# CEL-SCI Corporation

US / Biotechnology
NYSE, US; FSE, Germany
Bloomberg: CVM US
ISIN: US1508376076

Initiating coverage

| | |
|---|---|
| **RATING** | **BUY** |
| **PRICE TARGET** | **USD 8.40** |
| Return Potential | 200.0% |
| Risk Rating | High |

## MULTIKINE, A POTENTIAL NEW FIRST-LINE TREATMENT FOR HEAD AND NECK CANCER

**CEL-SCI Corporation (CEL-SCI) is a biotech company with a development-stage immunotherapeutic product pipeline focused on cancer. The company's lead drug candidate, Multikine, is a biological product that contains a mixture of naturally derived and naturally occurring human proteins called cytokines, capable of activating a patient's immune system to fight and kill cancerous tumours. The drug candidate has been primarily developed as a neo-adjuvant (prior to standard therapy which mostly implies surgical removal of the tumour) immunotherapy for the treatment of various types of solid tumours, the lead indication, primary advanced head and neck squamous cell carcinoma (HNSCC). While Multikine did not meet the primary endpoint of the overall phase 3 trials in 923 patients, it demonstrated superior performance compared to standard of care in the pre-defined low-risk arm (n=380). Moreover, post-hoc data analysis of the whole study showed that the drug candidate achieves an even stronger performance in less sick locally advanced disease patients meeting certain criteria (No lymph node involvement – N0 – and low PD-L1 tumour expression). These patients showed a 73% 5-year survival rate vs 45% for the control group, a 28 percentage point overall survival advantage vs control (p=0.0015). Importantly, 38% of these patients saw pre-surgical responses with Multikine which led to a >32% 5-year absolute overall survival advantage vs control (p=0.0019). Based on this data, we believe CEL-SCI's lead drug candidate, Multikine, has a good chance of receiving conditional approval in Canada and the UK in H2 2024, followed by Europe and the US in 2025. Subject to approval, the company will be able to commercialise the drug while conducting a confirmatory study. We project sales potential for Multikine in these markets of >USD970m. We expect positive news flow from Multikine's approval process to add substantial value to CEL-SCI and positively impact the share price. We initiate coverage of CEL-SCI with a Buy rating and a USD8.40 (€7.70) price target.**

**Buy recommendation** Our pipeline valuation model yields a price target of USD8.40, which represents a return potential of ~200% from the current level.

(p.t.o.)

### FINANCIAL HISTORY & PROJECTIONS

| | 2019/20 | 2020/21 | 2021/22 | 2022/23E | 2023/24E | 2024/25E |
|---|---|---|---|---|---|---|
| Revenue (USD m) | 0.00 | 0.00 | 0.00 | 0.00 | 0.26 | 9.13 |
| Y-o-y growth | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| EBIT (USD m) | -28.99 | -36.19 | -36.06 | -30.80 | -44.03 | -28.28 |
| EBIT margin | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Net income (USD m) | -30.26 | -36.36 | -36.70 | -31.40 | -44.73 | -28.98 |
| EPS (diluted) (USD) | -0.82 | -0.90 | -0.87 | -0.71 | -1.00 | -0.65 |
| DPS (USD) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| FCF (USD m) | -17.97 | -27.83 | -16.99 | -21.24 | -38.96 | -25.97 |
| Net gearing | -78.6% | -63.8% | -70.5% | -18.9% | -52.3% | -47.9% |
| Liquid assets (USD m) | 15.51 | 42.21 | 22.67 | 1.77 | 11.26 | 13.61 |

### RISKS

Risks include, but are not limited to development, regulatory, competition and financial risks.

### COMPANY PROFILE

Founded in 1983, CEL-SCI Corporation is a leading US immuno-therapeutic biotech company focused on the development of new drugs to treat cancer. The company's lead drug candidate, Multikine, has completed international phase 3 trials for the treatment of locally advanced primary squamous cell carcinoma of the head and neck (SCCHN). CEL-SCI will seek conditional approval in Europe, UK, Canada, and the US.

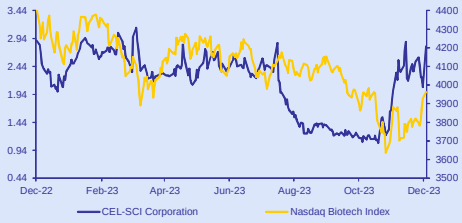
### MARKET DATA

As of 12/4/2023

| | |
|---|---|
| Closing Price | USD 2.80 |
| Shares outstanding | 44.75m |
| Market Capitalisation | USD 125.30m |
| 52-week Range | USD 1.07 / 3.13 |
| Avg. Volume (12 Months) | 490,499 |

| Multiples | 2021/22 | 2022/23E | 2023/24E |
|---|---|---|---|
| P/E | n.a. | n.a. | n.a. |
| EV/Sales | n.a. | n.a. | n.a. |
| EV/EBIT | n.a. | n.a. | n.a. |
| Div. Yield | 0.0% | 0.0% | 0.0% |

### STOCK OVERVIEW




### COMPANY DATA

As of 30 Jun 2023

| | |
|---|---|
| Liquid Assets | USD 5.14m |
| Current Assets | USD 7.73m |
| Intangible Assets | USD 0.18m |
| Total Assets | USD 32.32m |
| Current Liabilities | USD 5.29m |
| Shareholders' Equity | USD 14.79m |

### SHAREHOLDERS

| | |
|---|---|
| Vanguard Group Inc. | 4.0% |
| Geert Kersten | 2.5% |
| BlackRock Inc. | 1.6% |
| Free float and other | 91.9% |

**Analyst:** Christian Orquera, Tel. +49 (0)30 - 80 93 96 90

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# INVESTMENT CASE

**CEL-SCI's multinational, randomised controlled phase 3 study for the lead drug candidate Multikine in 923 patients with locally advanced SCCHN achieved statistically significant improvement against control in the arm with patients at lower risk of cancer recurrence** CEL-SCI completed a 10-year pivotal phase 3 study and published the top-line data in June 2021. The three-arm study investigated administration of (1) Multikine coupled with a cocktail of three adjuvants (CIZ: low-dose Cyclophosphamide, one-time only), Indomethacin and Zinc-multivitamins to increase the efficacy of Multikine) plus subsequent standard of care (SOC) in 395 patients, (2) Multikine alone + SOC in 134 patients and (3) SOC alone (control group) in 394 patients. Depending on the physician's assessment of the patient's risk of cancer recurrence following surgery, the SOC treatment comprised either (A) surgery + radiotherapy for the patients with a lower risk of recurrence or (B) surgery + chemotherapy for the patients with a higher risk of recurrence. The read out of the study for the lower-risk patients (n=380) receiving Multikine+CIZ+SOC (1A) showed the following positive overall survival benefit compared to the control arm (3A): 62.7% 5-year overall survival in patients treated with Multikine +CIZ+SOC vs. 48.6% for the control group (SOC), which equates to a 14.1 percentage point benefit (with a 0.68 hazard ratio and p-value of 0.0236). 101.7 months median overall survival for Multikine+CIZ+SOC vs 55.2 months for the control group, which corresponds to almost four years of survival benefit. 16.0% of patients saw partial or complete tumour response in the three weeks prior to surgery vs 0% tumour response in the control group. No safety issues arose during or after the study-directed treatments in the Multikine-treated arms of the study as compared to the control group.

**The second arm with patients categorised after surgery as at high-risk for recurrence and the entire study population failed to show a statistically significantly superior result compared with the control group** Unfortunately, both the patients categorised as high-risk (n=467) and the entire study population (n=923) failed to show statistically significant superiority against control and so the study as a whole did not meet the primary endpoint. This suggests that the immune system in higher-risk patients is too weak to efficaciously fight this highly aggressive cancer even with the help of Multikine immunotherapy and that the cisplatin chemotherapy may be detrimental to the immune response created by Multikine.

**New exciting findings presented at the 2023 European Society for Medical Oncology (ESMO) conference in Madrid, Spain – Based on thorough data analysis from the phase 3 study, CEL-SCI identified markers that narrowed the target population to patients who benefited most from Multikine treatment** CEL-SCI conducted additional analysis of the data from the phase 3 study in the overall population. Following these results, the company identified the less sick patients in the overall population who would benefit most from Multikine and refined the target population using the following criteria: (1) no tumour involvement of the lymph nodes known as "N0" and no extracapsular spread of the tumour and (2) low tumour PD-L1 expression. The narrower target patient group can be easily identified prior to SOC treatment with two standard diagnostic tests – positron emission tomography (PET) scan and a tumour sample – which would facilitate label specification for drug approval. The new target population may amount to ~37k p.a. in the core North American (FBe: ~1k p.a. in Canada and ~11k p.a. in the US) and European (FBe: ~2k p.a. in the UK and ~23k p.a. in the EU) markets and ~145k patients p.a. globally.

**Multikine+CIZ+SOC showed a much stronger efficacy in the narrower target population who met the new criteria** In the phase 3 study, patients who met the narrower criteria (n=114 of which Multikine+CIZ+SOC n=60 and control n=54) and who received Multikine+CIZ+SOC achieved an impressive 73% 5-year survival rate compared to 45% for the control group (this represents a 28 percentage point higher survival) with statistical

significance (p=0.0015). The hazard ratio, which indicates the reduction in the mortality risk, amounted to 0.35 (p=0.0012), meaning that on average a SCCHN patient's chance of dying within five years of diagnosis was reduced by 65% with Multikine administration and was ~3 times lower than in the control group.

**Pre-surgical tumour responses in the patients treated with Multikine+CIZ was seen in the overall and in the target patient population, which led to higher 5-year survival** Remarkably, Multikine elicited two types of pre-surgery tumour response: (1) tumour reduction (~13% of Multikine-treated patients in the target population vs 0% in the corresponding control group) and (2) tumour downstaging (~35% of Multikine-treated patients in the target population vs 13% in the corresponding control group), both of which led to >32% 5-year absolute overall survival advantage vs control with a statistical significance of p=0.0019.

**Multikine may act synergistically to check point inhibitors, creating an attractive market opportunity** We particularly view the last criterion to define the target population as very interesting. From a marketing perspective, Multikine showed the highest efficacy in tumours with low PD-L1 expression, the patient population that does not respond well to checkpoint inhibitors such as Bristol Myer's Opdivo and Merck's Keytruda, the current "stars" of immuno-oncology therapy. Multikine would thus be complementary to and not in competition with these blockbuster drugs. The complementary and potentially synergistic mode of action of the drugs creates an attractive market opportunity for combination therapy to improve patient outcomes.

**We expect Multikine's near-term approval in Canada and the UK, followed by the US and EU, conditioned to the commitment to conduct a confirmatory study based on powerful data in the newly identified target population. – We estimate >USD970m revenue potential in these markets** The positive results could enhance the chances of obtaining conditional drug approval, which the company is seeking in multiple international markets. CEL-SCI has submitted consultation applications for potential conditional drug approval in the UK and Europe, and Canada has already suggested that the company apply for a conditional approval designation (NOC/C). Recently, the UK's National Institute for Health and Care Excellence (NICE) selected Multikine as the potential new SOC for SCCHN in the UK, based on a detailed report from the UK's National Institute for Health and Care Research (NIHR). We expect the company to submit the applications in H1 2024 and the first approvals in Canada and the UK could be granted in H2 2024 or early 2025, possibly followed by Europe and the US in 2025. These approvals are linked to the obligation to conduct a confirmatory study which management plans to start in 2024. Upon approval, the company can start drug commercialisation and conduct the trial in parallel. CEL-SCI is planning to raise funds to extend the cash runway beyond Q2 2024 and to finance the confirmatory trial. We conservatively project peak sales for Multikine four years after launch of >USD970m.

**We initiate coverage with a price target of USD8.40 and a Buy recommendation** Chiefly based on Multikine, our proprietary risk-adjusted sum-of-the-parts valuation model suggests a fair value for CEL-SCI of USD8.40 (€7.70) per share. We believe investors do not yet appreciate the potential of the immuno-oncology drug candidate Multikine which is close to obtaining conditional approval. During the next twelve months, we expect positive news flow from the Multikine registration progress as well as on licensing agreements to trigger appreciation of CEL-SCI's share price.

# SWOT ANALYSIS

## STRENGTHS

- **Experienced management team** Mr Geert Kersten (CEO), Dr Eyal Talor, PhD, (CSO) and Mr John Cipriano (VP of regulatory affairs and a former FDA deputy biologics division director) are highly qualified executives with over 90 years of combined experience in the pharmaceutical, biotech and banking industries, as well as in academia and the US regulatory agency FDA.
- **Analysis of data from Multikine's phase 3 study in 923 patients with primary locally advanced HNSCC showed higher and statistically significant efficacy in a refined target population** The lead drug candidate demonstrated efficacy in the low-risk arm in the phase 3 study. However, post-hoc data analysis showed that the drug candidate achieves an even stronger performance in less sick patients meeting certain criteria (No lymph node involvement – N0 –, no extracapsular spread and low PD-L1 tumour expression). These patients showed a 73% 5-year survival rate vs 45% for the control group (p=0.0015). Importantly, 38% of these patients saw pre-surgical responses with Multikine, which led to >32% 5-year absolute overall survival advantage vs control (p=0.0019).
- **Conditional approval of Multikine in the first two countries in H2 2024 seems likely** Based on the recently published data, there is a strong likelihood that CEL-SCI's lead drug candidate Multikine may receive conditional approval in Canada and the UK in H2 2024, followed by Europe and the US in 2025. Based on the strong data in the refined patient population which was highly statistically significant, the required confirmatory trial entails relatively low risk in our view.

## WEAKNESSES

- **Limited financial latitude** The company had cash resources of USD5.6m at the end of 9M 22/23. These funds, coupled with the USD5m capital increase completed on 20 November 2023, will finance ongoing operations into ~Q2 2024. The company will need to raise capital to continue funding operations and we anticipate that an additional >USD25m will be required to fund Multikine's confirmatory study-related costs.
- **Lead drug candidate Multikine missed the primary endpoint in the phase 3 HNSCC study** Even though Multikine did not demonstrate superiority against standard of care in the overall phase 3 study, the drug candidate showed superiority in the pre-defined low-risk arm and even better efficacy in the refined target population of least sick patients with locally advanced HNSCC meeting specific criteria. These encouraging findings may justify approval of the drug conditional on the conduct of a confirmatory study.

## OPPORTUNITIES

- **Newsflow from the process of filing for conditional approval of Multikine in Canada, UK, Europe and the US may create significant shareholder value** The company plans to submit the applications in H1 2024 and the first approvals in Canada and the UK could be granted in H2 2024 or early 2025, followed by Europe and the US in 2025. These approvals are likely to be linked to the obligation to conduct a confirmatory study which management plans to start in 2024.
- **Development deals with pharmaceutical companies may lead to significant upfront and milestone payments** We expect CEL-SCI to close a collaboration agreement with a pharmaceutical company to commercialise Multikine. A commercialisation deal could generate upfront and milestone payments. It would in our view validate the drug's potential and attract attention from the industry for further potential co-development deals in other indications or even make CEL-SCI a takeover target.
- **Market potential expansion for Multikine in other cancer indications** CEL-SCI is currently focusing its resources on Multikine's lead HNSCC indication. Multikine is in phase 1 clinical development in further attractive cancer indications. Once Multikine is approved in HNSCC, the company intends to pursue development of the drug for the following potential indications: breast cancer, skin cancer, cervical cancer, anal warts in HIV/HPV co-infected men and women, and melanoma. These new indications hold out the prospect of significant additional market potential.

