment for an unmet need that is safe. To this point, we highlight the case of aducanumab, which demonstrated minimal, if any, efficacy, but was approved by the FDA given the substantial unmet need. We discuss the FDA's thinking on this matter in a recent article here which may be applicable to CEL-SCI's situation as well.

Now that the company has made its announcement, key drivers for valuation include the FDA's willingness to accept the data available for a Biologic License Application (BLA) consideration. Additional data and information may be required prior to acceptance. At this point, there is very limited information available and we will need to receive additional guidance from the company on the FDA's response to the information it is presented.

Multikine Near Term Milestones

- Release of subset data for IT MATTERS – June 28, 2021
- Development of clinical study report – 2021
- Request meeting with FDA to determine path forward – 2021
- Presentation of data package to review with FDA – 2021
- Address FDA Comments – 2021/2022
- Submission of BLA to FDA - 2022

[1] Compiled by Zacks' analysts from company press release.

Second Quarter Fiscal Year 2021 Operational and Financial Results

CEL-SCI announced second quarter fiscal year 2021 results, issuing a press release and filing Form 10-Q with the SEC on May 18, 2021. Management participated in the Bioconnect Virtual Conference in early January. During FY 2Q:21, CEL-SCI has been expanding and upgrading its cGMP manufacturing facility for Multikine in anticipation of commercial launch. Upgrade construction is expected to be completed soon, which will double capacity.

In the financial realm, CEL-SCI recognized no revenues and incurred operating expenses totaling $8.53 million for the quarter. This resulted in a net loss of ($11.3) million, or ($0.28) per share.

For the fiscal second quarter ending March 31, 2021, compared to the fiscal second quarter ended March 31, 2020:

- Expenses for R&D were $5.22 million, up 17% from $4.46 million due to manufacturing facility preparation, increase in employee stock compensation expense and expenses related to the Phase III trial;
- G&A expenses were $3.31 million, up 29% from $2.56 million on increases in employee stock compensation expense;
- Loss on derivative instruments was $3.04 million compared to $3.05 million, due to fluctuations in the company's share price;
- Other non-operating gains were $553,630 compared with $934,511;
- Net interest expense was ($260,735) compared with ($253,407);
- Net loss totaled ($11.3) million versus ($9.09) million or ($0.28) and ($0.25) per share, respectively.

As of March 31, 2021, cash and equivalents totaled $17.6 million. Cash burn for the quarter amounted to approximately ($8.44) million which includes $3.5 million for capital expenditures on the manufacturing facility. CEL-SCI also purchased approximately $11.1 million in US Treasury Bills during the quarter. CEL-SCI carries lease obligations valued at approximately $12 million, primarily for the manufacturing facility (San Tomas) lease as well as other leases. CEL-SCI carries no debt on its balance sheet as of March 31, 2021.

IT-MATTERS Trial Background

After almost a decade, 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 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.

The trial enrolled three arms including:

1) Multikine plus CIZ (M+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 will 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

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, 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.

Valuation

Although we were only given limited information regarding the data from the IT-MATTERS trial, it was sufficient to refine our analysis and model and provide an updated valuation. We make three changes. The first is a reduction in the addressable population to reflect the 40% of patients that do not receive chemotherapy out of the advanced primary squamous cell head and neck carcinoma patients. We assume a similar penetration rate into this population that peaks at 40% of the, now modified, addressable market by the fifth year of commercialization. The second change is to increase the probability of success from 70% to 85% to reflect the statistically significant results generated by Multikine in the population treated by surgery and radiotherapy. The third modification is to push back our revenue estimates by approximately six months, with first sales occurring in 2023. The net result is a change of our target price to $12 per share.

CEL-SCI provided detail on the updated market size that are similar to the estimates we included in our initiation. The numbers below include the extra cut to identify the size of the population that does not receive chemotherapy (only surgery followed by radiotherapy) based on market data provided by CEL-SCI.

Exhibit II – Addressable Population[2]

Addressable Market	US	Globally	Proportion
Head and Neck Cancer	60,000	650,000	
Squamous Cell	54,000	585,000	90%
Advanced Primary	35,640	386,100	66%
Surgery + RT only	14,256	154,440	40%

Due to the limited information provided, the uncertainty regarding the FDA's willingness to accept the data "as is," the timeline over which a BLA will be submitted and the likely penetration rate given the stronger benefit in a subpopulation, our valuation will be in flux. We anticipate additional updates from the company regarding FDA interaction will help us refine the valuation in the months to come. Additional information regarding the magnitude and statistical significance of the primary endpoint will also be helpful in determining the need for additional data and the FDA's willingness to accept the results.[3]

Summary

CEL-SCI reached the final event in the IT-MATTERS trial in May 2020 and released selected data for a key subpopulation in June 2021. While the company did not release information regarding the primary endpoint, it did demonstrate a meaningful advantage over SoC in the MK+Surgery+RT population. Meanwhile, CEL-SCI is making improvements to its manufacturing facility in anticipation of commercialization with completion expected soon. Based on adjustments to the addresable population, the probability of success and timing, we change our valuation to $12.00 per share.

[2] Compiled by Zacks' analysts from company provided data
[3] SoC is taken directly from the NCCN guideline. With few alternatives, physicians will likely be favorably disposed to prescribing Multikine based on the lack of safety issues and the favorable 5-year OS.

