CEL-SCI Corporation

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

9M 2023/24 results & pipeline update

RATING	**BUY**
PRICE TARGET	**USD 6.20**
Return Potential	474.1%
Risk Rating	High

ANALYSIS SHOWED THAT THE PHASE 3 STUDY HAD NO BIAS

CEL-SCI's 9M 23/24 financial results (as of 30 June 2024) were roughly as expected. The company reported no revenue and reduced its OPEX compared to the previous year. EBIT came in at USD-20.2m (9M 22/23: USD-24.0m) and the cash position dropped to just USD385k (FY 22/23: USD22.7m). However, in July 2024, CEL-SCI carried out a capital increase of USD10.85m. The company's cash position should now be sufficient to finance operations into Q1 2025. Given CEL-SCI's plan to start a confirmatory trial of the lead drug candidate Multikine in Q4 2024/Q1 2025, we expect the company to conduct another capital increase. We estimate that the confirmatory study will cost ~USD30m, part of which may be paid by CEL-SCI's marketing partners Teva Pharmaceuticals (based in Israel) and Orient Europharma (based in Taiwan). The green light given by the FDA in May 2024 for the confirmatory study provided a clear path to approval and therefore is a good basis for the additional financing. The company also published positive results of a recent bias analysis of its completed Multikine phase 3 study. A bias analysis is a standard procedure to ensure that the results of a study are reliable. The outcome was that the study showed no bias in favour of the drug. This analysis reinforces our positive view on Multikine's prospects as a potential new first line treatment of locally advanced primary head and neck squamous cell carcinoma (HNSCC). We reiterate our Buy recommendation and price target of USD6.20.

Cost base reduced in 9M 23/24, but funds still needed to finance the planned confirmatory study The company reported EBIT of USD-20.2m (9M 22/23: USD-24.0m), with R&D expenses amounting to USD13.7m (9M 22/23: USD25.4m) chiefly related to phase 3 data analysis and preparation for the confirmatory study of its lead drug candidate Multikine. The net result came in at USD-20.8m (9M 22/23: USD-24.6m). However, operating cash flow totalled only USD-14.0m (9M 22/23: USD-17.8m), as depreciation & amortisation amounted to USD3.0m (9M 22/23: USD3.0m) and CEL-SCI made ~USD4.3m in share-based compensation/payments (9M 22/23: USD5.5m). (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2019/20	2020/21	2021/22	2022/23	2023/24E	2024/25E
Revenue (USD m)	0.0	0.0	0.0	0.0	0.0	0.0
Y-o-y growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT (USD m)	-29.0	-36.2	-36.1	-31.5	-44.2	-34.4
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (USD m)	-30.3	-36.4	-36.7	-32.2	-44.9	-35.1
EPS (diluted) (USD)	-0.82	-0.90	-0.87	-0.72	-0.65	-0.36
DPS (USD)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (USDm)	-18.0	-27.8	-18.9	-23.2	-39.5	-32.4
Net gearing	-78.6%	-63.8%	-70.5%	-31.4%	-48.5%	-32.5%
Liquid assets (USD m)	15.5	42.2	22.7	4.1	13.1	9.0

RISKS

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

COMPANY PROFILE

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 in 750 patients for the treatment of locally advanced primary head and neck squamous cell carcinoma (HNSCC). CEL-SCI will seek conditional approval in the US, Europe, UK and Canada.

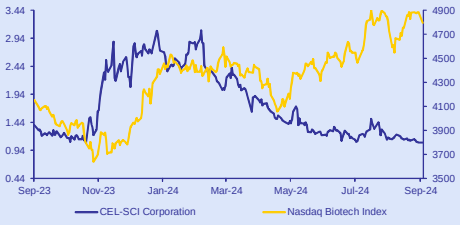
MARKET DATA

As of 03 Sep 2024

Closing Price	USD 1.08
Shares outstanding	65.40m
Market Capitalisation	USD 70.63m
52-week Range	USD 1.07 / 3.08
Avg. Volume (12 Months)	814,840

Multiples	2022/23	2023/24E	2024/25E
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 2024