## THREATS

- **Financing risks** The company will need to raise funds to finance ongoing operations and the confirmatory study of its lead drug candidate Multikine. A difficult financing environment or negative feedback from the regulatory authorities would be an impediment to raising more capital.
- **Development and regulatory risks** Development of the lead drug candidate Multikine in HNSCC may progress more slowly than expected. The product may also fail to demonstrate efficacy in the confirmatory trial in HNSCC (even though the survival benefit vs control seen in the phase 3 study in the new target population was highly statistically significant at p=0.0015). Moreover, even despite Multikine's strong results in phase 3 clinical trials in the target population and the first encouraging feedback given by regulators and advisors in initial meetings, there is still a risk that the regulatory agencies (Canada Health, HMRA, FDA and EMA) will not grant the drug a conditional approval or may request a high percentage of patient enrollment (e.g. in the US) for the confirmatory trial before commercialisation is allowed.
- **Competitive risks** CEL-SCI's pipeline, particularly the lead drug candidate Multikine, may face competitive pressure. At present, there are only two pharmaceutical companies developing a neoadjuvant candidate at an advanced stage, Merck (Keytruda in phase 3) and Bristol Myers Squibb (Opdivo in phase 2). However, these products tend to show highest efficacy in patients with high tumour PDL-1 expression, while Multikine will be approved in the low PDL-1 segment. Still, any unexpected breakthrough by one or more competitors could hit CEL-SCI's potential revenues.

# VALUATION

Biotechnology valuation is notoriously difficult since there is high risk in the development of the R&D pipeline, which leads to uncertainty in projecting cash flows. We have assessed CEL-SCI's fair value based on a sum-of-the-parts methodology. We believe this is the most appropriate valuation method for CEL-SCI because it reflects the implicit risk-adjusted value of every drug candidate in the R&D pipeline. Development risks, including clinical and regulatory risks, are taken into account as are market size and the expected timing of cash flows post-approval for each project.

We have used a risk-adjusted NPV model for the drug candidate Multikine in the lead HNSCC indication and the key commercialisation regions, namely Canada, UK, the US and the EU. We believe that Multikine has substantial value in further indications (e.g. breast cancer, skin cancer, cervical cancer, anal warts which are a potential precursor of anal cancer in HIV/HPV co-infected men and women, and melanoma), and that the LEAPS technology platform also has potential. However, these areas are currently not the main focus of the company and we consider them an upside to our valuation.

During the forecasting process, we adjusted our sales estimates and resulting cash flows for success probabilities to obtain risk-adjusted expected values. We base our probability coefficients on statistical sector studies, such as the Tufts CSDD, and on our own estimates. In this instance, we have derived an 85% probability of success for the drug candidate Multikine in HNSCC (completed phase 3 clinical development and is preparing to file for conditional approval). We consider Multikine in HNSCC to be the most important value driver for the company.

Additionally, using First Berlin methodology, which takes into account company-specific risk factors, we have derived a cost of equity (COE) of 17% for CEL-SCI. Based on a debt ratio of 0%, we arrive at a WACC of 17%, which we have used to discount projected cash flows. Including projected proforma net cash of USD77.0m, we value CEL-SCI at USD612.1m, which implies a fair value of USD8.40 per share on a proforma fully diluted basis. Using our ten-factor risk analysis, we set a High risk rating for CEL-SCI. The main risk factors that we have identified are financing, development, regulatory and competition.

**Figure 1: "Sum-of-the-parts" valuation model**

| Compound | Project[1] | Present Value | Patient Pop (K) | Treatment Cost (USD) | Market Size (USDM) | Market Share (%) | Peak Sales (USDM) | Royalty Rate (%) | PACME Margin[2] (%) | Discount Factor (%) | Year of market launch |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Multkine | HNSCC - Canada | USD 24.3M | 1K | 90,000 | 110.0M | 25% | 32.8M | 35% | 67% | 17% | 2024 |
| Multkine | HNSCC - UK | USD 40.1M | 2K | 90,000 | 178.9M | 25% | 53.4M | 35% | 67% | 17% | 2024 |
| Multkine | HNSCC - US | USD 229.8M | 11K | 110,000 | 1,218.7M | 24% | 341.6M | 35% | 67% | 17% | 2025 |
| Multkine | HNSCC - EU | USD 348.3M | 24K | 90,000 | 2,199.4M | 20% | 546.4M | 35% | 67% | 17% | 2025 |
| PACME PV | | USD 642.5M | | | 3,707.0M | | 974.2M | | | | |
| Costs PV[4] | | USD 147.8M | | | | | | | | | |
| NPV | | USD 494.7M | | | | | | | | | |
| Milestones PV | | USD 40.4M | | | | | | | | | |
| Net cash (proforma) | | USD 77.0M | | | | | | | | | |
| Fair Value | | USD 612.1M | | | | | | | | | |
| Share Count (proforma) | | 72,851K | | | | | | | | | |
| Price Target | | USD 8.40 | | | | | | | | | |
| Price Target | | EUR 7.70 | (based on EUR-USD exchange rate of 1.09) | | | | | | | | |

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining market exclusivity after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

*Source: First Berlin Equity Research*

### Estimation of price and sales potential

Pricing of comparable drugs such as checkpoint inhibitors with a US average of USD 144k p.a. (source: Guirguis et al., 2021) suggests that a sales price of USD110k per patient per year should be achievable for Multikine in the US. We have assumed a lower price of USD90k for the Canadian, UK and European markets. Our conservative price estimate implies a discount to the peer drugs which will in our view promote the achievement of faster reimbursement and market penetration.

We have assumed that CEL-SCI can achieve a market share in the range of 20-25% in the targeted country markets. We believe this is a conservative assumption, considering that there is no treatment alternative in the market capable of improving patient survival beyond standard of care. Based on statistical data on the incidence of head and neck cancer (see page 23) and CEL-SCI's estimate that approximately 27% of patients with primary advanced HNSCC belong to the target population that meets the inclusion criteria of N0/low PD-L1 expression, we project the following target population in the core regions:

**Table 1: Estimation of the company's target population in the core region**

| Patient population | % | US | Canada | UK | EU | Total core market | Worldwide |
|---|---|---|---|---|---|---|---|
| New Head and neck cancers | 100% | 68,000 | 7,500 | 12,200 | 150,000 | 225,500 | **890,000** |
| Squamous cell carcinomas | 90% | 61,200 | 6,750 | 10,980 | 135,000 | 202,950 | 801,000 |
| Advanced primary | 66% | 40,392 | 4,455 | 7,247 | 89,100 | 133,947 | **528,660** |
| **Target population - meet criteria** | **27%** | **11,079** | **1,222** | **1,988** | **24,438** | **36,739** | **145,000** |

*Source: First Berlin Equity Research estimates*

We have assumed that the HNSCC segment will grow at a CAGR of 3% by 2040. Due to the orphan drug designation, we expect Multikine to enjoy seven years of market exclusivity in the US. We project a potential Canadian and UK approval and market launch in H2 2024, followed by approval and launch in the rest of Europe and the US in 2025. We project total peak sales potential of >USD970m four years after launch for Multikine in the core North American and European markets.

We assume that the company will license the product to a pharmaceutical partner who will support the confirmatory study with their expertise. Given that this distribution partner will be appointed during 2024, at a stage close to commercialisation, we assume an attractive royalty rate of 35% and a gross PACME margin of ~67%, roughly equating to a net PACME margin of ~23% upon commercialisation. The partner will conduct commercialisation and bear the marketing expenses. These assumptions are in accordance with metrics we have observed in the industry.

# COMPANY PROFILE

## HISTORY AND COMPANY OVERVIEW

**History of CEL-SCI and its lead drug candidate Multikine** Headquartered in Vienna, Virginia, in the Washington DC area in the US, CEL-SCI Corporation is an immunotherapy biotech company with a clinical-stage product pipeline focused on cancer and infectious diseases. The firm's roots can be traced back to the Max Planck Institute in Germany, where its core immune-oncology approach and lead drug candidate Multikine, a mixture of small proteins called cytokines, was discovered. The inventor was Mr Maximilian de Clara, a visionary, entrepreneur and angel investor who deeply believed that the immune system could fight cancer. In 1983, Mr de Clara founded CEL-SCI to develop Multikine further. In 1987, Mr Geert Kersten, a lawyer and financial expert, joined the company as Director of Corporate and Investment Relations. He was promoted to COO in 1992 and CEO in 1995 to drive the development of Multikine through commercialisation. CEL-SCI struggled with funding limitations and development progressed relatively slowly. Multikine's first phase 1 clinical trial was conducted by Dr Dudley Dumonde, the renowned scientist who coined the term cytokine, in England between 1985 and 1988. He successfully demonstrated preliminary safety and substantial levels of immune response by administration of Multikine to 49 patients suffering from various forms of solid cancers.

In 1993, CEL-SCI raised more funding, which allowed it to acquire the technology necessary to develop and manufacture Multikine as a biological drug product on a scale sufficient to conduct widespread studies in humans and future commercialisation. The company hired professional management and scientific personnel including Dr Talor to develop Multikine, built a research laboratory, a small pilot and commercial-ready manufacturing plant. From 1995 to 2004, CEL-SCI completed a series of phase 1/2 and phase 2 clinical trials for Multikine as a neoadjuvant, focusing on head and neck cancer. Due to a challenging financing environment during the financial crisis of 2008 and 2009, the company could not secure enough funds until H2 2009 to fund the phase 3 study. Multikine's multinational, randomised, pivotal phase 3 study as neoadjuvant treatment in 923 patients with primary advanced head and neck squamous cell carcinoma (HNSCC) took place between 2010 and 2020. This trial primarily investigated Multikine in a regimen coupled with a cocktail of three adjuvants (CIZ: low-dose Cyclophosphamide, Indomethacin and Zinc-multivitamins to increase the effectiveness of Multikine's effect) plus subsequent standard of care (SOC).

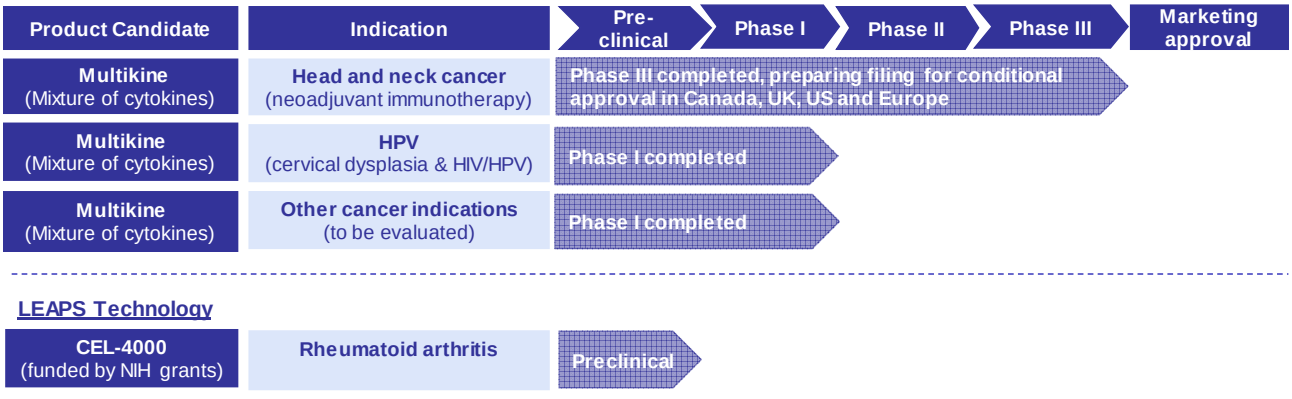
**Multikine+CIZ+SOC: the phase 3 study has been completed, and the company is preparing documentation to submit a conditional approval application in the North American and European markets; approval likelihood seems high** CEL-SCI published the top-line data of the phase 3 study in June 2021, achieving statistically significant overall survival improvement against control in the arm of patients with lower risk of cancer recurrence. Unfortunately, the second arm with high-risk patients and the entire study population failed to show a superior result compared with the control group. The main reasons are that the immune system in higher-risk patients may be too weak to fight this highly aggressive cancer efficaciously and the cisplatin chemotherapy may be detrimental to the immune response created by Multikine. However, the company conducted additional analysis of the data from the phase 3 study in the overall population, presenting the results at the European Society for Medical Oncology (ESMO) conference on 22 October 2023. CEL-SCI identified markers (No lymph node involvement – "N0" – and low PD-L1 tumour expression) which could be easily measured with standard cancer screening tests that narrowed the target population to less sick patients (whose survival rate is usually only ~49% at 5 years). Identifying the target population is critical because without it regulators cannot write an approval label. Importantly, these patients showed an impressive 73% 5-year survival rate for Multikine+CIZ+SOC treatment compared to 45% for the control group, with statistical significance (p=0.0015). Many of these patients also showed pre-surgical

tumour responses (i.e. tumour reduction and/or downstaging), which translated to higher survival (see details in the Multikine chapter). Based on this positive data, we expect near-term approval of Multikine in Canada and the UK (FBe: H2 2024), followed by Europe and the US (FBe: 2025), conditional on the commitment to conduct a small confirmatory study in an estimated 200-250 patients. In a first meeting with Health Canada, the agency looked favourably at the data presented by CEL-SCI. It recommended that CEL-SCI submit an accelerated approval application, allowing for immediate commercialisation upon approval. Initial discussions with UK regulatory advisors suggest that their response may be similar. Canada and the UK may offer the fastest route to market. A favourable response from Europe (EMA) and the US (FDA) is als opossible but approval timelines are usually longer.

**Multikine offers potential for additional cancer indications which could start directly with phase II studies after first drug approval** Due to financial limitations, CEL-SCI has concentrated all its development efforts and resources on Multikine in the the lead HNSCC indication. However, the company has shown the safety and first signs of efficacy of Multikine in phase 1/2 clinical trials in additional solid tumours. Therefore, once Multikine is approved in head and neck cancer, the company intends to pursue development of the drug for the following potential cancer indications: breast cancer, skin cancer, cervical cancer, anal warts (potential precursor to anal cancer) in HIV/HPV co-infected men and women, and melanoma. This will most likely be done in conjunction with a large pharma partner.

**LEAPS Technology for T-cell modulation in preclinical investigation** CEL-SCI's patented technology, referred to as LEAPS (Ligand Epitope Antigen Presentation System), uses hetero-conjugates to selectively stimulate the human immune system to more effectively fight bacterial, viral and parasitic infections as well as autoimmune, allergies, transplantation rejection and cancer when it cannot do so on its own. CEL-SCI is conducting preclinical studies to investigate a peptide-based immunotherapy (CEL-4000) as a vaccine for rheumatoid arthritis using its LEAPS technology platform.

**Figure 2: Snapshot of the clinical stage R&D pipeline focusing on cancer**




*Source: First Berlin Equity Research, CEL-SCI Corporation*

**Own production facilities to capture higher margins** CEL-SCI is a fully integrated company and has the relevant value creation steps for Multikine production in-house. The company has a dedicated commercial-size cGMP plant specifically built for Multikine production outside Baltimore, Maryland, USA. The leased facility has over 73k ft2 (>6,700 m2) of manufacturing and R&D space available, of which ~45k ft2 (~4,200 m2) are fully developed. The plant was built before the Phase 3 trial started and the capacity was recently doubled in preparation for commercialisation. The facility includes a True Cold Fill (approx. +4°C) capability to avoid loss of biological activity during fill. The plant has completed a lengthy and costly manufacturing process validation to meet the required US and European regulations and specifications. The company has invested well over USD200m in state-of-the-art facilities that will enable a high level of productivity through economies of scale once production ramps up to meet commercialisation needs.