PROJECTED FINANCIALS

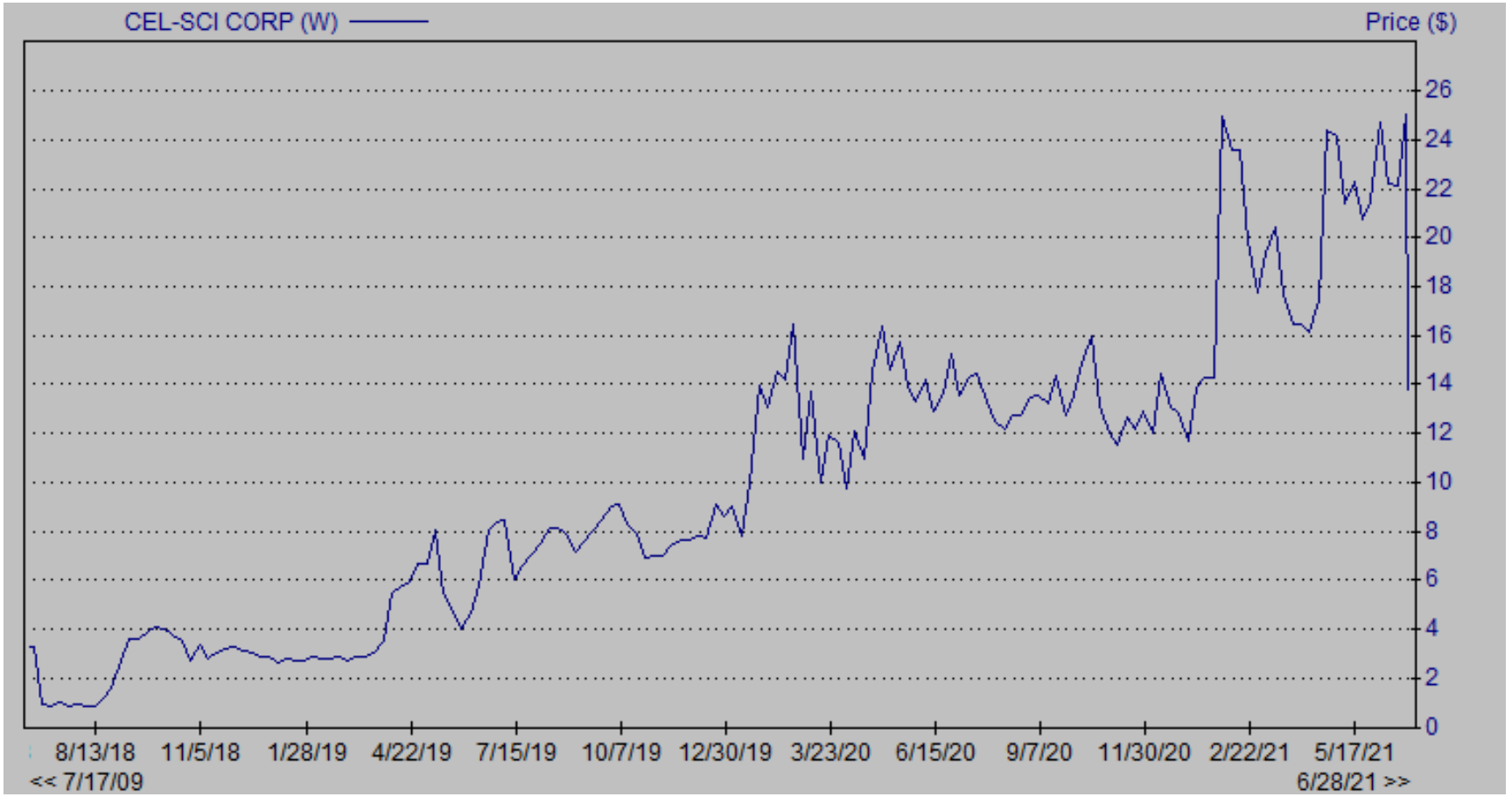
CEL-SCI Corporation - Income Statement

CEL SCI Corporation	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues	**$0.6**	**$0.0**	**$0.0**	**$0.1**	**$0.1**	**$0.2**	**$0.4**	**$80.1**
YOY Growth	21%	-100%	-100%	-49%	250%	-64%	100%	19936%
Research & Development	$17.8	$5.4	$5.2	$3.1	$2.0	$15.7	$4.0	$4.0
General & Administrative	$11.7	$3.3	$3.3	$3.1	$3.2	$12.9	$12.4	$12.8
Income from operations	($29.0)	($8.7)	($8.5)	($6.1)	($5.1)	($28.5)	($16.0)	$63.4
Other Income	($0.2)	$1.0	($2.5)	$0.0	$0.0	$0.0	$0.0	$0.0
Interest Expense	($1.0)	($0.3)	($0.3)	($0.3)	($0.3)	($1.1)	($1.6)	($1.6)
Pre-Tax Income	($30.3)	($8.0)	($11.3)	($6.4)	($5.4)	($29.6)	($17.6)	$61.8
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($4.4)	$17.9
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	29.0%
Net Income	**($30.3)**	**($8.0)**	**($11.3)**	**($6.4)**	**($5.4)**	**($29.6)**	**($13.2)**	**$43.8**
Reported EPS	**($0.82)**	**($0.21)**	**($0.28)**	**($0.13)**	**($0.10)**	**($0.66)**	**($0.23)**	**$0.74**
Basic Shares Outstanding	36.76	38.67	40.05	48.00	52.00	44.68	58.00	59.00

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

HISTORICAL STOCK PRICE

CEL-SCI Corporation – Share Price Chart



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