Liquid Assets	USD 0.38m
Current Assets	USD 3.54m
Intangible Assets	USD 0.17m
Total Assets	USD 24.07m
Current Liabilities	USD 5.51m
Shareholders' Equity	USD 8.47m

SHAREHOLDERS

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

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The reported cash position of USD385k (FY 22/23: USD22.7m) was boosted by a capital increase of USD10.85m completed on 29 July. The company placed 10.8m shares at USD1.00 p/s. This capital raise has extended the cash runway out to ~Q1 2025. As CEL-SCI plans to carry out the confirmatory trial on Multikine in Q4 2024/Q1 2025, we expect the company to conduct a further capital increase. We estimate that the confirmatory study will cost ~USD30m, part of which could be covered by CEL-SCI's marketing partners Teva Pharmaceuticals (Israel) and Orient Europharma (Taiwan), as was the case for the phase 3 trials. The two partners have licensed the commercialisation rights in Israel/Turkey and eight Asian & Pacific countries respectively. In parallel, we expect CEL-SCI to seek a partnership with a large pharmaceutical company for the core US and European markets, which could potentially co-finance the confirmatory trial for Multikine and market the drug.

Bias analysis confirmed reliability and validity of the positive results obtained with Multikine in the completed phase 3 trials CEL-SCI reported positive results from a bias analysis of the concluded phase 3 study of Multikine, the company's first-line immunotherapy candidate for HNSCC. The analysis was conducted for the entire phase 3 study population of 923 patients and for the subgroup of 114 patients. It assessed potential sources of bias and confirmed that the treatment and control groups were well-balanced in terms of demographics and baseline characteristics, with no bias detected. This supports the reliability and validity of the study's results, showing that Multikine achieved an impressive 73% 5-year survival rate compared to 45% for the control group (see Company Snapshot figure 6). This systematic assessment is crucial for the regulatory submission, as it strengthens the credibility of the trial results and supports the overall conclusions drawn from the study. The findings will therefore bolster regulator and investor confidence as CEL-SCI prepares for the confirmatory registration study and seeks to tap capital markets for additional funding. The confirmatory study will further evaluate Multikine's efficacy, particularly in a subgroup target population with no lymph node involvement (N0) and low PD-L1 tumour expression.

Figure 1: Overview of the bias analysis of the phase 3 study target population with N0 and TPDL1<10 (n=114, considers baseline characteristics and demographics)

Baseline Covariate	Covariate Level	MK+CIZ+SOC (n=60)	SOC Only (n=54)
		Percents	Percents
Age	Mean (Range)	56.9 (33-76)	58.0 (35-80)
Sex	% Male	76.7	88.9
Race	% Asian % Black/AA % White/Caucasian	0.0 3.3 96.7	7.4 0.0 92.6
Ethnicity	% Not Hispanic/Latino % Not Reported	46.7 53.3	46.3 53.7
BMI	Mean (Range)	24.9 (17.4-33.4)	23.9 (18.2-36.1)
Tumor Location	% Oral Tongue % Floor of Mouth % Cheek (buccal mucosa) % Soft Palate	26.7 55.0 6.7 11.7	33.3 44.4 7.4 14.8
Baseline Stage	% Stage III % Stage IVa	65.0 35.0	74.1 25.9

Conclusion: The treatment group's demographics and baseline characteristics were comparable for Multikine+CIZ+SOC vs SOC only (control)

Source: First Berlin Equity Research, CEL-SCI Corp

The next milestone will be the submission of a final version of the registration protocol for Multikine to the FDA In May, the FDA gave the green light for the protocol proposed by CEL-SCI for a confirmatory study in 212 patients (see Company Snapshot figure 5). We believe this confirmed the positive results of the phase 3 study and the potential benefit of Multikine for the treatment of HNSCC. The company is now incorporating some comments and answering some questions from the FDA to finalise and submit a final version of the registration protocol that will allow CEL-SCI to begin the confirmatory trial. CEL-SCI plans to submit the registration protocol within the next few months and start the registration study in Q4 2024/Q1 2025, provided funding is secured by then. Assuming that patient enrolment in the study takes about one year to 18 months, we expect that CEL-SCI will seek FDA approval to market the drug based on tumour response rate data available by mid-2026. Depending on how consistent the data is, the agency will then decide whether accelerated approval is justified. We expect a potentially accelerated approval to allow commercialisation in 2026. We assume a similar timeline for Europe, Canada and the UK.