**Figure 3: State of the art production facility in Baltimore, Maryland, USA**

*Source: First Berlin Equity Research, CEL-SCI Corporation*

**Complex production creates barriers to entry and protects the product from future competition** Multikine is a complex biotechnological product and therefore manufacturing requires sophisticated processes and equipment to ensure consistently high product quality. Multikine's formulation comprises cytokines in undisclosed dosage and composition (details on the formulation are kept secret) that mimics the way immune regulators are naturally found and function within the body. The overall production process is so important for the quality of Multikine that patents play only a minor protection role in this case. Moreover, management believes it will be nearly impossible for a competitor to copy the product. CEL-SCI process uses proprietary techniques for producing high yields of the mixture of natural human cytokines. The cytokines are taken from healthy human white blood cell samples (i.e. buffy coat material) obtained under contract from the American Red Cross, which are then multiplied through cell culture techniques. Importantly, cell-cultured cytokines are glycosylated (have sugars attached). Sugar attachments play a crucial role in cell recognition and have a significant effect on how fast a body clears out proteins. In contrast, recombinant production techniques in bacteria, yeast or insect cells have no sugar attachments, or the sugar molecules are not in the right amount or at the right locations. This may explain why recombinant IL-2-based products require the administration of large doses before any benefits are observed, and the patients usually suffer severe side effects. Management thus believes the synergy between glycosylated IL-2 and the other lymphokines/cytokines from its mixture allows Multikine to be administered in low dosages, avoiding side effects.

**IP portfolio**…The company's scientific team formulated the lead compound Multikine and developed intellectual property (IP) used in its innovative cytokines formulation capable of efficiently triggering an immune response against cancerous tumours. Besides the composition of matter patent which will expire between 2023 and 2026 on the key international markets, CEL-SCI obtained the European patent EP 1 879 618 B1 titled "A method for modulating HLA class II tumour cell surface expression with a cytokine mixture". This patent was issued in 2017 and addresses Multikine's mechanism of action to make tumours more visible to the immune system, explaining how the drug enables the immune system to recognise and attack the tumour. However, the method of manufacturing Multikine is a trade secret, and for a complex biological drug this represents the best protection against future competition.

**Listing on US Nasdaq and trade on German exchanges** In order to finance Multikine's development, the founder, Mr de Clara, decided to take the company public in 1983, shortly after its foundation. CEL-SCI is listed on the New York Stock Exchange (NYSE) in the US where the stock is very actively traded. The shares are also registered for trading in Germany on all main German Stock Exchanges.

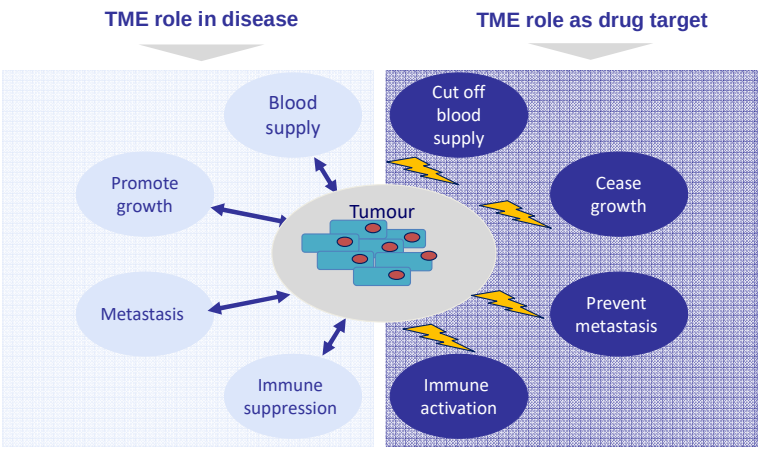
# MULTIKINE – LEAD DRUG CANDIDATE TO TREAT HEAD AND NECK CANCER

## MULTIKINE – A COCKTAIL OF CYTOKINES FOR NEOADJUVANT ADMINISTRATION

**Drug profile** CEL-SCI's lead drug candidate Multikine, is a biological product that contains a mixture of naturally derived and naturally occurring human proteins called cytokines for the treatment of various types of cancer, including head and neck squamous cell carcinoma (HNSCC). Multikine has been developed as a neo-adjuvant (prior to standard therapy which mostly implies surgical removal of the tumour) immunotherapy in treating HNSCC. The basic concept of cancer immunotherapy is to utilize certain parts of the immune system to fight the disease. This can be done by stimulating or supporting the immune system to attack cancer cells or by introducing immune system components into the body, as is the case in Multikine. Multikine is injected ½ daily dose peritumorally (around the tumour) and ½ daily dose perilymphatically (in the vicinity of the nearby draining lymph nodes). The compound primarily seeks to eliminate the small tumour cells that may be missed in surgery but which are thought to cause cancer recurrence in many patients. Important reasons for the neoadjuvant administration are: 1) the treatment may shrink the tumour, which can mean less extensive and more successful surgery; 2) some studies have shown that immunotherapy produces a stronger response to the tumour in earlier cancer stages where the immune system is still strong enough to fight the cancer (e.g. TME Pharma and its glioblastoma drug candidate NOX-A12). Also, neoadjuvant administration is a successful strategy pursued by additional players, which has led to approved drugs (e.g. pembrolizumab + surgery + more pembrolizumab) for early-stage breast cancer; nivolumab/Opdivo + surgery for early-stage lung cancer).

**The tumour microenvironment in HNSCC** As is the case in other solid tumours, HNSCCs create a favourable tumour microenvironment (TME). The TME is defined as the cellular environment in which cancer cells exist. This includes the surrounding blood vessels, immune cells, fibroblasts, signalling molecules, such as cytokines and chemokines, and the extracellular matrix. Substantial evidence indicates that the TME plays a critical role in all aspects of cancer biology, including the HNSCC tumour's ability to escape from being eliminated by the immune system through several mechanisms such as physical blockade of immune cell infiltration, dysregulation of cytokines, perturbation of immune checkpoints (e.g. PD-1 and CTLA-1 which can downregulate immune response) and recruitment of inhibitory cell populations, ultimately creating a permissive environment for tumour growth (source: Schaaf et al., 2018: Peng et al., 2018 and 2020).

**Figure 4: Role of the tumour microenvironment (TME)**



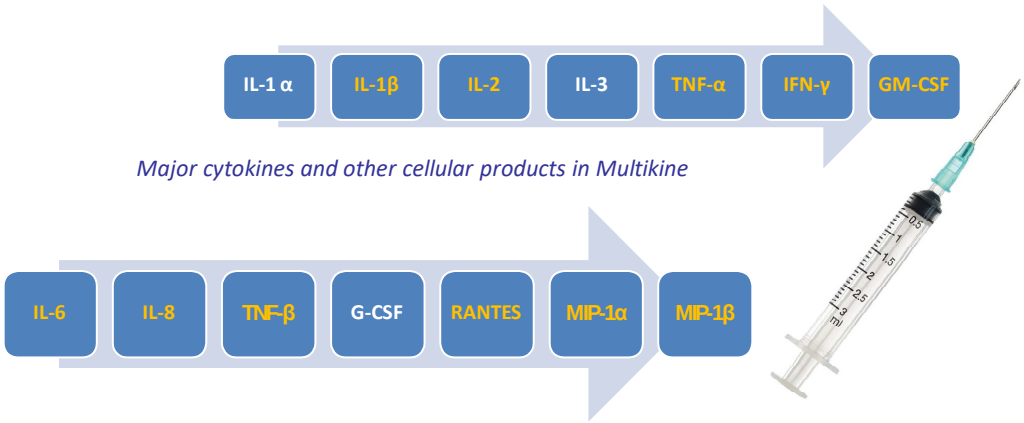

*Source: First Berlin Equity Research; TME*

**Cytokines and the importance of picking the right cytokines** Cytokines are small signalling proteins located in the TME which are heavily involved in regulating pro- and antitumor activities, such as immune activation and suppression, inflammation, cell damage, angiogenesis, invasion, and metastasis. There are different types of cytokines with different functions for the immune system. Cytokines can either create a permissive microenvironment for tumour growth and metastasis (pro-tumorigenic) or can make immune cells move toward a target (e.g. tumour) to fight cancer (anti-tumorigenic). Chemokines (e.g. RANTES, MIP) are an important subtype of cytokines particularly relevant for mobilising immune cells. There are different kinds of cytokines, including interleukins (e.g., IL-2, IL-6, IL-8), interferons (e.g. IFN-α, IFN-γ), tumour necrosis factors (e.g., TNF-α) and growth factors (source: Morris et al., 2022). For immunotherapeutic use, understanding the function and interaction of cytokines to pick the suitable cytokines capable of producing therapeutic effect is a key challenge. So far, two cytokines have demonstrated clinical benefit and consequently have been approved by the FDA for the treatment of several malignant diseases. These are IL-2, for the treatment of advanced renal cell carcinoma and metastatic melanoma and IFN-α, for hairy cell leukaemia, follicular non-Hodgkin lymphoma, melanoma and AIDS-related Kaposi's sarcoma (source: Berraondo at al., 2019).

**Multikine, a well-chosen mixture of cytokines** For Multikine, CEL-SCI chose, among others, a mixture of three relevant "families" of bioactive cytokines that act differently on the tumour, but which in their additive effect seem to synergistically cause the destruction of solid tumours. The provided mixture is frozen in a borosilicate glass serum vial containing 2.2 mL of the drug at 200 international units (IU) of IL-2 per mL. The drug candidate contains:

(1) tumour-killing/tumour-halting cytokines (tumoricidal/tumoristatic) such as TNF-α, TNF-β and IFN-γ;
(2) mobilising (chemotactic) cytokines and chemokines (e.g. RANTES, IL-8, MIP-1α, MIP-1β); and
(3) cytokines that trigger lymphocyte (i.e. B-cells. T-cells and natural killer cells) proliferation (lymphoproliferative) and inflammation such as IL-1, IL-2 IL-6, and TNF.

**Figure 5: Multikine's cytokines mixture.**




*Note: Research at the US National Institutes of Health (NIH) has shown that the cytokines (shown in yellow) are crucial to reject a tumour*

*Source: First Berlin Equity Research, CEL-SCI Corp*

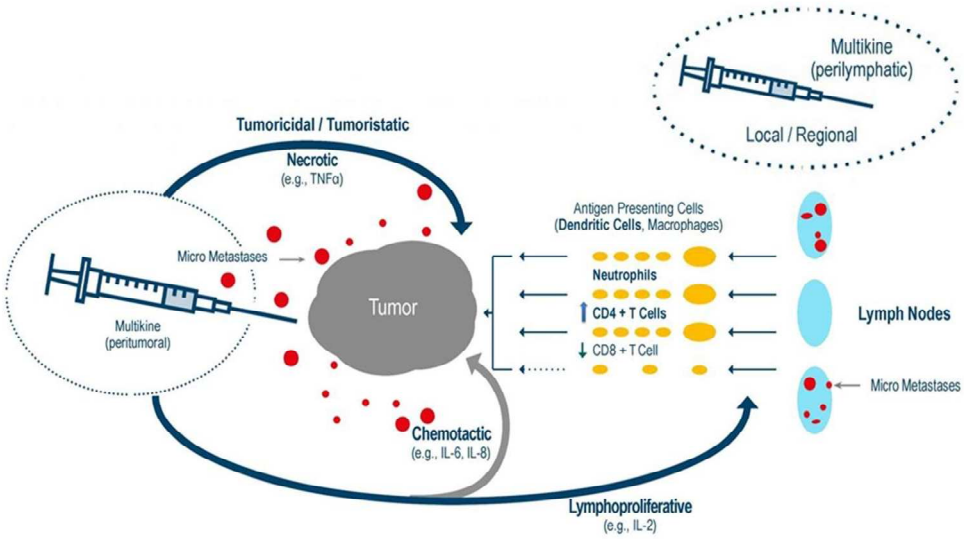
**Mode of action** Preclinical data and results from phase 2 and phase 3 clinical trials provide firm evidence of the ability of Multikine to effectively trigger an immune response and hence overcome the immune privilege of solid tumours, particularly HNSCC. In 2005, following the completion of a phase 2 trial, the lead investigators, Dr Talor and Dr Timar, determined the potential mode of action of the drug candidate. Based on the properties of

the drug's cytokines, Dr Talor and Dr Timar determined that Multikine's potential mode of action is based on the combined activity of the different cytokines present which induce a cascade of events as follows (source: Timar et al, 2OO5):

(1) Tumor necrosis factors present in Multikine (such as TNF- α) attack the tumour, leading it to release tumour antigens;
(2) Antigen-presenting cells (e.g., dendritic cells) transport the newly released tumour antigens to the lymph nodes, where lymphoproliferative cytokines (e.g., IL-1, IL-2) induce an expansion of tumour-specific T-cells to address primarily cancer cells in the lymph nodes;
(3) Multikine (cytokines/chemokines) recruits CD4+ T-cells from local lymph nodes via chemotactic factors (mobilising chemokines such as RANTES, IL-8, MIP-1α, MIP-1β), and reverts the balance of intra-tumoural CD4+ / CD8+ cells in favour of CD4+ T-cells in the TME. CD4+ T-cells further upregulate the antitumour immune response, resulting in tumour cell destruction;
(4) Multikine recruits neutrophils from the circulation (via GM-CSF, also present in Multikine), which propagate the destruction of the tumour cell nests.
(5) Multikine-derived cytokines or the de novo cytokine production by the tumour infiltrating cells induce local fibrosis.

Summarising, CEL-SCI believes that Multikine replicates the pro-inflammatory cytokine immune response a healthy body produces daily. We give an overview of Multikine mode of action below:

**Figure 6: Mode of action**




*Source: First Berlin Equity Research, CEL-SCI Corp*

**Multikine + CIZ regimen: the drug candidate is administered together with three adjuvant agents (abbreviated CIZ) that support efficacy** Multikine's therapy involves the administration of the following three agents abbreviated as CIZ: (1) a single intravenous infusion of low-dose Cyclophosphamide at a sub-chemotherapeutic dose to reduce T suppression activity; (2) oral Indomethacin, which may diminish macrophage suppression by inhibiting prostaglandin synthesis; and (3) multivitamins containing Zinc to boost T-cell function by stimulating thymulin hormone production. Overall, these three adjuvants should help to increase the efficacy of Multikine.

