

# **CEL-SCI** Corporation

# NYSE AMEX: CVM

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Statements made during the course of this presentation that state the Company's or management's intentions, hopes, beliefs, expectations or predictions of the future are forward-looking statements. It is important to note that the Company's actual results could differ materially from those projected in such forward-looking statements. This presentation only highlights some of the progress CEL-SCI has made to date. It is not meant to be a complete document as it forms only the visual basis of the company's presentation.

Additional information in general and concerning factors that could cause actual results to differ materially from those in the forward-looking statements is contained from time to time in the Company's SEC filings, including but not limited to the Company's report on Form 10-K for the year ended September 30, 2009. Copies of this presentation may be obtained by contacting the Company.



# **CEL-SCI Stock Summary**

<ul> <li>Name of Company:</li> </ul>	CEL-SCI Corporation
• Location:	Washington, D.C. (USA) metro area
<ul> <li>Stock symbol:</li> </ul>	NYSE AMEX: CVM
<ul> <li>Shares outstanding:</li> </ul>	205 million
Current valuation:	About \$140 million
<ul> <li>Average daily trading volume, last</li> </ul>	t 90 days: About 0.9 million
• 52 week range:	\$0.43 - \$1.70
• Cash on hand June 30, 2010:	\$30 million



CANDIDATE	PRECLINICAL	PHASE I	PHASE II	PHASE III	SALES
MULTIKINE					
Head and Neck Cancer (first-line)					
Cervical Cancer					
Enhancement of radiation/chemotherapy					
L.E.A.P.S. Technology					
H1N1 Flu treatment				AN A	
Rheumatoid Arthritis CEL-2000			20 1		
Malaria					
Viral Encephelities			R		
Herpes					



### Key Points to Understand the Novelty of Multikine

- Multikine immunotherapy is designed for newly diagnosed, not yet treated patients, not for recurrent patients. It is designed to make the first cancer treatment more successful.
- Multikine is designed to activate a robust and comprehensive anti-tumor immune response in cancer patients. It attacks the tumor on multiple fronts and has been shown to reduce cancer recurrence and increase overall survival in a Phase II clinical trial.
- Multikine works by activating the intact immune system since it is given before the ravages of surgery, chemo and radiation.
- The Multikine Phase III study is the first study to ever test the assumption that stimulation of an intact immune system prior to any other cancer therapies will be better for the patient's survival than the stimulation of the immune system after surgery, chemo and radiation, as is usually done with cancer immunotherapy.
- A win in Phase III would be significantly bigger than normal for investors because:
  - First line treatment
  - Standard of Care
  - CEL-SCI still owns all key marketing rights
  - Multikine is non-toxic
  - Commercial facility near Baltimore able to produce 20,000 treatments



- Multikine is a defined mixture of cytokines.
- Injected locally around the tumor and the lymph nodes to produce an effective and sustainable anti-tumor immune response.
- The primary goal of the Multikine therapy is to kill the local tumor micrometastases which are known to exist around the tumor and often also in the local lymph nodes. These micro-metastases are thought to be the cause of most cancer recurrences, and therefore death.
- We believe that the stimulation of an anti-tumor immune response <u>prior</u> to surgery, radiation and/or chemotherapy is the best way to kill the tumor micro-metastases and prevent recurrence, thereby increasing overall survival.
- The Phase II clinical data suggest a clear increase in patient survival.
- The pivotal Phase III study, designed to lead to marketing approval, is scheduled to start within the next few months.







#### Head and neck cancer:

6% of all cancers, or about 650,000 new cases annually.

- Multikine would be approved for all newly diagnosed head and neck cancer patients.
- Approval would make Multikine part of the standard of care treatment along with the first treatment of surgery, radiation and chemo (first line standard of care).
- Multi-billion \$ market opportunity.



#### Multiple early studies to establish the best treatment regimen

- Conducted multiple Phase I/II studies in US, Canada, Europe and Israel to establish the best treatment regimen. Tested 6 doses of Multikine, 2 weeks of administration versus 3 weeks, 3 times per week versus 5 times per week and peritumoral administration alone versus peritumoral and perilymphatic administration (studies conducted GCP/ICH).
- The Proof of Concept final Phase II study incorporated the best components from all the earlier studies.
- The key data from this study were presented and published in top tier peerreviewed scientific and clinical journals (e.g. ASCO, Journal of Clinical Oncology, Journal of Oral Oncology).
- The treatment regimen for the Phase III trial is the same as the treatment regimen for the Proof of Concept final Phase II trial.



- Locally advanced primary head & neck cancer patients
- Multikine administered peri-tumorally and peri-lymphatically at daily supraphysiological doses 200 IU to a maximum of 3,200 IU (as IL-2) + CIZ\*
- Current standard of care:
  - Surgery followed by Radiation Therapy (+/- Chemo)
- Standard of care with Multikine:



\* CIZ = Cyclophosphamide ( $300mg/M^2$ , IV, day -3), Indomethacin (25mg,tid,po), and Zinc (50mg, po, as elemental Zinc)

CIZ is added to decrease tumor suppressor mechanisms and increase Multikine effectiveness



# Phase I / II studies with Multikine

# Safety

- Over 220 patients treated
- Tolerable and safe
- No Serious Adverse Events associated with Multikine at any dose administered.
  - Multikine is given locally in the area of the tumor and in very low doses; all cytokine components in Multikine are several logs below the known levels of toxicity for these cytokines.