VALUATION MODEL

Buy rating and price target unchanged CEL-SCI has made significant progress with its lead HNSCC drug candidate Multikine in the first nine months of FY 2023/24. The FDA's green light for the proposed confirmatory trial design and the positive results from the bias analysis strengthen the drug candidate's efficacy profile and its path to potential approval and commercialisation. We continue to view CEL-SCI as a unique, highly attractive and substantially de-risked (see Company Snapshot figure 7) investment opportunity in the biotech space. Based on unchanged estimates, we reiterate our price target of USD6.20 and our Buy rating.

Figure 2: "Sum-of-the-parts" (SOTP) 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 22.5M	1K	90,000	110.0M	25%	32.8M	35%	67%	17%	2026
Multkine	HNSCC - UK	USD 39.3M	2K	90,000	178.9M	25%	53.4M	35%	67%	17%	2026
Multkine	HNSCC - US	USD 237.6M	11K	110,000	1,218.7M	24%	341.6M	35%	67%	17%	2026
Multkine	HNSCC - EU	USD 348.3M	24K	90,000	2,199.4M	20%	546.4M	35%	67%	17%	2026
PACME PV		USD 647.7M			3,707.0M		974.2M				
Costs PV[4]		USD 141.0M									
NPV		USD 506.7M									
Milestones PV		USD 40.2M									
Net cash (proforma)		USD 92.7M									
Fair Value		USD 639.6M									
Share Count (proforma)		102,897K									
Price Target		USD 6.20									
Price Target		EUR 5.70	(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

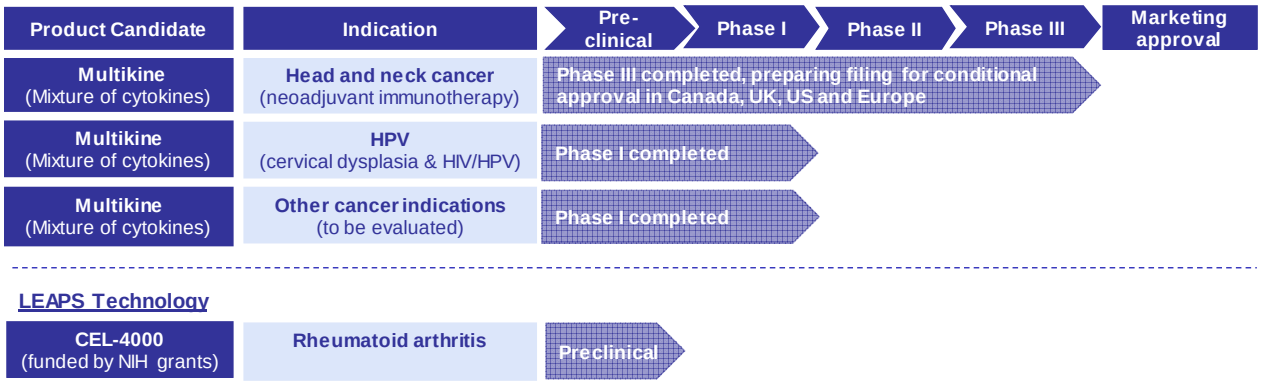
2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of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