## PRECLINICAL AND PHASE 1 - 2 CLINICAL DEVELOPMENT

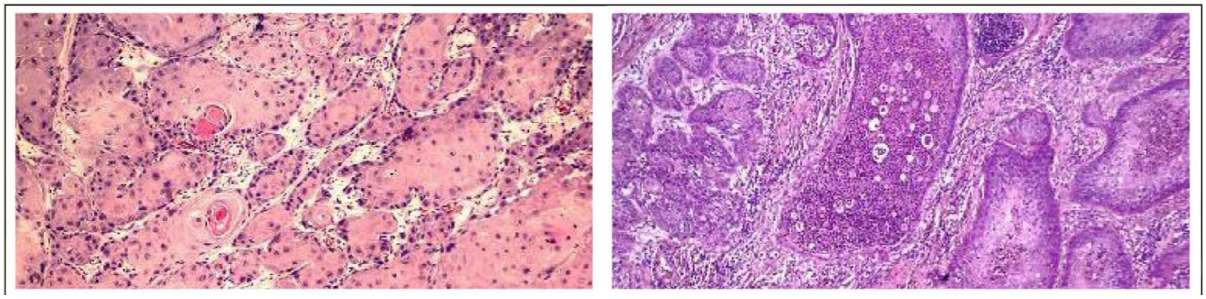
**Preclinical studies** In-vitro and in vivo studies in mice with Multikine demonstrated significant ($p<0.01$) increases in natural killer cell (NK) and cytotoxic T-lymphocyte (CTL) responses with low doses of the drug administered by multiple routes. NK cell activity remained elevated for over five days following only one treatment, and multiple in vivo treatments did not lead to a depression of NK cell activity. Toxicity studies in mice and guinea pigs showed that the drug candidate was safe and well tolerated.

**Phase 1 clinical development showed safety and first signs of efficacy in several solid tumours** The first phase 1 clinical trials of Multikine were conducted by Dr Dudley Dumonde, the renowned scientist who coined the term cytokine, in England between 1985 and 1988. He successfully demonstrated safety and substantial levels of immune response by administration of Multikine to 49 patients suffering from various forms of solid cancers, including malignant melanoma, breast cancer and colon cancer. This was later confirmed for HNSCC in several phase 1/2 studies.

**Phase 1/2 and phase 2 clinical trials confirmed the positive safety profile and efficacy in HNSCC** From 1995 to 2004, CEL-SCI completed a series of phase 1/2 and phase 2 clinical trials for Multikine with a focus on head and neck cancer. The administered Multikine +CIZ regimen proved safe, and no toxicity was seen across all studies. We summarise the three most relevant studies published on Multikine+CIZ in the period 2003-2007 in peer-reviewed scientific journals conducted by CEL-SCI:

1. **Phase 1/2 trial in Hungary:** A multicentre, dose-escalating phase 1/2 trial in 54 patients (27 treated with Multikine + CIZ and 27 in the control group) with advanced primary HNSCC studied the effects of Multikine neoadjuvant administration over a three weeks period, prior to surgery and radiotherapy/chemotherapy. In three arms, patients were injected doses of 400 IU 3x weekly, and 800 IU 3x and 5x weekly, around the tumour. Histopathology results showed a marked anti-tumour response resulting in necrosis, marked lymphocytic infiltration (i.e. B-cells, T-cells and NK cells) and fibrosis. This study demonstrated that Multikine+CIZ stimulate T-cells to migrate and infiltrate the tumour, causing tumour cell death and necrosis. Findings suggest that Multikine has the potential to enhance the effectiveness of chemotherapy and radiation (source: Timar et al., 2003). A presentation of follow-up data took place at the annual American Society of Clinical Oncology (ASCO) meeting (Talor et al., 2004), showing that patients treated with the Multikine+CIZ regimen did not have an increase in recurrence at 24 months vs the control group, and eight patients did not have any recurrence at 24 months.
2. **Phase 2 trial in Hungary:** This was a multicentre, phase 2 trial in 39 patients, 19 treated with Multikine + CIZ, and 20 were pathology samples from the repository of the National Institute of Oncology in Hungary, which were used as a historical control group. Multikine+CIZ was injected around the tumour in a similar regimen as in the phase 1/2 study, but it was also injected into the lymph nodes. The drug candidate achieved two complete responses (tumour 100% remission), two major (>50% remission), and four minor responses (>30% but <50%), leading to an overall response rate of 42% (8 of 19 patients). The investigators confirmed per histopathology an increased population of CD4+ T-cells (vs CD-8 T-cells), an infiltration of activated CD4+ T-cells in the tumour, causing tumour cell death and necrosis (see figure 7 overleaf). Head and neck cancer is considered to be an immunosuppressive tumour. Activated CD4+ T-cells are relevant due to their ability to break what is referred to as "tumour tolerance," allowing the immune system to see and attack the tumour (source: Timar et al., 2005).

**Figure 7: Phase 2 - Histopathology of the tumour microenvironment**



**Non Multikine treated (control)**
The NOSCC histological sample shows lack of necrosis

**Multikine treated**
The entire cancer nest is necrotic, filled with debris and leucocytes

*Source: First Berlin Equity Research, CEL-SCI Corp, Timar et al., 2005*

3. **Phase 2 follow-up analysis in Hungary**: A follow-up report looking for survival benefit was done ~three years after the phase 2 study. These results were compared to results which could be gleaned from a review of 55 peer-reviewed publications in the same SCCHN patient population treated only with standard of care (SOC), published between 1987 and 2007. Multikine reported a 63.2% overall survival rate at a median of 3.3 years from surgery vs 47.5% at 3.5 years from SOC for the historic data. As a result, Multikine showed a ~33% increase in overall survival at 3.5 years after surgery vs historical data (Talor et al., 2007).

## PHASE 3 CLINICAL TRIALS

**Multikine – upon approval, the drug will benefit from 7-year market exclusivity protection in the US through orphan drug designation** In January 2007, the US FDA cleared the multinational, randomised, pivotal phase 3 trial for Multikine and awarded it an orphan drug designation as neoadjuvant treatment in patients with HNSCC. Multikine could benefit from expedited or accelerated approval and seven years of marketing exclusivity upon approval as an orphan drug. Due to a challenging financing environment during the financial crisis of 2008 and 2009, the company could not secure enough funds until H2 2009 to finance the phase 3 study.

**Multikine's phase 3 clinical trials in HNSCC took about ~10 years** The phase 3 study was unusually long, taking place between 2010 and 2020. Unfortunately, the appointed contract research organisation (CRO) did not execute its enrolment task properly, causing a delay of about three years, for which it was sued and replaced. The two new CROs, ICON and Ergomed, performed well and completed the study enrolment of 928 patients in 20 countries in September 2016, requiring about three years. In addition, due to Multikine's good performance, the company was not able to record the number of deaths needed to assess the primary endpoint until 2020.

**Phase 3 IT - MATTERS study design** The study protocol, entails an international, multi-centre, open-label, randomised pivotal phase 3 trial to assess the efficacy, safety and tolerability of Multikine in patients with primary (previously untreated) advanced (stages III and IVA) HNSCC. (see the study design at: https://classic.clinicaltrials.gov/ct2/show/NCT01265849). The study had three arms which investigated the administration of:

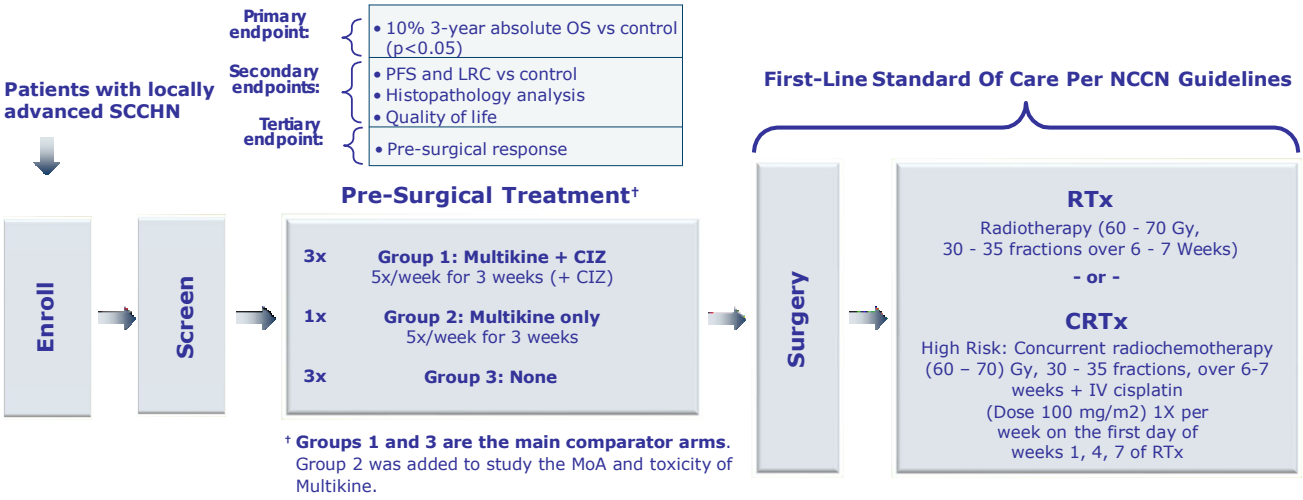
(1) Multikine coupled with a cocktail of three adjuvants (CIZ: low-dose Cyclophosphamide, Indomethacin and Zinc to increase the effectiveness of Multikine's effect) plus subsequent standard of care (SOC) in 395 patients;

(2) Multikine alone + SOC in 134 patients; and

(3) SOC alone (control group) in 394 patients.

Arms 1 and 3 are the main comparator arms, whereas arm 2 was added to study the mode of action and toxicity of Multikine. Depending on the assessment of patients' risk of cancer recurrence per NCCN Guidelines recommendations conducted by the patient's oncology team, the SOC treatment comprised either (A) surgery + radiotherapy for the patients with lower risk of recurrence or (B) surgery + chemotherapy for the patients with higher risk of recurrence. The primary outcome goal was the achievement of at least 10% 3-year absolute overall survival (OS) vs control with p<0.05. Secondary outcomes were progression-free survival (PFS) and local regional control (LRC) vs control, histopathology analysis and quality of life (based on Quality of Life Questionaires, EROTC QLQ30 and H&N 35). The phase 3 study was conducted as an event-driven study.

**Figure 8: Overview of the Multikine + CIZ phase 3 pivotal trial design**




*Source: First Berlin Equity Research, CEL-SCI Corp*

**The phase 3 study achieved statistically significant improvement against control in the arm of patients with a lower risk of cancer recurrence** The company completed the pivotal phase 3 study and published the top-line data in June 2021. The read-out of the study for the lower-risk patients (n=380) receiving Multikine+CIZ+SOC (1A) showed the following positive overall survival benefit compared to the control arm (3A):

- 62.7% 5-year overall survival in patients treated with Multikine +CIZ+SOC vs 48.6% for the control group (SOC), which equates to 14.1 percentage point benefit, exceeding the protocol required 10% or better. This result was statistically significant with a p-value of 0.0236, exceeding the protocol-required p-value of <0.05. The Hazard Ratio was 0.68, better than the protocol required 0.72;
- 101.7 month median overall survival for Multikine+CIZ+SOC vs 55.2 months for the control group, which corresponds to almost 4 years survival benefit;
- 16.0% of patients saw partial or complete tumour response in the three weeks prior to surgery vs 0% tumour response in the control group;
- No safety issues arose during or after the study-directed treatments in the Multikine treated arms of the study as compared to control.

**The second arm with high-risk patients and the entire study population failed to show a statistically significantly superior result than control** Unfortunately, neither the second arm with high-risk patients (n=481) nor the entire study population (n=923) met the primary endpoint failing to show statistical significant superiority against control. The main reason is that the immune system in higher-risk patients may be too weak to efficaciously fight this highly aggressive cancer.

## POST-HOC ANALYSIS OF THE PHASE 3 STUDY – DEFINITION OF TARGET POPULATION

**New exciting findings presented at the 2023 ESMO conference – Based on further data analysis from the phase 3 study, CEL-SCI identified criteria as markers that narrowed the target population to patients who showed a stronger benefit from Multikine treatment** CEL-SCI conducted an in-depth analysis of the data from the phase 3 study in the overall population. The company looked for patients among the whole population who would benefit most from the treatment with Multikine. A main challenge for CEL-SCI was to find diagnostic markers that could be easily assessed with the diagnostic tools available in each hospital to identify this patient population before any treatment was given. This was of great relevance as regulatory authorities would require this for the drug label definition for approval purposes. The company involved regulators and key physician opinion leaders as advisors during this process. The analysis succeeded, and CEL-SCI presented the results at the European Society for Medical Oncology (ESMO) conference in Madrid, Spain, on 22 October 2023. The patients who meet the following criteria, which could be easily identified with two standard practice diagnostic tests, will define the new target population:

(1) No lymph node involvement – N0 – and no extracapsular spread (per PET imaging scan)

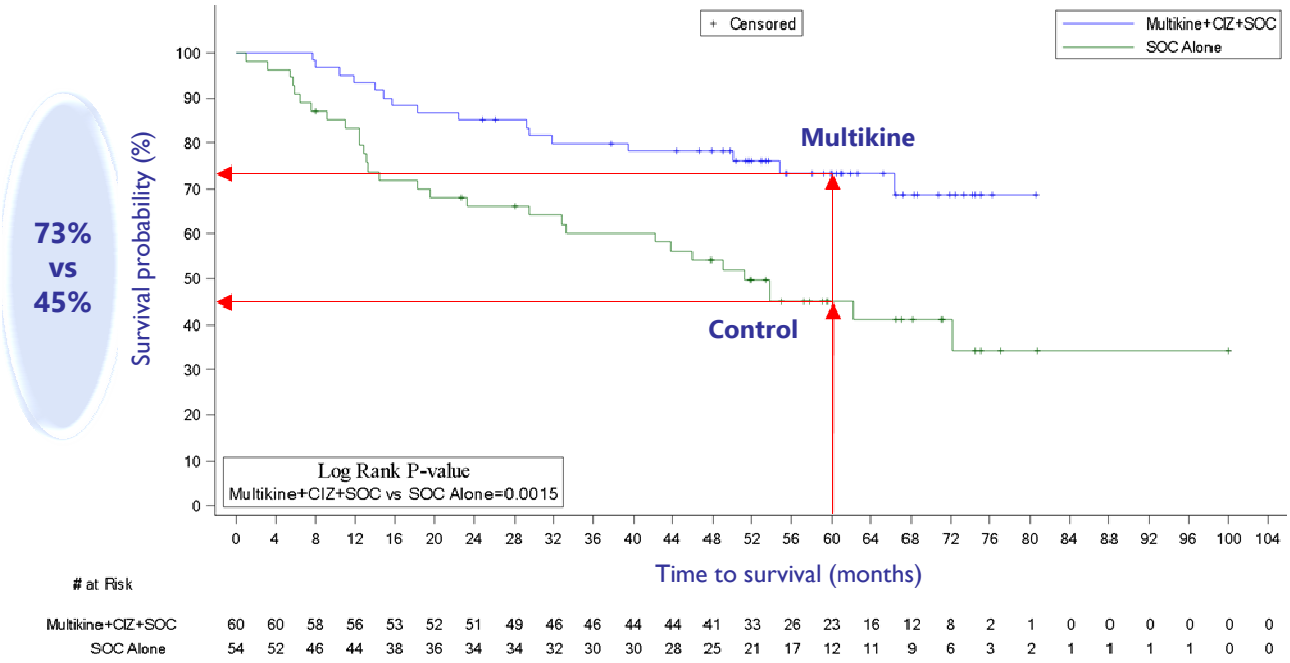
(2) Low PD-L1 tumour expression showing tumour proportional score (TPS) <10 (per tumour sample)

**Multikine may act synergistically with checkpoint inhibitors, creating an attractive market opportunity** The first criterion reflects the less sick patients with advanced HNSCC in whom the tumour has not yet spread to the lymph nodes which also means that the great majority will not be given chemotherapy. We particularly view the second criterion as highly attractive. The product delivered the best efficacy in tumours with low PD-L1 expression, which represents the patient population that does not respond well to checkpoint inhibitor drugs such as Opdivo and Keytruda, the current “stars” of immuno-oncology therapy. Multikine would thus be complementary to and not in competition with these blockbuster drugs. Moreover, the drugs' complementary and potentially synergistic mode of action creates an attractive market opportunity for combination therapy.

