CEL-SCI Corporation

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Company Overview

Potential Blockbuster Immunotherapy for Head & Neck Cancer: Summer 2025

CEL-SCI presents a unique investment opportunity into a late-stage cancer company that has robust efficacy and safety data in over 740 patients for its immunotherapy drug, Multikine. Multikine is given before surgery to boost the immune system while it is still strong. In a Phase 3 study, Multikine significantly increased survival in the target head and neck cancer patient population demonstrating a 73% survival rate with Multikine vs. only 45% without, at 5 years after treatment and reduced the chance of death by 65%. CEL-SCI is pursuing a dual-track strategy that could lead to commercial launch of Multikine as early as summer of 2025 in Saudi Arabia and potential U.S. FDA approval by 2026/2027.

EQUITY OVERVIEW (May 28, 2025)

NYSE American: CVM Stock Price: \$2.50

Market cap: ~ \$12 M (clean cap structure)

ANALYST COVERAGE

EF Hutton : ThinkEquity : Zacks : FirstBerlin

POTENTIAL COMMERCIAL LAUNCH SUMMER 2025

- Saudi Food and Drug Authority

 encouraged CEL-SCI to file for

 Breakthrough Medicine Designation
 based on prior Phase 3 data
- ✓ If Breakthrough is granted, Multikine would be <u>commercially available by</u> summer of 2025
- ✓ Saudia Arabia has a national healthcare system with reimbursement, potentially leading to near-term revenues for CFI-SCI
- ✓ U.S. Food and Drug Administration gave CEL-SCI the go-ahead to start a pivotal Confirmatory Registration Study based on Phase 3 data in the target population
- ✓ 95% probability of success
- ✓ 212 patient study could potentially lead to FDA approval by 2026/2027 near-term revenues for CEL-SCI

READY FOR COMMERCIAL PRODUCTION

\$2 B

Potential annual manufacturing capacity

\$200 M

Invested in 73,000 sq ft

Disclaimer: Except for historical information contained herein, the statements in this fact sheet are "forward looking" within the meaning of the Private Securities Litigation Act of 1995. A fuller discussion of CEL-SCI Orporation's risks and uncertainties are described in the Company's filings with the Securities and Exchange Commission, which should be reviewed in conjunction with this overview. "Multikine is the trademark that CEL-SCI has registered for this investigational therapy, and this proprietary name is subject to FDA review in connection with our future anticipated regulatory submission for approval. Multikine has not been licensed or approved for sale, barter or exchange by the FDA or any other regulatory agency. Similarly, Its safety or efficacy has not been established for any use

Investment Highlights

Multikine Modulates & Mobilizes Intact Immune Response to Kill Cancer

Multikine is a copy of the pro-inflammatory cytokine immune response our bodies produce every day and is designed to empower a person's intact immune system cells to attack their own cancer. Patients are treated with Multikine right after diagnosis, before any other standard of care treatment (surgery, radiation & chemo) since that is when the immune system is strongest. The goal is to help the intact immune response detect and kill the tumor and micro-metastases in order to reduce recurrence and improve overall survival. Prior studies have proven that in the target population, patients had a pre-surgical response (during the 3 weeks prior to surgery) including elimination and reduction in tumor size and downstaging of disease.



Global Regulatory Approval Strategy: Saudi Arabia Focus First

CEL-SCI's global studies have spanned over 20 countries where approvals are expected. The Company's goal is to obtain approval of Multikine worldwide. CEL-SCI recently met with the Saudi Food and Drug Authority (SFDA) which recommend the Company apply for approval and Breakthrough Medicine Designation based on Multikine's efficacy and safety in the prior Phase 3 study. CEL-SCI plans to submit the Breakthrough application with a local Saudi partner, one of the leading pharma companies in the Kingdom. The SFDA typically takes 60 days to respond. If Breakthrough is given to Multikine, it would become immediately available in Saudi Arabia for patient access and commercial sales, as early as summer 2025.

U.S. FDA Registration Study Likely to Succeed: 95% Confidence

Success in the Confirmatory Registration Study requires an absolute 10% improvement in overall survival (OS) of patients treated with Multikine vs the control group. Prior Multikine studies demonstrate that the target population had a much higher OS than the absolute 10% needed for success.

Clear Efficacy in Target Population: Potential New Standard of Care

The FDA Confirmatory Registration Study is a repeat of the completed Phase 3 study which treated 928 patients, but focuses only on patients with the best survival (which is why it is a small 212 patient study):

- <u>Risk of death cut in half at 5 years</u> versus the control
- 5-year survival Multikine 73% vs. control 45%
- 28.6% absolute 5-year overall survival benefit versus control (p=0.0015)
- >35% rate of pre-surgery tumor reductions and/or downstages (p<0.01;
- More effective for patients with low PD-L1 tumor expression (vs high PD-L1 where Keytruda and Opdivo work best)
- No toxicity added

MULTIKINE HAS SHOWN ACTIVITY IN NUMEROUS OTHER SOLID TUMOR CANCERS