COMPANY SNAPSHOT

Figure 3: Overview of the R&D pipeline focusing on cancer



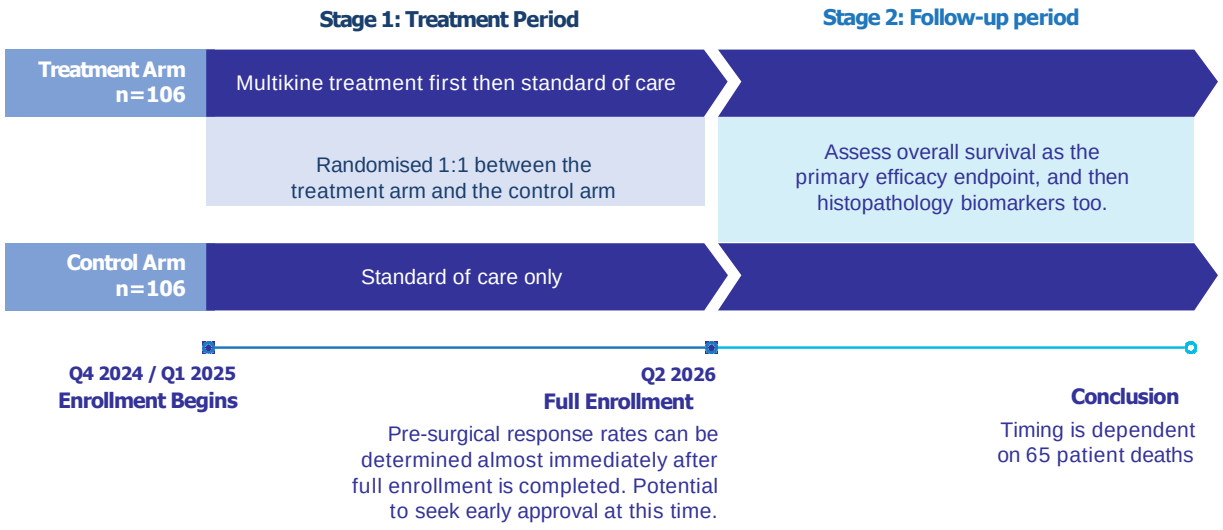
Source: First Berlin Equity Research, CEL-SCI Corporation

Figure 4: Multikine accelerated approval pathway with the US FDA

- In May 2024, the FDA gave the green-light for a confirmatory clinical trial (n=212) potentially leading to an accelerated approval pathway.
- The company needs to incorporate some comments from the FDA to finalise and submit a final version of the registration protocol (management guidance: this summer).
- A law (Food and Drug Omnibus Reform Act) passed in December 2022 requires enrolment in the confirmatory study to be completed before accelerated approval is given in the US.
- The FDA has acknowledged the longstanding need for improved treatments for head and neck cancer. The agency is open to a close collaboration with CEL-SCI to help demonstrate that Multikine could be such a therapy.

Source: First Berlin Equity Research, CEL-SCI Corporation

Figure 5: Overview of the Multikine + CIZ phase confirmatory pivotal trial design (n=212)