**Highly superior survival benefit of Multikine+CIZ+SOC vs control in the new target population** In the newly identified target population meeting these criteria, patients administered Multikine+CIZ+SOC achieved an impressive 73% 5-year survival rate compared to 45% for the control group. This represents a 28-percentage point higher absolute survival rate vs control (see figure 9 overleaf) and means that Multikine+CIZ+SOC lowered the risk of death from 55% in the control group to 27% at 5 years, i.e., halving the risk of death at 5 years. This would be an excellent drug performance for a sick patient. As a result, the hazard ratio, which indicates the reduction in the risk of death, amounted to 0.35 (p=0.0012), meaning that on average a SCCHN patient’s chance of dying within five years of diagnosis was reduced by 65% with Multikine administration and was ~3 times lower than in the control group. The 5-year survival benefit was statistically significant with p=0.0015.

**Figure 9: Overall survival in Multikine target population**

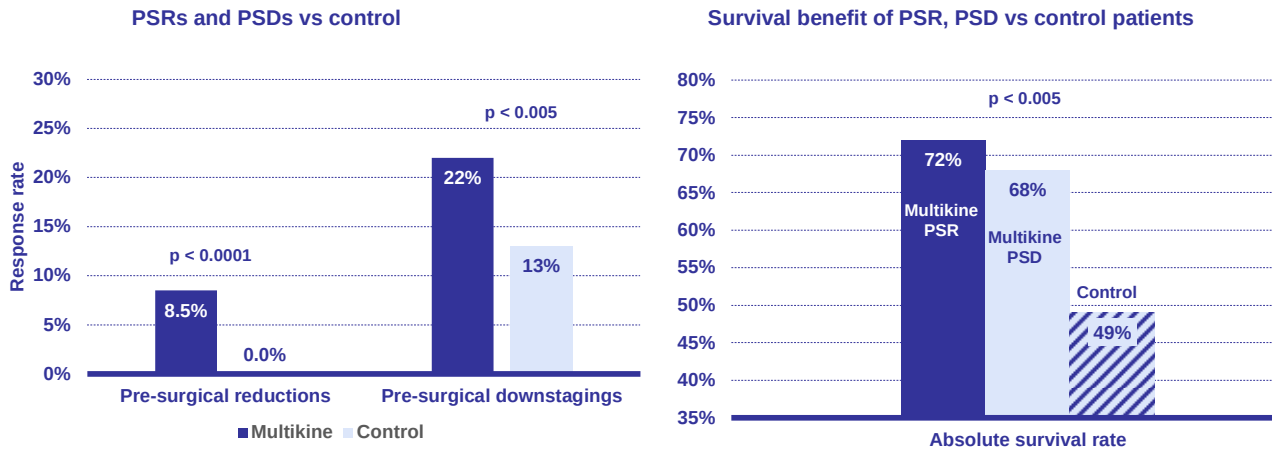
*Kaplan-Meier overall survival for Multikine target population (n=114) in the phase 3 study*




*Source: First Berlin Equity Research, CEL-SCI Corp*

**Pre-surgical tumour responses in the patients treated with Multikine + CIZ was seen in the overall patient population, which led to higher 5-year survival** According to the phase 3 protocol, pre-surgical tumour reduction (PSR: a partial tumour response was defined as >30% reduction of the longest dimension or the tumour, and complete response meant no discernible tumour) and tumour downstaging (PSD; from stage IV to III or from III to II) were assessed via PET imaging at screening before the initiation of the treatment and after the 3-weeks of Multikine+CIZ administration through a pathology analysis from a tumour sample taken at the surgery. Results analysis of the overall population showed that Multikine induced significant increases in pre-surgical responses, either as PSR or PSD with strong statistical significance of p<0.0001 and p<0.005 respectively. These responses led to survival benefit (see figure 10).

**Figure 10: Benefit of pre-surgical responses of Multikine+CIZ vs control (n=923) in all patients in the phase 3 trial**

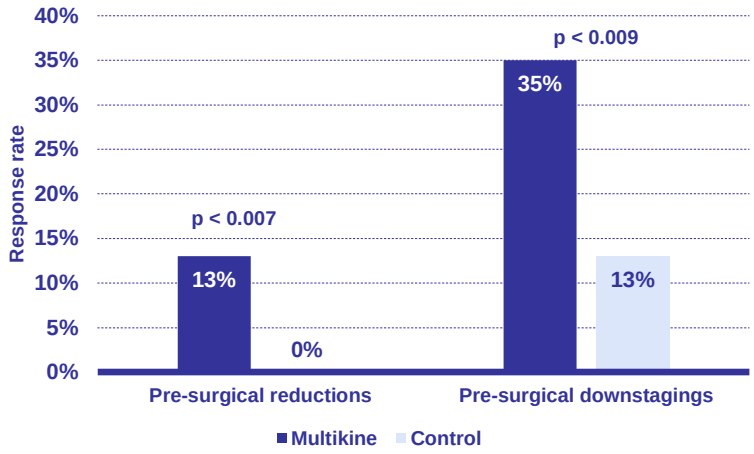



*Source: First Berlin Equity Research, CEL-SCI Corp*

In the overall study (n=923), Multikine produced tumour PSR in 8.5% of the population vs 0% seen in the control group. Importantly, these responses led to >25% absolute 5-year survival advantage against control with statistical significance of p<0.005. Multikine also produced tumour PSD in 22% of the overall population vs 13% in the control group. Here, subjects with PSD saw >30% 5-year absolute survival advantage vs control (p<0.005). We also believe overall pre-surgical responses demonstrate how real Multikine+CIZ benefit is for the treatment of advanced HNSCC.

**Tumour responses and survival advantage were higher in the target population** In the target population (n=114 patients), 48% of Multikine+CIZ subjects had statistically significant PSR and/or PSD. 13% of these target patients saw PSR vs 0% in the control group (p<0.007) and 35% experienced PSD vs 13% in the control group (p<0.009). Again, pre-surgical responders saw >32% 5-year absolute overall survival advantage vs control (p=0.0019).

**Figure 11: Higher response rates of Multikine+CIZ vs control in the target population (n=114)**




*Source: First Berlin Equity Research, CEL-SCI Corp*

**The defined target population represents ~37k p.a. in the core North American and European markets and ~145k patients p.a. globally** According to CEL-SCI's estimates, the defined target population represents ~27% of all advanced HNSCCs. Based on recent incidence statistics for new head and neck cancer and advanced HNSCC (see the HNSCC incidence chapter), the target population may amount to ~37k p.a. in the core North American (FBe: ~1k p.a. in Canada and ~11k p.a. in the US) and European (FBe: ~2k p.a. in the UK and ~23k p.a. in the rest of Europe) markets and ~145k patients p.a. globally.

## CONDITIONAL APPROVAL IN CANADA & UK, FOLLOWED BY EUROPE AND THE US IS LIKELY

Due to budget limitations, CEL-SCI will focus its registration strategy on the most attractive markets: Canada, the UK, the US and Europe. The company has already conducted initial discussions with registration advisors and two registration agencies (Canada and the US). In general, the feedback was positive and encouraging. The company has also filed consultation requests on the approval process to the other two agencies (UK and EU).

**The powerful data in the newly identified target population seems sufficient to allow for Multikine's near-term commercialisation in Canada and the UK conditioned to the commitment to conduct a confirmatory study** Health Canada has its Notice of Compliance with conditions (NOC/c) policy in place to facilitate earlier access of new therapies. Eligible drugs need to demonstrate safety and promising evidence of efficacy, be

indicated for a serious, life-threatening or severely debilitating disease or condition, and address an unmet medical need. In a first meeting with Health Canada in early 2023, the agency looked at the presented data positively. It recommended CEL-SCI submit an NOC/c approval application, which would allow for immediate commercialisation upon approval conditioned to the conduction of a small confirmatory study. Initial discussions with UK regulatory advisors suggest a similar procedure as in Canada. In October 2023, CEL-SCI filed a request with the UK's Healthcare Products Regulatory Agency (MHRA) about the path of approval for Multikine. On 4 December, the UK's National Institute for Health and Care Excellence (NICE) selected Multikine as the potential new SOC for SCCHN in the UK, based on a detailed report on the drug candidate from the UK's National Institute for Health and Care Research (NIHR – see: https://www.nice.org.uk/guidance/awaiting-development/gid-ta11475/documents). This is encouraging news and paves the way for a potential meeting with the MHRA to discuss the path of approval. In the meantime, the company is preparing the applications and plans to submit them for all its core regions in H1 2024. Health Canada usually takes ~7-9 months to approve an NOC/c application (e.g. Janssen's cancer drug TECVAYLI for multiple myeloma submitted the application in December 2022 and obtained NOC/c 7 months later, in July 2023). The UK's MHRA needs up to 150 business days (~7-8 months) to review an accelerated approval application (source: Northwest Therapeutics). These two countries may offer the fastest route to market, and it is thus possible that CEL-SCI might be able to start commercialisation of Multikine in the UK and Canada by YE 2024 or early 2025.

**EU also offers the conditional approval route, but timelines for approval are somewhat longer** In September 2023, CEL-SCI submitted a request for advice to the European Medicines Agency (EMA) to discuss Multikine's phase 3 data and the fastest route to market. In general, the EMA's regulation also offers the possibility of conditional approval, although the EMA usually takes more prolonged periods for approval. (see: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation). We anticipate a potential conditional approval in 2025.

**US commercialisation may also take longer – Legislation reforms approved in the US in December 2022 requires the enrolment of a certain proportion of patients in a confirmatory study before warranting accelerated approval of life-saving drugs** Pharmaceutical companies in the US were increasingly misusing the accelerated approval pathway with most post-approval studies being delayed or not completed at all. Nor were the drugs required to be withdrawn if confirmatory studies failed. This led to a reform in legislation by the Senate in December 2022 known as Collins & Kaine Bill (see: https://www.collins.senate.gov/newsroom/collins-kaine-bill-to-improve-accelerated-approvals-for-lifesaving-drugs-signed-into-law). This bill chiefly established a council of senior leadership at the FDA that will ensure a more efficient use of this pathway, and the Secretary of this council may require that the confirmatory studies should be underway (e.g. meet certain enrolment targets) before the approval is granted. Therefore, the US commercialisation may take somewhat longer than the above-mentioned countries. CEL-SCI's most recent discussion with the FDA was encouraging. The agency was positive about focusing on selection criteria to establish a target population. The company is preparing a development plan for the next meeting with the agency.

## MULTIKINE OFFERS POTENTIAL IN FURTHER CANCER INDICATIONS BEYOND HNSCC

**Multikine offers potential for additional cancer indications which could start directly with phase II studies after first drug approval** Due to financial limitations, CEL-SCI has prioritised all its development efforts and resources in Multikine for the head and neck cancer indication. However, in 2002, the company completed a phase 1 clinical trial in eight

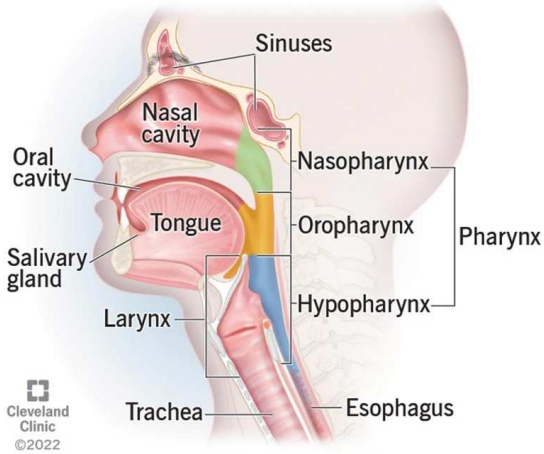
HIV-infected women with Human Papilloma Virus-induced cervical dysplasia, the precursor stage before the development of cervical cancer, at the University of Maryland Biotechnology Institute (UMBI). The study looked for safety and preliminary efficacy data with Multikine's treatment, showing a positive safety profile and disease resolution/improvement in five out of the eight patients at the two investigated doses. CEL-SCI also explored the potential use of Multikine in additional solid tumours, such as prostate cancer in 1988 (5 patients), and various forms of solid cancers by Dr Dumonde's study in 1988 (49 patients). Therefore, once Multikine is approved for head and neck cancer, the company intends to pursue development of the drug for the following potential cancer indications: breast cancer, skin cancer, cervical cancer, anal warts (potential precursor to anal cancer) in HIV/HPV co-infected men and women, melanoma and enhancement of radiation.

# HEAD AND NECK CANCER

## A DEADLY KILLER WITH FEW TREATMENT OPTIONS

**Description of head and neck squamous cell carcinoma (HNSCC)** Cancer is one of the leading causes of death and generates among the highest costs to healthcare systems around the globe. The unmet medical need in certain solid tumours remains very high. When the cancer is not detected before it spreads outside of the location in which it arises, this greatly increases the risk for patients that treatment will not be successful. Head and neck cancer originates in various cell types of the head and neck region. Approximately 90% of all head and neck cancers are HNSCC (source Gormley et al., 2022). HNSCC originates in the squamous cells that line the mucosal surfaces of the head and neck, for example, those inside the mouth, nose, throat, or voice box. Squamous cells typically cover internal (mucosal) and external (e.g. skin) surfaces of the body and have several important protective functions, helping to reduce friction, prevent dehydration, and guard against infection and foreign substances. Alcohol and tobacco consumption are the two most important risk factors for head and neck cancers of the oral cavity and larynx area. Cancers of the pharynx are increasingly associated with infection with human papillomavirus (HPV), primarily HPV-16, and to a lesser extent, HPV-18 and other strains (see figure 12).

**Figure 12: Head and neck cancer**




*Source: Cleveland Clinic*

**HNSCC staging** HNSCC can be classified depending on how widespread or advanced the cancer is. This system helps healthcare professionals determine the extent of the cancer and guide treatment decisions. The stage can be first determined after a physical exam and

the results from the diagnostic and imaging tests. In general, there are five stages of HNSCC going from zero to four (0, I, II, III, and IV):

- Stage 0: It is called carcinoma in situ; there are abnormal cells in the lining of the affected area that have the potential to become cancer;
- Stages I and II: There is a tumour which size is ⩽ 2cm (stage I) or >2cm but ⩽4cm (stage II). The cancer is localised and has not reached the lymph nodes;
- Stage III: The tumour is either >4cm or has spread to nearby tissue such as a lymph node on the same side of the neck as the tumour and its size is ⩽3cm;
- Stage IV is the most advanced stage of HNSCC. The tumour may be any size and has spread to either nearby tissue (e.g. lymph node(s) on the other side of the neck) or distant parts of the body (e.g. lungs, liver, bones).