**Multikine** 

#### **Mechanism of action**





#### A sustainable anti-tumor immune response

#### **Pathology:**

- The goal of the 3 week Multikine treatment is to eliminate the micro metastases around the tumor.
- Yet, 12% of the patients had no tumor left after 3 week treatment with Multikine (ASCO and Journal of Clinical Oncology).
- 50% reduction in the number of tumor cells before any other treatment following 3 week treatment with Multikine (ASCO and Journal of Clinical Oncology).

#### **Patient follow-up showed:**

• 33% improvement in overall survival over current standard of care at 3.5 years (Journal of Oral Oncology)



# **A Paradigm Shift in Tumor Microenvironment**



\* Talor et al., ASCO Annual Meeting Proceedings 22(14S): 189S, 2004 Timar et al., Journal of Clinical Oncology 23(15) May 20, 2005







# **Multikine**

#### **Treatment effect -- Breaking tumor tolerance for an effective immune response**

# Oral Squamous Cell Carcinoma (Locally Advanced Primary H&N Cancer)

Histological appearance of necrosis in Oral Squamous Cell Carcinoma (OSCC) [HE staining]:



# **Non-Multikine treated**



# **Multikine treated**

**Non-Multikine treated:** Lack of necrosis in the epithelial nests of OSCC **Multikine treated:** Entire cancer nest is necrotic and filled with debris and leukocytes



# **One pivotal Phase III trial for approval**

- FDA and Canadian regulators gave go-ahead to Multikine Phase III study
- Advanced primary (not yet treated) head & neck cancer represents an unmet medical need (about 50% of the patients die within 3 years following treatment) with minimal progress over the last 50 years
- Orphan drug status in the US codifies that only one trial is needed



# **Study Design and Statistical Parameters**

# Methodology:

•Phase III open-label, randomized, controlled, multi-center study to be conducted in about 48 centers in 9 countries

- > Enroll 880 patients to have about 780 evaluable patients
- Reference Therapy: Standard of Care = Surgery + Radiation +/-Chemotherapy
- Three (3) week administration of Multikine + standard of care median three year follow-up (event-driven)
- Primary end point: Overall Survival

#### Statistics:

•80% Power; 95% confidence - to show a 10% Overall Survival advantage



# **Multikine: Phase III trial**



\* SOC treatment for "high-risk" patients, defined as those with positive surgical margins, 2+ clinically positive nodes, or extra capsular nodal spread. Patients not deemed to be "high-risk" receive only radiation after surgery.



#### **Trial Design - outcome**

#### CEL-SCI Corporation The Impact of Multikine® on Standard Therapies for Head & Neck Cancer



\* Based on a literature survey of 55 trials in advanced primary head and neck cancer published from 1987 to 2007.



#### Steps taken to reduce the risk of failure of the Multikine Phase III trial

The most common reasons for Phase III study failures or the failure to receive approval to sell a drug, other than the drug not working, are:

#### 1. Phase III study not reviewed by FDA and not acceptable to FDA:

Multikine Phase III study was reviewed in detail and we made changes to the Phase III protocol based on FDA's comments.

#### 2. Study too small:

Multikine study will enroll 880 patients, a very large number.

#### 3. Clinical endpoint not relevant:

Multikine study follows overall survival of the patients, the gold standard. The clinical endpoint cannot be more relevant.

# 4.Change in treatment protocol between Phase II and Phase III without additional studies:

Multikine Phase III study is the same as Phase II, we have made no changes. Therefore, we expect the Phase II results to be representative of the results one can expect in the Phase III trial.

#### 5. Insufficient attention to manufacturing issues:

Multikine manufacturing process is validated and we built a dedicated manufacturing facility for Multikine.



- Located outside Baltimore, Maryland, USA
- \$25 million commercial size cGMP Drug Production facility dedicated to Multikine
- Facility includes True Cold Fill (+4°C) capability to avoid loss of biological activity during fill
- Meets US and European regulations
- Facility will supply Phase III study and subsequent commercial sale
  - Current capacity about 20,000 treatments annually
  - > Fully built out capacity about 60,000 treatments annually
  - First line standard of care use would likely require the construction of another facility



CEL-SCI believes that it can develop Multikine without a major partner in the US, and potentially even in Europe, leaving shareholders with the full upside.

CEL-SCI's existing partners that will participate in the Phase III trial are:

- Teva Pharmaceuticals of Israel (Israel and Turkey)
  - > Teva will run and pay for part of the Phase III trial in Israel
  - > Revenue share upon sale
- Orient EuroPharma of Taiwan (parts of the Far East, not Japan or China)
  - OEP will run and pay for part of the Phase III trial in Taiwan and Hong Kong
  - Revenue share upon sale



# **Intellectual property protection**

#### **Patents and other protection for Multikine:**

- Composition of matter patent protection until 2024
  - US Patent # 6,896,879
- Additional patent applications world-wide
- Orphan drug designation in US
- Proprietary manufacturing and quality control know-how (most important since Multikine is a complex biologic and impossible to copy)







#### Summary of key points:

- 1. Potential new Standard of Care cancer therapy for a multi-billion dollar market. Phase III trial to start very soon.
- 2. Multikine is un-partnered in the US, Europe and Japan (unencumbered late stage oncology drug).
- 3. Commercial sized manufacturing facility is commercial ready.
- 4. Substantial cash position.
- 5. Investigative trial for hospitalized H1N1 patients at Johns Hopkins.
- 6. Rheumatoid arthritis product also shows equivalence or possibly superiority to Enbrel (2009 sales of about \$4 billion dollars) in animal tests.