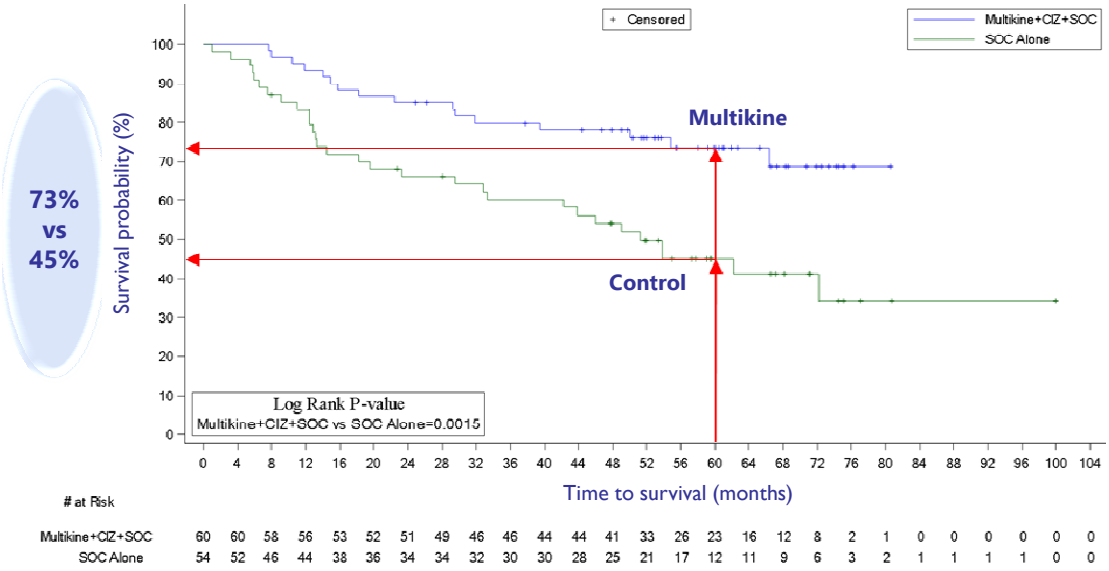


Source: First Berlin Equity Research, CEL-SCI Corp

The confirmatory study will be a randomised, controlled trial in 212 HNSCC patients with two equally sized arms: (1) an arm administering 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); and (2) a control arm administering SOC alone. SOC treatment consists of surgery + radiotherapy or surgery + radiotherapy and chemotherapy depending on pathology from surgery.

Figure 6: Overall survival in the Multikine target population in the phase 3 study

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



Source: First Berlin Equity Research, CEL-SCI Corp

CEL-SCI conducted an in-depth analysis of the data from the phase 3 study in the overall population of patients with primary advanced head and neck squamous cell carcinoma (HNSCC). The patients who meet the following criteria, which can be easily identified with two standard practice diagnostic tests, are defined as the new target population:

(1) No lymph node involvement – N0 – (per PET imaging scan)

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

In the newly identified target population, patients administered Multikine+CIZ+SOC achieved an impressive 73% 5-year survival rate compared to 45% for the control group (p=0.0015).

Figure 7: Risk profile of Multikine's confirmatory study

The planned confirmatory study involving 212 patients is considerably less risky and, in our view, has a better chance of success than a standard phase 3 study, as the main objectives (i.e. absolute survival benefit and hazard ratio) were already achieved in the phase 3 study with high statistical significance and these were well above the minimum requirements for approval:

Multikine results required in the confirmatory study in the target population for approval	Multikine results obtained in the phase 3 study in the target population
Survival benefit greater than absolute 10%	Absolute 28% survival benefit
Hazard ratio below 0.72	Hazard ratio of 0.35
Hazard ratio below 0.72	Upper bound of hazard ratio amounted to 0.66

Source: First Berlin Equity Research, CEL-SCI Corp

INCOME STATEMENT

All figures in USD '000	2019/20	2020/21	2021/22	2022/23	2023/24E	2024/25E
Revenue	**0**	**0**	**0**	**0**	**0**	**0**
Cost of goods sold	0	0	0	0	0	0
Gross profit	559	0	0	0	0	0
General & Administrative	-11,703	-13,085	-10,707	-9,005	-9,200	-9,400
Research & Development	-17,840	-23,109	-25,355	-22,471	-35,000	-25,000
Total operating expenses (OPEX)	**-29,544**	**-36,194**	**-36,063**	**-31,476**	**-44,200**	**-34,400**
Operating income (EBIT)	**-28,985**	**-36,194**	**-36,063**	**-31,476**	**-44,200**	**-34,400**
Net financial result	-1,042	-1,149	-1,081	-675	-700	-700
Non-operating income/expenses	-228	982	443	-43	0	0
Pre-tax income (EBT)	**-30,255**	**-36,361**	**-36,701**	**-32,194**	**-44,900**	**-35,100**
Income taxes	0	0	0	0	0	0
Net income / loss	**-30,255**	**-36,361**	**-36,701**	**-32,194**	**-44,900**	**-35,100**
Diluted EPS (USD)	**-0.82**	**-0.90**	**-0.87**	**-0.72**	**-0.66**	**-0.37**
Ratios						
Gross Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
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.	n.a.
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	2022/23	2023/24E	2024/25E
Assets						
Current Assets, Total	**17,697**	**45,272**	**25,436**	**6,918**	**17,712**	**17,598**
Cash	15,509	36,060	22,672	4,146	13,096	9,034
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	2,773	4,517	8,064
Non-Current Assets, Total	**22,839**	**30,598**	**25,088**	**23,610**	**23,261**	**22,713**
Property plant and equipment	5,844	13,664	11,889	10,188	11,579	12,576
Intangible assets	313	276	212	198	257	333
Other LT assets	15,011	14,748	12,822	10,830	9,031	7,411
Deposits and others	1,671	1,911	164	2,394	2,394	2,394
Total Assets	**40,536**	**75,870**	**50,524**	**30,528**	**40,974**	**40,311**
Shareholders' Equity & Debt						
Current Liabilities, Total	**4,266**	**3,937**	**4,664**	**5,586**	**3,796**	**4,024**
Accounts payable	2,023	1,676	1,618	2,010	1,900	1,995
Other current liabilities	2,242	2,261	3,045	1,772	1,896	2,029
Longterm Liabilities, Total	**16,544**	**15,399**	**13,697**	**11,728**	**10,178**	**8,498**
Other liabilities	12,992	15,399	13,697	11,728	10,178	8,498
Shareholders Equity	**19,727**	**56,534**	**32,163**	**13,215**	**27,000**	**27,790**
Total Consolidated Equity and Debt	**40,536**	**75,870**	**50,524**	**30,528**	**40,974**	**40,311**
Ratios						
Current ratio (x)	4.15	11.50	5.45	1.24	4.67	4.37
Quick ratio (x)	4.15	11.50	5.45	1.24	4.67	4.37
Net gearing	-78.6%	-63.8%	-70.5%	-31.4%	-48.5%	-32.5%
Book value per share (€)	0.54	1.39	0.75	0.30	0.40	0.29
Net debt	-15,509	-36,060	-22,672	-4,146	-13,096	-9,034
Equity ratio	48.7%	74.5%	63.7%	43.3%	65.9%	68.9%