**The American Joint Committee on Cancer (AJCC) staging system** The AJCC provides a widely used staging system for head and neck cancers, which CEL-SCI used during clinical trials. The AJCC staging system is based on the extent of the primary tumour (T), the involvement of regional lymph nodes (N), and the presence of distant metastasis (M). The stages are expressed as TNM categories, which increase depending on the severity as follows: 0-4 for T, 0-3 for N and 0-1 for M. The AJCC staging system then combines these categories to determine the overall stage, which is expressed as Stage 0, I, II, III, or IV. CEL-SCI's phase 3 study included advanced cancer patients in stages III-IVa (of the oral cavity and soft-palate), which, according to AJCC, represent these patients:

- Stage III: T1N1M0; T2N1M0; T3 N0-N2 M0
- Stage IVa: T1N2M0; T2N2M0; T3N2M0; T4 N0-N2 M0

Future studies will include:

- Stage III: T3N0M0
- Stage IVa: T4N0M0

**Incidence and mortality of HNSCC** According to GLOBOCAN estimates in 2020, HNSCC is the seventh most common cancer worldwide, with 890k new cases p.a. (~4.5% of all cancer diagnoses) and 450k deaths p.a. (~4.6% of global cancer deaths). The incidence of HNSCC continues to rise and is anticipated to increase by 30% (1.1m new cases annually) by 2030. This trend is partly attributed to changes in lifestyle factors, such as increased alcohol consumption and tobacco use in developing nations, lack of proper oral hygiene and a growing prevalence of HPV. In the US, the National cancer Institute (NCI) estimates that around 68k new cases of head and neck cancer were diagnosed in 2022. From these cases, ~27% were diagnosed in stages I and II, 51% were locally advanced in stages III-IVB, and 15% were metastatic (stage IVC). The overall 5-year survival was estimated at 68.5%, although some studies see this figure lower (40%-50%). Overall survival varies depending on the stage at diagnosis. The 5-year survival for localised disease is 86.3%, declining to 69.0% for locally advanced and 40.4% for metastatic disease. The prognosis of HNSCC patients remains poor due to late diagnosis, high rates of primary-site recurrence, and lymphatic metastasis. The median age at diagnosis is 64 (source: Miller et al., 2019; Islami et al., 2020; Chenhang Yu et al., 2022). In Europe, HNSCC incidence and mortality rates are higher, with an estimated 150k new head and neck diagnosed cases p.a. and 135k new HNSCC patients p.a. (source: Cordis Europe). In addition to deaths directly caused by HNSCC, the patients who survive have the second highest rate of suicide (63.4 cases per 100k individuals) of all cancers. Psychological distress and compromised quality of life are likely key underlying factors for suicide (source: Johnson et al., 2020).

**Diagnosis** The diagnosis of T1D is made upon the appearance of typical symptoms, which depending on the affected head and neck area, they can be can be persistent sore throat or hoarseness, a lump or mass in the neck, mouth sores that do not heal, changes in the

appearance of the mouth or throat (e.g. white or red patches) and chronic bad breath among others. HNSCC can be diagnosed through a combination of clinical evaluation, imaging tests, and laboratory procedures. The physician will typically inspect the oral cavity, throat, and neck for any visible abnormalities, such as tumours or swollen lymph nodes. If HNSCC is suspected, he will conduct imaging tests to assess the extent of the disease and determine if the cancer has spread to nearby structures or lymph nodes. Common imaging tools include: computerised tomography (CT) scans magnetic resonance imaging (MRI) or positron emission tomography (PET). The definitive diagnosis of HNSCC is usually made through a biopsy. During a biopsy, a small sample of tissue from the suspicious area is removed for laboratory analysis. This tissue sample is examined under a microscope by a pathologist to confirm the presence of cancer and determine its type (e.g. HNSCC).

**Treatment for primary HNSCC** The standard of care (SOC) treatment of primary HNSCC chiefly varies depending on the stage of the cancer. The first-line SOC treatment for early-stage HNSCC (stages I-II) is generally a single modality, either surgery or radiotherapy, which can achieve cure rates of >80% (source: Johnson et al., 2020). The treatment for locally advanced HNSCC is multimodal, with either surgery followed by adjuvant radiation or chemoradiotherapy (CRT- combined administration of both chemotherapy and radiotherapy) in cases where a local or regional approach is possible or surgery plus chemotherapy with or without a biological agent in more advanced cases with metastatic disease. Unfortunately, most patients are diagnosed with advanced-stage disease and are treated with platinum-based chemotherapy regimens that were approved by the US FDA in 1978. Due to low specificity, traditional chemotherapy usually applied to treat cancer also kills healthy cells, is poorly tolerated and has therapeutic and safety limitations. Tumour resistance is a further obstacle to effective treatment. Also, SOC treatment often misses tumour cells that are located around the margins of the tumour or in the lymph nodes, allowing for disease recurrence.

**Immunotherapeutic check point inhibitors are approved for recurrent metastatic (R/M) disease** In the event of localised cancer recurrence, re-administration of SOC is the main recommended approach. The more advanced metastatic patients usually receive systemic therapy such as chemotherapy and an immune checkpoint inhibitor targeting the PD-1 and PD-L1 pathways. Checkpoint inhibitors are immunomodulatory therapies that work by exposing cancer cells to the immune system for attack. In 2016, check point inhibitors pembrolizumab and nivolumab were first approved as a second-line treatment for R/M HNSCC by the FDA in the US:

- Nivolumab's (Opdivo) approval as second-line treatment for R/M HNSCC was based on data from the phase III CheckMate-141 trial in which nivolumab demonstrated a higher median overall survival (mOS) of 7.5 months vs 5.1 months for SOC. Follow-up data for 24 months showed that nivolumab provided an almost 3-fold increase in the 24-month OS rate to 16.9% compared to 6.0% in the standard treatment group (source: Ferris et al., 2018a)
- In 2019, pembrolizumab (Keytruda) was approved as first-line treatment in combination with chemotherapy for all patients with R/M HNSCC and as a single agent for the patients whose tumours express PD-L1 (Combined Positive Score - CPS ≥1) as determined by an FDA-approved test. This approval was based on the phase 3 KEYNOTE-048 clinical trial. Pembrolizumab monotherapy was non-inferior to the established second-line regimen (C+C: Cetuximab + chemotherapy) in the total population, but it improved survival in the subgroups of PD-L1-positive (CPS≥1) patients compared to C+C, with a more significant benefit in PD-L1 strongly positive (CPS≥20) patients. In the "CPS≥1" arm, pembrolizumab increased the mOS to 14.9 months vs. 10.8 months for C+C. In the "CPS≥20" arm, pembrolizumab achieved an mOS of 14.9 months vs. 10.8 months for C+C. Pembrolizumab plus chemotherapy prolonged mOS in the overall population to 13.0 months vs 10.7 months for C+C (Burtness et al., 2019, FDA).

**Peer immunotherapeutic pipelines focus on primary advanced metastasised or R/M HNSCC** Current research is focusing on a range of improved regimens (e.g. differentiated if HPV-positive or HPV-negative patients, area affected and cancer stage) combining surgery, radiation and chemotherapy, and treatment approaches that limit damage to healthy cells and more specifically target cancerous cells such as immune therapy (e.g. check-point inhibitors, CAR-T cells and therapeutic vaccines). Ongoing studies of immunotherapeutic agents are focusing on primary metastasised HNSCC or /R/M HNSCC. In the period 2019-2022, over eight targeted therapies in late-stage trials failed to demonstrate efficacy in primary locally advanced HNSCC (e.g. 2022: Monalizumab+Erbitux (Astra Zeneca & Innate), Keytruda (Merck); 2021: Bavencio (Pfizer & Merck), Opdivo+Yervoy (Bristol Meyers), Feladilimab (GSK), Urvalamab (Astra Zeneca). These failures show that this disease is very challenging to treat.

**Neoadjuvant pipeline for HNSCC is thin – Multikine is in our view the most advanced and most promising programme that may reach the market in the foreseeable future** The industry's clinical-stage development pipeline for the AM indication is thin. We have identified four relevant late-stage immunotherapeutic programmes addressing CELS-SCI's neoadjuvant setting (see table 2 below). In our view, Multikine, which has completed phase 3 development and is preparing applications for conditional approval, is the most promising drug candidate to address this disease. The main peer compound to watch is the check point inhibitor pembrolizumab (Keytruda). In an open-label phase 2 trial in 21 patients in the US, the drug candidate showed 43% tumour response and 48% tumour down-staging, with a good safety profile (source: Uppaluri et al., 2017). This drug candidate started 2018 the randomised open-label phase 3 trial KEYNOTE-689 to evaluate the efficacy and safety of pembrolizumab as neoadjuvant in combination with SOC (surgery + radiotherapy with or without chemotherapy) in 704 patients with stage III-IV locally advanced HNSCC (see: https://clinicaltrials.gov/study/NCT03765918; Lee et al., 2020). Efficacy outcomes will be stratified by PD-L1 CPS status. It is likely that the candidate will perform best in patients with high PD-L1 expression (CPS⩾20), making it complementary to Multikine. The study is estimated to be completed by 2025/2026. Nivolumab (Opdivo) underwent an open-label, multicohort, phase I/II study CheckMate-358 in patients with virus-associated cancers. In the head and neck cohort with 52 patients (26 HPV-positive and 26 HPV-negative), results were modest. 5.9% of patients achieved a major response, and 17.6% achieved a partial pathologic response after two preoperative doses of neoadjuvant nivolumab (Ferris et al., 2021). Nivolumab is undergoing further phase 1/2 and 2 studies in neoadjuvant setting.

**Table 2: Key immuno-oncology therapies in trials in neoadjuvant setting for HNSCC**

| Trial | Treatment | Phase | Patients | Status |
|---|---|---|---|---|
| IT-MATTERS | Efficacy and Safety Study of Leukocyte Interleukin Injection (Multikine) to Treat Cancer of the Oral Cavity | 3 | 928 | Complete, preparing filing |
| KEYNOTE-689 (NCT03765918) | Pembrolizumab as neoadjuvant therapy and in Combination with standard of care as adjuvant therapy | 3 | 704 | Recruiting |
| NCT03021993 | Nivolumab as neoadjuvant therapy for locally advanced oral cavity cancer | 2 | 17 | Complete |
| CA209–891 (NCT03721757) | Neoadjuvant and adjuvant Nivolumab in oral cavity cancer | 2 | 21 | Not recruiting |
| IMCISION (NCT03003637) | Neoadjuvant Ipilimumab plus Nivolumab | 1/2 | 33 | Complete |

*Source: First Berlin Equity Research, Fasano et al., 2022; ClinicalTrials.gov*

# FINANCIAL HISTORY AND OUTLOOK

CEL-SCI's financial statements are prepared in accordance with US Generally Accepted Accounting Principles (US GAAP). The company's financial year differs from the calendar year and runs from 1 August to 30 September of the following year.

## FINANCIAL HISTORY

**Income statement FY 2021/22** CEL-SCI's financial statements are typical of a development-stage biotech company. The company is not generating any revenue while it is incurring losses. OPEX remained roughly stable at about USD36m over the fiscal years 2020/21 and 2021/22 and ~40% of OPEX was non-cash, chiefly due to equity-based compensation/payments. Following the completion of Multikine's phase 3 study in December 2020, all of the company's resources have focused on conducting a very costly statistical analysis of the extensive data from 923 patients, commissioning and validating the manufacturing facility, and preparing a registration strategy. As a result, in 2021/22, nearly 80% of OPEX was spent on R&D (2020/21: 68%). The net financial result fell to USD-638k (FY 20/21: USD-167kk), chiefly thanks to a non-operating gain in FY 20/21 upon the resale of shares issued to its CRO Ergomed plc in connection with a Securities Purchase Agreement (SPA) to pay for conducting certain development activities related to Multikine's phase 3 study. CEL-SCI reported a net loss of USD-36.7m (FY 20/21: USD-36.4m), which equates to USD-0.87 p/s (FY 20/21: USD -0.90 p/s).

**Table 3: Income statement 2021/22 vs 2020/21 and 9M 2022/23 vs 9M 2021/22 (KPIs)**

| in USD'000 | 2021/22 | 2020/21 | Delta | 9M 2022/23 | 9M 2021/22 | Delta |
|---|---|---|---|---|---|---|
| **Revenue** | **0** | **0** | n.a. | **0** | **0** | n.a. |
| General & Administrative | -10,707 | -13,085 | n.a. | -6,805 | -8,221 | n.a. |
| Research & Development | -25,355 | -23,109 | n.a. | -17,204 | -18,894 | n.a. |
| OPEX | -36,063 | -36,194 | n.a. | -24,009 | -27,115 | n.a. |
| **EBIT** | **-36,063** | **-36,194** | n.a. | **-24,009** | **-27,115** | n.a. |
| Net financial result | -638 | -167 | n.a. | -555 | -1,124 | n.a. |
| **Net income** | **-36,701** | **-36,361** | n.a. | **-24,564** | **-28,239** | n.a. |

*Source: CEL-SCI Corporation*

**9M 2022/23 income statement – OPEX and R&D expenses declined slightly** OPEX (~30% non-cash) declined to USD24.0m (9M 21/22: USD27.1m) due to lower development expenses of USD17.2m (9M 21/22: USD18.9m) and G&A of USD6.8m (9M 21/22: USD8.2m). The company was in the final stages of phase 3 data analysis for Multikine, which was less costly; the results were presented at the ESMO Conference in October 2023. The net financial result improved to USD-0.6m (9M 21/22: USD-1.1m) chiefly due to higher costs for certain two-year warrant extensions (series N and X) amounting to USD635k, recorded as interest expense. The net result came in at USD-24.6m (9M 21/22: USD-28.2m).

**Balance sheet FY 21/22 and 9M 22/23** Following successful capital measures in FY 19/20 and FY 20/21, CEL-SCI raised USD 25m and USD 54m respectively through the sale of common stock and the exercise of warrants and options. By YE 2020/21, the company had a cash position of USD42.2m, including short-term investments in treasuries, which declined to USD22.7m by YE 21/22 and USD 5.1m at 9M 2023 due to funding of ongoing operations. Based on the company's planned burn rate, management expects the cash runway to reach Q1 2024. On 20 November 2023, a USD5m capital increase was completed. These funds should extend the cash runway into Q2 2024. Property and equipment and other LT assets (financial right of use assets) in connection with the manufacturing facility declined in the period 20/21-9M 22/23 due to ongoing depreciation (see table 4 overleaf). The corresponding finance lease liability (other LT liabilities) also declined in this period. CEL-SCI's equity position dropped from USD56.5m at YE 20/21 to USD14.8m at 9M 22/23. The equity ratio (ER) declined to 46% at 9M 22/23 (YE 20/21 ER: 75%).

