Zacks Small-Cap Research

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CEL-SCI Corporation (CVM: NYSE)

ASCO Abstract Acceptance

Based on our DCF model and a 15% discount rate, CEL-SCI is valued at approximately $13.00 per share. Our model applies an 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 (5/18/2022)	$3.06
Valuation	**$13.00**

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	**27.28**
52-Week Low	**2.49**
One-Year Return (%)	**-84.4**
Beta	**2.1**
Average Daily Volume (sh)	**1,863,618**
Shares Outstanding (mil)	**43.3**
Market Capitalization ($mil)	**132**
Short Interest Ratio (days)	**2.7**
Institutional Ownership (%)	**32.6**
Insider Ownership (%)	**3.9**
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 2022 Estimate	**N/A**
P/E using 2023 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)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2023					$93.9 E
2024					$174.1 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-$0.21 A	-$0.28 A	-$0.22 A	-$0.20 A	-$0.92 A
2022	-$0.20 A	-$0.23 A	-$0.15 E	-$0.13 E	-$0.49 E
2023					$0.91 E
2024					$2.61 E

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WHAT'S NEW

Second Quarter Fiscal Year 2022 Financial Results

On May 16, 2022, CEL-SCI Corporation (NYSE: CVM) submitted its 2Q:22 Form 10-Q with the SEC. Since our last update in mid-February it has been a light quarter while CEL-SCI has been analyzing data for its completed Phase III clinical trial for Multikine designated IT-MATTERS. The highlight for the previous three months has been the company's announcement of abstracts accepted for the American Society of Clinical Oncology (ASCO) meeting to be held June 3-7, 2022 in Chicago, IL.

CEL-SCI recognized no revenues and incurred operating expenses totaling $9.5 million during the quarter. This resulted in a net loss available to common shareholders of ($9.8) million, or ($0.23) per share.

For the second quarter ending March 31, 2022 versus the same ended March 31, 2021:

- Expenses for research and development increased by 25% to $6.5 million from $5.2 million. Major components of this increase include higher stock compensation expense and greater depreciation related to leasehold improvements to the manufacturing facility and additional cost related to preparing for the commercial sale of Multikine;
- General and administrative (G&A) expenses decreased by 9% to $3.0 million from $3.3 million attributable to a reduction in employee stock compensation expense partially offset by an increase in other net G&A expenses;
- Other non-operating gains were a gain of $2,000 compared to a loss of ($2.5) million largely related to fluctuations in the fair value of derivative liabilities;
- Net interest expense was ($0.3) million compared with ($0.3) million;
- Net loss totaled ($9.8) million versus ($11.3) million or ($0.23) and ($0.28) per share, respectively.

As of March 31, 2022, cash and equivalents totaled $34.3 million. Cash burn for the quarter amounted to approximately ($3.3) million versus ($8.4) million in the prior year period, with the majority of the difference attributable to higher depreciation and amortization add back, and a decrease in the "deposit" asset and other balance sheet items as well as the absence of material amounts of capital expenditures. CEL-SCI holds no debt on its balance sheet.

ASCO Abstract

CEL-SCI announced that submitted abstracts were accepted by American Society of Clinical Oncology (ASCO) for presentation during the organization's 2022 meeting from June 3 to 7 in Chicago, IL.

Regulatory Submission

Now that the company has completed the IT-MATTERS trial, key drivers for valuation include the FDA's willingness to accept the data available for a Biologic License Application (BLA). Additional data and information may be required prior to acceptance. The company has reached out to the FDA and contacted representatives from both the offices of oncology products and rare disease. We will update investors on these meetings, their outcomes and impact on valuation when details are made available.

Multikine Near Term Milestones

- Submission of data of clinicaltrials.gov – May 2022
- Presentation of abstract at ASCO – June 2022
- Development of clinical study report – 2022
- Request meeting with FDA to determine path forward – 2022
- Development of paper for publication in peer reviewed journal – 2022
- Presentation of data package to review with FDA – 2022
- Address FDA Comments – 2022
- Submission of BLA to FDA – 2022

Summary

CEL-SCI updated investors on its financial performance for its second quarter of fiscal year 2022. Since our last update, CEL-SCI has announced the acceptance of its abstract to ASCO 2022, to be held in early June. CEL-SCI recognized no revenues in the period and incurred operating expenses totaling $9.6 million allocated toward advancing Multikine towards regulatory approval in specific settings of head and neck cancer. As of March 31, 2022, cash and equivalents totaled $34.3 million. Cash burn for the quarter amounted to approximately ($3.3) million.

CEL-SCI reached the final event in the IT-MATTERS trial in May 2020 and released selected data for a key treatment arm in June 2021. The data demonstrated a 14.1% 5-year survival advantage for patients in the Multikine, surgery and radiotherapy treatment arm. Efforts now are centered on further analysis of the data, scheduling a pre-BLA meeting with the FDA and preparing a manuscript for publication of the study in a journal. There are a number of favorable factors that support the approval of Multikine, which we have listed above. Other cancer drugs have been approved on weaker data such as overall response rate and with less statistical significance than now presented by Multikine. In a disease where a majority of the treatments are toxic or are associated with serious side effects, CEL-SCI's candidate provides a favorable safety profile with no serious side effects, a must in a space where the first goal is to do no harm.

Since our previous update we adjust our revenue estimates to reflect a later launch of Multikine in 2023 compared to our original expectations. We anticipate a 2H:22 FDA submission and, if approved, first sales approximately one year later in collaboration with a partner. We maintain our price target of $13 per share.