CASH FLOW STATEMENT

All figures in USD '000	2019/20	2020/21	2021/22	2022/23	2023/24E	2024/25E
Net income	**-30,255**	**-36,361**	**-36,701**	**-32,194**	**-44,900**	**-35,100**
Interest payments, net	1,042	1,149	1,081	675	700	700
Tax provision	0	0	0	0	0	0
Non-operating items	228	-982	-443	43	0	0
EBIT	**-28,985**	**-36,194**	**-36,063**	**-31,476**	**-44,200**	**-34,400**
Depreciation and amortisation	2,160	2,231	3,829	3,958	3,850	3,578
EBITDA	**-26,825**	**-33,963**	**-32,234**	**-27,518**	**-40,351**	**-30,822**
Derivative liability	0	0	0	0	0	0
Share based payments	12,909	15,113	12,375	7,150	7,000	6,000
Changes in working capital	-1,250	-483	2,592	-1,777	-1,830	-3,720
Cash interest net	-1,042	-1,149	-1,081	-718	-700	-700
Other adjustments	932	1,696	107	15	0	0
Operating cash flow	**-15,276**	**-18,787**	**-18,240**	**-22,849**	**-35,880**	**-29,242**
CapEx	-2,695	-9,039	-661	-372	-3,620	-3,140
Free cash flow	**-17,971**	**-27,826**	**-18,901**	**-23,221**	**-39,500**	**-32,382**
Other investments	0	-6,146	6,151	0	0	0
Cash flow from investing	**-2,695**	**-15,185**	**5,491**	**-372**	**-3,620**	**-3,140**
Debt Financing, net	0	0	0	0	0	0
Equity Financing, net	25,650	53,769	-38	6,255	50,000	30,000
Payments for financial leases	-615	754	-600	-1,560	-1,550	-1,680
Cash flow from financing	**25,035**	**54,523**	**-638**	**4,694**	**48,450**	**28,320**
Net cash flows	**7,064**	**20,551**	**-13,388**	**-18,526**	**8,950**	**-4,062**
Cash, start of the year	8,445	15,509	36,060	22,672	4,146	13,096
Cash, end of the year	**15,509**	**36,060**	**22,672**	**4,146**	**13,096**	**9,034**
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.

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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.

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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

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	5 December 2023	USD2.80	Buy	USD8.40
2	14 February 2024	USD2.29	Buy	USD8.40
3	11 June 2024	USD1.28	Buy	USD6.20
4	Today	USD1.08	Buy	USD6.20

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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