**Table 4: Balance Sheet FY 2021/22, FY 2020/21 and 9M 2022/23 (KPIs)**

| in USD'000 | 2021/22 | 2020/21 | Delta | 9M 2022/23 | 2021/22 | Delta |
|---|---|---|---|---|---|---|
| Cash | 22,672 | 36,060 | -37% | 5,135 | 22,672 | -77% |
| Short-term investments | 0 | 6,151 | -100% | 0 | 0 | n.a. |
| Account receivables & others | 2,764 | 3,060 | -10% | 2,597 | 2,764 | -6% |
| **Current Assets, Total** | **25,436** | **45,272** | -44% | **7,732** | **25,436** | -70% |
| Property plant and equipment | 11,889 | 13,664 | -13% | 10,675 | 11,889 | -10% |
| Intangible assets | 212 | 276 | -23% | 183 | 212 | -14% |
| Other LT assets | 12,822 | 14,748 | -13% | 11,410 | 12,822 | -11% |
| Deposits and others | 164 | 1,911 | -91% | 2,319 | 164 | 1312% |
| **Non-Current Assets, Total** | **25,088** | **30,598** | **-18%** | **24,587** | **25,088** | **-2%** |
| Accounts payable | 1,618 | 1,676 | -3% | 1,743 | 1,618 | 8% |
| Other current liabilities | 3,045 | 2,261 | 35% | 3,550 | 3,045 | 17% |
| Other LT liabilites | 13,697 | 15,399 | -11% | 12,237 | 13,697 | -11% |
| **Total Liabilities** | **18,360** | **19,336** | **-5%** | **17,530** | **18,360** | **-5%** |
| Equity | 32,163 | 56,534 | -43% | 14,789 | 32,163 | -54% |
| Equity ratio | 64% | 75% | - | 46% | 64% | - |

*Source: CEL-SCI Corporation*

**Cash flow statement FY 2021/22** In FY 21/22, negative cash flow from operating activities declined slightly to USD-18.2m (FY 20/21: USD-18.8m). In this period, CEL-SCI paid about USD 12.2m in share-based compensation/payments vs USD 14.9m in the previous year. Depreciation and amortisation amounted to USD 3.8m (FY 20/21: USD2.2m). CAPEX declined to USD661k in FY 21/22 from USD9m in FY 20/21 chiefly due to purchase of laboratory equipment. Cash flow from investing amounted to USD5.5m (FY 20/21: USD-15.2m) in connection with the disposal of the short-term treasury bond worth USD6.2m, which was purchased in FY 20/21. In FY 21/22, cash flow from financing activities amounted to USD-638k, chiefly related to payments for finance leases. In FY 20/21, this position amounted to USD54.5m, primarily from a capital increase and the exercise of warrants and options. Thus, net cash flow in FY 21/22 came in at USD-13.4m (FY 20/21: USD20.6m).

**Table 5: Cash flow statement 2021/22 vs 2020/21 and 9M 2022/23 vs 9M 2021/22 (KPIs)**

| in USD'000 | 2021/22 | 2020/21 | Delta | 9M 2022/23 | 9M 2021/22 | Delta |
|---|---|---|---|---|---|---|
| Operating cash flow | -18,240 | -18,787 | n.a. | -17,804 | -13,327 | n.a. |
| Cash flow from investing | 5,491 | -15,185 | n.a. | -362 | 5,507 | n.a. |
| Cash flow from financing | -638 | 54,523 | n.a. | 629 | -167 | n.a. |
| Net cash flow | -13,388 | 20,551 | n.a. | -17,537 | -7,986 | n.a. |

*Source: CEL-SCI Corporation*

**Cash Flow Statement 9M 2022/23** In 9M 22/23, operating cash outflow rose to USD-17.8m (9M 21/22: USD-13.3m) chiefly due to a lower positive impact of equity-based compensation/payments which decreased to USD 5.4m (9M 21/22: USD 9.7m). CAPEX declined to USD362k (9M 21/22: USD622k), and cash flow from investment amounted to USD-362k (9M 21/22: USD5.5m) due to the change in marketable securities. Financing cash flow was USD629k (9M 21/22: USD-167k), chiefly stemming from a small capital increase and exercise of warrants/options totalling USD 1.8m, less payments for finance leases of USD 1.2m (9M 21/22: USD 1.0m). The net cash flow came in at USD-17.5m (9M 21/22: USD-8.0m).

## FINANCIAL OUTLOOK

**Income statement** Given that CEL-SCI's lead drug candidate Multikine for HNSCC has completed phase 3 trials and the company is preparing international submission of conditional approval application (company guidance: early 2024), we anticipate the approval in the first two countries, Canada and UK, and revenues from its potential market launch by Q4 2024. We have assumed the potential approval and market launch of Multikine in the US and the EU in H2 2025.

We have assumed that the company will finance operations, including the conduction of the required small confirmatory study in an estimated 200-250 patients (planned for 2024), until a sustainable breakeven is achieved through raising funds from investors. For the time being, we have left potential development in the less lucrative regions of Asia/Latin America out of our projections and leave this as upside.

Our FY 22/23 projections are the baseline for our projections going forward. We forecast OPEX of USD30.8m in FY 22/23, below the previous year's level of USD36.1m. We forecast a negative net financial result of USD-600k. We thus expect a net loss of USD31.4m. Going forward, we project OPEX to increase to USD44.2m in FY 23/24 due to the conduction of the confirmatory trial and decline to USD34.4m in FY 24/25. Our scenario includes expenses for the preclinical ongoing R&D and the costs to evaluate the confirmatory study results. Assuming successful approvals and market launches of Multikine, we anticipate CEL-SCI to achieve profitability in FY 25/26. We give an overview of our financial projections in Table 6 below.

**Table 6: Income Statement KPIs FY 19/20-24/25E**

| in USD'000 | 2019/20 | 2020/21 | 2021/22 | 2022/23E | 2023/24E | 2024/25E |
|---|---|---|---|---|---|---|
| Revenue | 559 | 0 | 0 | 0 | 260 | 9,134 |
| General & Administrative | -11,703 | -13,085 | -10,707 | -8,800 | -9,200 | -9,400 |
| Research & Development | -17,840 | -23,109 | -25,355 | -22,000 | -35,000 | -25,000 |
| OPEX | -29,544 | -36,194 | -36,063 | -30,800 | -44,200 | -34,400 |
| **EBIT** | **-28,985** | **-36,194** | **-36,063** | **-30,800** | **-44,026** | **-28,280** |
| Net financial result | -1,270 | -167 | -638 | -600 | -700 | -700 |
| **Net income** | **-30,255** | **-36,361** | **-36,701** | **-31,400** | **-44,726** | **-28,980** |

*Source: First Berlin Equity Research, CEL-SCI Corporation*

**Balance sheet** We estimate the company will progressively spend cash in the clinical development of its pipeline and its operations in the period FY 22/23-24/25 (see Table 13). Given that current cash may reach until approximately Q2 2024 (including the USD 5m raised in November 2023), we look for CEL-SCI to raise funding from capital increases of USD50m in FY 23/24 and USD 30m in FY 24/25. In our scenario, we project that the cash position will increase from USD1.8 at YE 22/23 to USD13.6m at YE 24/25. As CEL-SCI has done in the past, we assume that it will continue financing some of its personnel expenses and external services with stock payments. With the above-mentioned capital measures, the company will be capable of adequately funding operations until the business model of CEL-SCI becomes self-sustaining in FY 25/26 (assuming a successful approval and market launch of Multikine). At that point, the company will generate enough cash to finance further organic growth. This will be reflected in a progressively growing cash position from 2026.

**Table 7: Balance sheet KPIs FY 19/20-24/25E**

| in USD'000 | 2019/20 | 2020/21 | 2021/22 | 2022/23E | 2023/24E | 2024/25E |
|---|---|---|---|---|---|---|
| Cash | 15,509 | 36,060 | 22,672 | 1,770 | 11,259 | 13,609 |
| Short-term investments | 0 | 6,151 | 0 | 0 | 0 | 0 |
| Account receivables & others | 2,188 | 3,060 | 2,764 | 2,610 | 4,339 | 8,049 |
| **Current Assets, Total** | **17,697** | **45,272** | **25,436** | **4,380** | **15,598** | **21,658** |
| Property plant and equipment | 5,844 | 13,664 | 11,889 | 10,119 | 11,510 | 12,506 |
| Intangible assets | 313 | 276 | 212 | 287 | 347 | 422 |
| Deposits and others | 1,671 | 1,911 | 164 | 164 | 164 | 164 |
| Other LT assets | 15,011 | 14,748 | 12,822 | 10,854 | 9,055 | 7,435 |
| **Non-Current Assets, Total** | **22,839** | **30,598** | **25,088** | **21,424** | **21,076** | **20,528** |
| Accounts payable | 2,023 | 1,676 | 1,618 | 1,456 | 1,529 | 1,606 |
| Other current liabilities | 2,242 | 2,261 | 3,045 | 2,741 | 2,933 | 3,138 |
| Other LT liabilites | 12,992 | 15,399 | 13,697 | 12,247 | 10,697 | 9,017 |
| **Total Liabilities** | **20,810** | **19,336** | **18,360** | **16,444** | **15,159** | **13,761** |
| Equity | 19,727 | 56,534 | 32,163 | 9,360 | 21,515 | 28,425 |
| Equity ratio | 49% | 75% | 64% | 36% | 59% | 67% |

*Source: First Berlin Equity Research, CEL-SCI Corporation*

**Cash flow statement** We expect the conduction of Multikine's confirmatory study will lead to a peak in negative operating cash flows in FY 23/24. We forecast a negative operating cash flow of USD-20.6m for 22/23, increasing to USD-35.3m in 23/24, before dropping again to USD-22.8m in 24/25. We expect CEL-SCI to increase CAPEX investment to a range of USD 3.1m-3.6m p.a. in the period 23/24-24/25 to complete small upscaling improvements in the plant required for commercial production. In 23/24 and 24/25 we have assumed capital increases of USD50m and USD30m respectively. We expect net cash flow to total USD-20.9m in 22/23 and provide an overview of our cash flow projections in Table 8 below. Going forward, we project that a potential approval and commercialisation of Multikine for HNSCC in 23/24 (Canada and UK) and 24/25 (US and Europe) will drive strengthening operating performance, having a positive impact on the company's free cash flow and net cash flow.

**Table 8: Cash flow statement KPIs FY 19/20-24/25E**

| in USD'000 | 2019/20 | 2020/21 | 2021/22 | 2022/23E | 2023/24E | 2024/25E |
|---|---|---|---|---|---|---|
| Operating cash flow | -15,276 | -18,787 | -18,240 | -20,648 | -35,340 | -22,831 |
| Cash flow from investing | -2,695 | -15,185 | 5,491 | -590 | -3,620 | -3,140 |
| Cash flow from financing | 25,650 | 54,523 | -638 | 335 | 48,450 | 28,320 |
| Net cash flow | 7,679 | 20,551 | -13,388 | -20,903 | 9,490 | 2,349 |

*Source: First Berlin Equity Research, CEL-SCI Corporation*

# NEWSFLOW

In our view, CEL-SCI's stock price will be driven by news about its pipeline as well as by the achievement of financial milestones. We expect the company to make a number of announcements during the coming 12-18 months which will act as catalysts for the stock. These include:

**Pipeline**

- Update of the consultation requests for registration of Multikine in the UK and the EU in Q4 2023 or Q1 2024.
- Submission of the conditional approval application of Multikine in Canada, UK, EU and the US is planned for H1 2024. The approvals in the UK and Canada are expected in H2 2024, in the EU and the US in 2025.
- Initiation of the confirmatory study is expected for ~mid-2024, provided the required funding has been secured.

**Financial results**

The company publishes financial results and a business update on a quarterly basis. We expect the publication of financial results, including detailed updates on the business development and the R&D pipeline, as follows:

- FY 2023 results including business update is due on 31 December 2023
- Q1 2024 results including business update is due on 14 February 2024
- Q2 2024 results including business update is due on 14 May 2024
- Q3 2024 results including business update is due on 14 August 2024.

# MANAGEMENT

## MANAGEMENT BOARD

### Geert R. Kersten, Chief Executive Officer, Member of the Board of Directors

Mr. Kersten has been Director and CEO of CEL-SCI since 1995 and has been with the company since 1987. He has been involved in the pioneering field of cancer immunotherapy for almost two decades and has successfully steered CEL-SCI through many challenging cycles in the biotechnology industry. Prior to CEL-SCI, Mr. Kersten worked at the law firm Finley & Kumble and worked at the investment banking firm Source Capital, which helps him provide CEL-SCI with his expertise in the fields of finance and law. Mr. Kersten completed his Undergraduate Degree in Accounting, received an M.B.A. from George Washington University, and a law degree (J.D.) from American University in Washington, DC. Mr. Kersten is also the inventor of a patent on the potential use of Multikine in managing cholesterol.

### Eyal Talor, Ph.D., Chief Scientific Officer

Dr. Talor joined CEL-SCI in October 1993. In October 2009, Dr. Talor was promoted to Chief Scientific Officer. Prior to this promotion, Dr. Talor was the Senior Vice President of Research and Manufacturing. He is a clinical immunologist with over 28 years of hands-on management of clinical research and drug development for immunotherapy application; pre-clinical to phase 3, in the biopharmaceutical industry. His expertise includes biopharmaceutical R&D and Biologics product development, GMP (Good Manufacturing Practices) manufacture, Quality Control testing, and the design and building of GMP manufacturing and testing facilities. He served as Director of Clinical Laboratories (certified by the State of Maryland) and has experience in the design of pre-clinical and clinical trials (phase 1 - 3) and GCP (Good Clinical Practices) requirements. Before coming to CEL-SCI, he was Director of R&D and Clinical Development at CBL, Inc., Principal Scientist - Project Director, and Clinical Laboratory Director at SRA Technologies, Inc. Prior to that he was a full-time faculty member at The Johns Hopkins University, Medical Intuitions; School of Public Health. He has invented technologies which are covered by ten issued patents; on Multikine's composition of matter and method of use in cancer and two platform Peptide technologies, Antigen Directed Apoptosis of T-cells ('Adapt') and Ligand Epitope Antigen Presentation System (LEAPS), for the treatment of autoimmune diseases, asthma, allergy, transplantation rejection and infectious diseases. He also is responsible for numerous product and process inventions as well as a number of pending US and PCT patent applications. He received his Ph.D. in Microbiology and Immunology from the University of Ottawa, Ottawa, Ontario, Canada, and had post-doctoral training in clinical and cellular immunology at The Johns Hopkins University, Baltimore, Maryland, USA. He holds an Associate teaching position at the Johns Hopkins University Medical Institution.

### John Cipriano, Senior VP Regulatory Affairs

John Cipriano brings to CEL-SCI over 30 years of experience in both biotech and pharmaceutical companies. He held positions at the United States Food and Drug Administration (FDA) as Deputy Director, Division of Biologics Investigational New Drugs, Office of Biologics Research and Review and was the Deputy Director, IND Branch, Division of Biologics Evaluation, Office of Biologics. Mr. Cipriano completed his B.S. in Pharmacy from the Massachusetts College of Pharmacy in Boston, Massachusetts. He received his M.S. in Pharmaceutical Chemistry from Purdue University in West Lafayette, Indiana.

## BOARD OF DIRECTORS

### Geert R. Kersten, Chief Executive Officer and Member of the Board of Directors

(see above).

### Peter R. Young, Ph.D. – Board member

Peter Young has been a Director of CEL-SCI since August 2002. Dr. Young has been a senior executive within the pharmaceutical industry in the United States and Canada for most of his career, originally in organizations that are now part of Sanofi S.A. Since November 2001, Dr. Young has been the President of Agnus Dei, LLC, which has acted as a partner in an organization managing immune system clinics which treat patients with diseases such as cancer, multiple sclerosis, and hepatitis. Between 1997 and 2006, Dr. Young was also the President and Chief Executive Officer of SRL Technology, Inc., a company involved in the development of pharmaceutical drug delivery systems. Between 1998 and 2001, Dr. Young was the Chief Financial Officer of Adams Laboratories, Inc, the developer of Mucinex®. Dr. Young received his Ph.D. in Organic Chemistry from the University of Bristol, England after obtaining his bachelor's degree in Honors Chemistry, Mathematics and Economics. Subsequently, he qualified as a Fellow of the Chartered Institute of Management Accountants.

### Bruno Baillavoin, Board member

Mr. Baillavoine has been a Director of CEL-SCI since June 2015. In 2017 Mr. Baillavoine became the Director, Head of Pericles Group UK, the subsidiary of the Paris based leading French consulting firm, which is an expert in the field of Banking, Finance, Asset Management, and Insurance with over 350 institutional clients. He has decades of experience in the financial sector, having been the CEO of companies across a wide range of industries and has turned around several companies in the FTSE 100, most notably BET group plc. He received an undergraduate degree from the University of Wisconsin-Eau Claire.