PROJECTED FINANCIALS

CEL-SCI Corporation - Income Statement

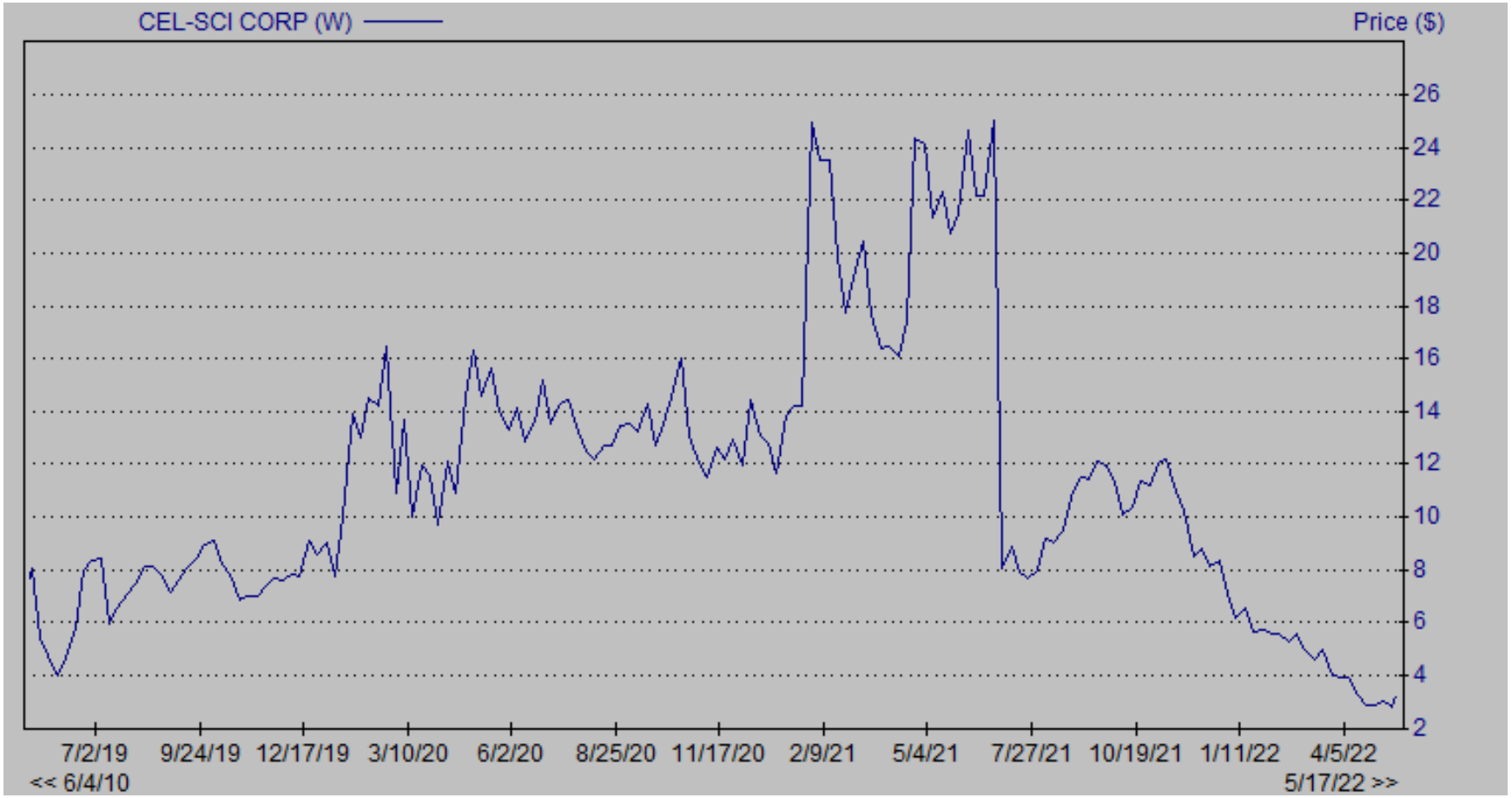
CEL SCI Corporation	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$40.8**	**$129.1**
Research & Development	$23.1	$6.1	$6.5	$3.0	$2.2	$17.8	$4.0	$3.0
General & Administrative	$13.1	$2.8	$3.0	$3.1	$3.2	$12.1	$12.5	$12.8
Income from operations	($36.2)	($8.8)	($9.6)	($6.1)	($5.4)	($29.9)	$24.3	$113.3
Other Income	$0.0	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest Expense	($1.2)	($0.3)	($0.3)	($0.3)	($0.3)	($1.1)	($1.6)	($1.6)
Pre-Tax Income	($37.4)	($8.8)	($9.8)	($6.4)	($5.7)	($31.0)	$22.7	$111.7
Provision for Income Tax	$0.0	$0.0	$0.0			($7.8)	$6.6	$0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	29.0%	29.0%
Net Income	**($37.4)**	**($8.8)**	**($9.8)**	**($6.4)**	**($5.7)**	**($23.3)**	**$16.1**	**$111.7**
Reported EPS	**($0.92)**	**($0.20)**	**($0.23)**	**($0.15)**	**($0.13)**	**($0.54)**	**$0.27**	**$1.86**
Basic Shares Outstanding	40.69	43.08	43.12	43.25	43.30	43.19	59.00	60.00

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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