### Robert Watson, Board member

Mr. Watson has over 35 years of experience in the healthcare information technology industry as a CEO, board member and advisor to multiple HCIT companies. He has participated in over 75 acquisitions, raised nearly $750,000,000 in capital, completed three public offerings and successfully sold four companies. Mr. Watson holds an MBA from the Wharton School of Business at the University of Pennsylvania and a BA degree from Syracuse University.

### Gail K. Naughton, Ph.D., Board member

Gail Naughton has been a Director of CEL-SCI since August 2022. Dr. Naughton has been a pioneer in the field of regenerative medicine for over 35 years. She was the founder of Advanced Tissue Sciences, where she oversaw the design and development of the world's first up-scaled manufacturing facility for cell-based products, established corporate development and marketing partnerships with companies including Smith & Nephew, Ltd., Medtronic and Inamed Corporation, was pivotal in raising over USD350m from the public market and corporate partnerships, and brought four human cell-based products from concept through FDA approval and market launch. Dr. Naughton founded Histogen Inc. in 2007, holds more than 125 U.S. and foreign patents and has been extensively published in the field. Dr. Naughton served as Dean of the College of Business Administration at San Diego State University from 2002 until 2011, where she helped to make SDSU the first US campus to establish a Ph.D./MBA in life sciences. In 2000, Dr. Naughton received the 27th Annual National Inventor of the Year award by the Intellectual Property Owners Association in honour of her pioneering work in the field of tissue engineering and regenerative medicine. Dr. Naughton received her Ph.D. and M.S. from NYU Medical Center, and an MBA from UCLA. She currently sits on the Board of directors of Therapeutics MD and is the Chair of the Board of the La Jolla Institute for Immunology.

# SHAREHOLDERS & STOCK INFORMATION

| Stock Information | |
|---|---|
| ISIN | US1508376076 |
| WKN | A2DY0D |
| Bloomberg ticker | CVM US |
| No. of issued shares | 44.75m |
| Transparency Standard | NYSE |
| Country | US |
| Sector | Healthcare |
| Subsector | Biotech |

*Source: Börse Frankfurt, First Berlin Equity Research*

| Shareholder Structure | |
|---|---|
| Vanguard Group Inc. | 4.0% |
| Geert Kersten | 2.5% |
| BlackRock Inc. | 1.6% |
| Free float and other | 91.9% |

*Source: CEL-SCI Corporation*

# INCOME STATEMENT

| All figures in USD '000 | 2019/20 | 2020/21 | 2021/22 | 2022/23E | 2023/24E | 2024/25E |
|---|---|---|---|---|---|---|
| **Revenue** | **0** | **0** | **0** | **0** | **260** | **9,134** |
| Cost of goods sold | 0 | 0 | 0 | 0 | -86 | -3,014 |
| **Gross profit** | 559 | 0 | 0 | 0 | 174 | 6,120 |
| General & Administrative | -11,703 | -13,085 | -10,707 | -8,800 | -9,200 | -9,400 |
| Research & Development | -17,840 | -23,109 | -25,355 | -22,000 | -35,000 | -25,000 |
| **Total operating expenses (OPEX)** | **-29,544** | **-36,194** | **-36,063** | **-30,800** | **-44,200** | **-34,400** |
| **Operating income (EBIT)** | **-28,985** | **-36,194** | **-36,063** | **-30,800** | **-44,026** | **-28,280** |
| Net financial result | -1,270 | -167 | -638 | -600 | -700 | -700 |
| **Pre-tax income (EBT)** | **-30,255** | **-36,361** | **-36,701** | **-31,400** | **-44,726** | **-28,980** |
| Income taxes | 0 | 0 | 0 | 0 | 0 | 0 |
| **Net income / loss** | **-30,255** | **-36,361** | **-36,701** | **-31,400** | **-44,726** | **-28,980** |
| **Diluted EPS (USD)** | **-0.82** | **-0.90** | **-0.87** | **-0.71** | **-1.00** | **-0.65** |
| **Ratios** | | | | | | |
| Gross Margin on Revenue | n.a. | n.a. | n.a. | n.a. | 67.0% | 67.0% |
| EBIT Margin on Revenue | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| EBITDA Margin on Revenue | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Net Margin on Revenue | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| **Expenses as % of OPEX** | | | | | | |
| Sales & Marketing | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| General & Administrative | 39.6% | 36.2% | 29.7% | 28.6% | 20.8% | 27.3% |
| Research & Development | 60.4% | 63.8% | 70.3% | 71.4% | 79.2% | 72.7% |
| **Y-Y Growth** | | | | | | |
| Revenue | n.a. | n.a. | n.a. | n.a. | n.a. | 3408.1% |
| Operating income | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Net income/ loss | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |

# BALANCE SHEET

| All figures in USD '000 | 2019/20 | 2020/21 | 2021/22 | 2022/23E | 2023/24E | 2024/25E |
|---|---|---|---|---|---|---|
| **Assets** | | | | | | |
| **Current Assets, Total** | **17,697** | **45,272** | **25,436** | **4,380** | **15,598** | **21,658** |
| Cash | 15,509 | 36,060 | 22,672 | 1,770 | 11,259 | 13,609 |
| Short-term investments | 0 | 6,151 | 0 | 0 | 0 | 0 |
| Accounts receivables | 55 | 55 | 0 | 0 | 100 | 500 |
| Other current assets | 2,133 | 3,005 | 2,764 | 2,610 | 4,239 | 7,549 |
| **Non-Current Assets, Total** | **22,839** | **30,598** | **25,088** | **21,424** | **21,076** | **20,528** |
| Property plant and equipment | 5,844 | 13,664 | 11,889 | 10,119 | 11,510 | 12,506 |
| Intangible assets | 313 | 276 | 212 | 287 | 347 | 422 |
| Other LT assets | 15,011 | 14,748 | 12,822 | 10,854 | 9,055 | 7,435 |
| Deposits and others | 1,671 | 1,911 | 164 | 164 | 164 | 164 |
| **Total Assets** | **40,536** | **75,870** | **50,524** | **25,804** | **36,674** | **42,185** |
| **Shareholders' Equity & Debt** | | | | | | |
| **Current Liabilities, Total** | **4,266** | **3,937** | **4,664** | **4,197** | **4,462** | **4,744** |
| Accounts payable | 2,023 | 1,676 | 1,618 | 1,456 | 1,529 | 1,606 |
| Other current liabilities | 2,242 | 2,261 | 3,045 | 2,741 | 2,933 | 3,138 |
| **Longterm Liabilities, Total** | **16,544** | **15,399** | **13,697** | **12,247** | **10,697** | **9,017** |
| Other liabilities | 12,992 | 15,399 | 13,697 | 12,247 | 10,697 | 9,017 |
| **Shareholders Equity** | **19,727** | **56,534** | **32,163** | **9,360** | **21,515** | **28,425** |
| **Total Consolidated Equity and Debt** | **40,536** | **75,870** | **50,524** | **25,804** | **36,674** | **42,185** |
| **Ratios** | | | | | | |
| Current ratio (x) | 4.15 | 11.50 | 5.45 | 1.04 | 3.50 | 4.57 |
| Quick ratio (x) | 4.15 | 11.50 | 5.45 | 1.04 | 3.50 | 4.57 |
| Net gearing | -78.6% | -63.8% | -70.5% | -18.9% | -52.3% | -47.9% |
| Book value per share (€) | 0.54 | 1.39 | 0.75 | 0.21 | 0.48 | 0.63 |
| Net debt | -15,509 | -36,060 | -22,672 | -1,770 | -11,259 | -13,609 |
| Equity ratio | 48.7% | 74.5% | 63.7% | 36.3% | 58.7% | 67.4% |

# CASH FLOW

| All figures in USD '000 | 2019/20 | 2020/21 | 2021/22 | 2022/23E | 2023/24E | 2024/25E |
|---|---|---|---|---|---|---|
| **Net income** | **-30,255** | **-36,361** | **-36,701** | **-31,400** | **-44,726** | **-28,980** |
| Interest payments, net | 1,042 | 1,149 | 1,081 | 600 | 700 | 700 |
| Tax provision | 0 | 0 | 0 | 0 | 0 | 0 |
| Non-operating items | 228 | -982 | -443 | 0 | 0 | 0 |
| **EBIT** | **-28,985** | **-36,194** | **-36,063** | **-30,800** | **-44,026** | **-28,280** |
| Depreciation and amortisation | 2,160 | 2,231 | 3,829 | 4,065 | 3,850 | 3,578 |
| **EBITDA** | **-26,825** | **-33,963** | **-32,234** | **-26,735** | **-40,176** | **-24,702** |
| Derivative liability | 0 | 0 | 0 | 0 | 0 | 0 |
| Share based payments | 12,909 | 15,113 | 12,375 | 7,000 | 7,000 | 6,000 |
| Changes in w orking capital | -1,250 | -483 | 2,592 | -313 | -1,464 | -3,428 |
| Cash interest net | -1,042 | -1,149 | -1,081 | -600 | -700 | -700 |
| Other adjustments | 932 | 1,696 | 107 | 0 | 0 | 0 |
| **Operating cash flow** | **-15,276** | **-18,787** | **-18,240** | **-20,648** | **-35,340** | **-22,831** |
| CapEx | -2,655 | -9,016 | 1,250 | -590 | -3,620 | -3,140 |
| **Free cash flow** | **-17,971** | **-27,826** | **-16,990** | **-21,238** | **-38,960** | **-25,971** |
| Other investments | 0 | -6,386 | 8,062 | 0 | 0 | 0 |
| **Cash flow from investing** | **-2,695** | **-15,185** | **5,491** | **-590** | **-3,620** | **-3,140** |
| Debt Financing, net | 0 | 0 | 0 | 0 | 0 | 0 |
| Equity Financing, net | 25,650 | 53,769 | -38 | 1,785 | 50,000 | 30,000 |
| Payments for financial leases | 0 | 0 | 0 | 0 | 0 | 0 |
| **Cash flow from financing** | **25,650** | **54,523** | **-638** | **335** | **48,450** | **28,320** |
| **Net cash flows** | **7,064** | **20,551** | **-9,566** | **-20,903** | **9,490** | **2,349** |
| Cash, start of the year | 8,445 | 15,509 | 36,060 | 22,672 | 1,770 | 11,259 |
| **Cash, end of the year** | **15,509** | **36,060** | **22,672** | **1,770** | **11,259** | **13,609** |
| | | | | | | |
| **Y-Y Growth** | | | | | | |
| Operating Cashflow | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Free cashflow | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |

# Imprint / Disclaimer

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First Berlin Equity Research GmbH

**Authored by: Christian Orquera, Analyst**
**All publications of the last 12 months were authored by Christian Orquera.**

**Company responsible for preparation: First Berlin Equity Research GmbH, Friedrichstraße 69, 10117 Berlin**

The production of this recommendation was completed on 5 December 2023 at 15:18

**Person responsible for forwarding or distributing this financial analysis: Martin Bailey**



## INFORMATION PURSUANT TO SECTION 85 (1) SENTENCE 1 OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO ART. 20 (1) OF REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO ART. 37 OF COMMISSION DELEGATED REGULATION (EU) NO 2017/565 (MIFID) II.

First Berlin Equity Research GmbH (hereinafter referred to as: "First Berlin") prepares financial analyses while taking the relevant regulatory provisions, in particular section 85 (1) sentence 1 of the German Securities Trading Act [WpHG], art. 20 (1) of Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) and art. 37 of Commission Delegated Regulation (EU) no. 2017/565 (MiFID II) into consideration. In the following First Berlin provides investors with information about the statutory provisions that are to be observed in the preparation of financial analyses.

### CONFLICTS OF INTEREST

In accordance with art. 37 (1) of Commission Delegated Regulation (EU) no. 2017/565 (MiFID) II and art. 20 (1) of Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) investment firms which produce, or arrange for the production of, investment research that is intended or likely to be subsequently disseminated to clients of the firm or to the public, under their own responsibility or that of a member of their group, shall ensure the implementation of all the measures set forth in accordance with Article 34 (2) lit. (b) of Regulation (EU) 2017/565 in relation to the financial analysts involved in the production of the investment research and other relevant persons whose responsibilities or business interests may conflict with the interests of the persons to whom the investment research is disseminated. In accordance with art. 34 (3) of Regulation (EU) 2017/565 the procedures and measures referred to in paragraph 2 lit. (b) of such article shall be designed to ensure that relevant persons engaged in different business activities involving a conflict of interests carry on those activities at a level of independence appropriate to the size and activities of the investment firm and of the group to which it belongs, and to the risk of damage to the interests of clients.

In addition, First Berlin shall pursuant to Article 5 of the Commission Delegated Regulation (EU) 2016/958 disclose in their recommendations all relationships and circumstances that may reasonably be expected to impair the objectivity of the financial analyses, including interests or conflicts of interest, on their part or on the part of any natural or legal person working for them under a contract, including a contract of employment, or otherwise, who was involved in producing financial analyses, concerning any financial instrument or the issuer to which the recommendation directly or indirectly relates.

With regard to the financial analyses of CEL-SCI Corporation the following relationships and circumstances exist which may reasonably be expected to impair the objectivity of the financial analyses: The author, First Berlin, or a company associated with First Berlin reached an agreement with the CEL-SCI Corporation for preparation of a financial analysis for which remuneration is owed.

Furthermore, First Berlin offers a range of services that go beyond the preparation of financial analyses. Although First Berlin strives to avoid conflicts of interest wherever possible, First Berlin may maintain the following relations with the analysed company, which in particular may constitute a potential conflict of interest:

- The author, First Berlin, or a company associated with First Berlin owns a net long or short position exceeding the threshold of 0.5 % of the total issued share capital of the analysed company;
- The author, First Berlin, or a company associated with First Berlin holds an interest of more than five percent in the share capital of the analysed company;

- The author, First Berlin, or a company associated with First Berlin provided investment banking or consulting services for the analysed company within the past twelve months for which remuneration was or was to be paid;
- The author, First Berlin, or a company associated with First Berlin reached an agreement with the analysed company for preparation of a financial analysis for which remuneration is owed;
- The author, First Berlin, or a company associated with First Berlin has other significant financial interests in the analysed company;

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## ASSET VALUATION SYSTEM

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

### ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

| Category | | 1 | 2 |
|---|---|---|---|
| Current market capitalisation (in €) | | 0 - 2 billion | > 2 billion |
| Strong Buy[1] | An expected favourable price trend of: | > 50% | > 30% |
| Buy | An expected favourable price trend of: | > 25% | > 15% |
| Add | An expected favourable price trend of: | 0% to 25% | 0% to 15% |
| Reduce | An expected negative price trend of: | 0% to -15% | 0% to -10% |
| Sell | An expected negative price trend of: | < -15% | < -10% |

*[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.*

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

### RISK ASSESSMENT

The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

## RECOMMENDATION & PRICE TARGET HISTORY

| Report No.: | Date of publication | Previous day closing price | Recommendation | Price target |
|---|---|---|---|---|
| Initial Report | Today | USD2.80 | Buy | USD8.40 |

## INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

## UPDATES

At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

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**Legally required information regarding**

- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

**can be accessed through the following internet link: https://firstberlin.com/disclaimer-english-link/**

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