

Egetis submitted a marketing authorisation application for *Emcitate* for the treatment of MCT8 deficiency to the EMA

- Egetis secured approximately SEK 462 million in a combined financing comprising a SEK 172 million equity private placement and SEK 290 million debt financing
- ReTRIACt study progressing with results expected during the first half of 2024

Financial overview July-September

- Quarterly Revenue MSEK 12.2 (5.1)
- Quarterly loss MSEK -86,2 (-53.9)
- Cash at the end of the quarter amounted to MSEK 85.0 (190.1)
- Cash flow for the quarter was MSEK -94.2 (-43.2)
- Earnings per share before/after dilution SEK -0.3 (-0.3)

Financial overview January-September

- Revenue for the period MSEK 25.0 (16.9)
- Net loss for the period MSEK -240.7 (-115.9)
- Cash at the end of the period amounted to MSEK 85.0 (190.1)
- Cash flow for the period MSEK -43.2 (43.3)
- Earnings per share before/after dilution SEK -1.0 (-0.6)

Significant events during the quarter

Emcitate

- Announced first patient included and second site activated in the ReTRIACt trial, which is pivotal for the US NDA submission
- ReTRIACt trial design presented at the Annual Meeting of the European Society for Paediatric Endocrinology

Significant events after the period

- Secured approximately SEK 462 million in a combined financing comprising a SEK 172 million equity private placement and SEK 290 million debt financing
- Resolved on directed issues of warrants and a convertible bond within the framework of the drawdown of Tranche A of the previously communicated debt financing
- Recruited Desiree Luthman as Vice President Global Regulatory Affairs

Emcitate

- Submitted marketing authorisation application (MAA) for *Emcitate* for the treatment of MCT8 deficiency to the EMA

Financial overview

	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Net revenues, MSEK	12.2	5.1	25.0	16.9	22.6
Result after tax, MSEK	-86.2	-53.9	-240.7	-115.9	-193.8
Cash flow, MSEK	-94.2	-43.2	-43.2	43.3	-19.5
Cash, MSEK	85.0	190.1	85.0	190.1	127.7
Equity ratio %	87%	94%	87%	94%	90%
Earnings per share, SEK	-0.3	-0.3	-1.0	-0.6	-1.0
Earnings per share after dilution, SEK	-0.3	-0.3	-1.0	-0.6	-1.0
Average number of employees	28	14	25	14	15

Comments from the CEO

The past few months have been transformative for Egetis. In July, we recruited the first patients for the Phase 3 clinical trial ReTRIACt, which is pivotal for the New Drug Application (NDA) in the USA, and we expect results from the study in the first half of 2024. I am also pleased that in early October, we submitted a marketing authorisation application (MAA) for *Emcitate* for the treatment of MCT8 deficiency with the European Medicines Agency (EMA). Shortly thereafter, we secured approximately SEK 462 million in combined financing, consisting of a SEK 172 million (gross) private placement and a debt financing of SEK 290 million. Our largest shareholder is now the well-renowned specialist investor Frazier Life Sciences from Menlo Park, California and we are delighted to have attracted them as a new strategic shareholder in Egetis.

Egetis submitted marketing authorisation application for *Emcitate* for the treatment of MCT8 deficiency to the EMA

On October 9, we filed our application for marketing authorisation for *Emcitate* for the treatment of MCT8 deficiency with the European Medicines Agency (EMA). On October 27, we announced that this MAA had been validated and is now under formal review by the Committee for Medicinal Products for Human Use (CHMP) at the EMA. The average duration of the review process for MAAs in the EU is approximately 13-14 months

The first patients entered into Egetis' ReTRIACt trial, which is pivotal for the NDA

As agreed with the FDA, Egetis is conducting a confirmatory randomized, placebo-controlled study (ReTRIACt) in 16 evaluable patients to verify the results from previous clinical trials and publications regarding normalization of thyroid hormone T3 levels, to be part of the NDA in the USA. The ReTRIACt study commenced in June, and we expect results from the study in the first half of 2024. As previously

communicated, this will allow the initiation of a rolling submission for an NDA in the USA with a 'fast track' designation in mid-2024.

The design of the study is available on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05579327) under the code [NCT05579327](https://clinicaltrials.gov/ct2/show/study/NCT05579327).

***Emcitate* is available for patients in need through an Expanded Access Program in the USA**

On the request of the FDA Egetis submitted in the fourth quarter of 2022 an 'Expanded Access Program' in the USA, which has now been implemented. Our Expanded Access Program for *Emcitate* reduces the administrative burden for treating physicians in the US, should they wish to prescribe *Emcitate* to MCT8 patients under their care, until the product gains market approval. This program is also important for those patients finishing the ReTRIACt trial, enabling them to continue *Emcitate* treatment after the trial has ended.

There is continued large and increasing interest from physicians all over the world to treat patients suffering from MCT8-deficiency with *Emcitate*, and it is already prescribed on an individual license to patients in over 25 countries. In total, approximately 190 patients are now being treated with *Emcitate*, and more and more patients are gaining access to treatment, a true verification of the unmet medical need for these patients.

Egetis continues to raise awareness of MCT8 deficiency among medical specialists and other key stakeholders

During the first nine months of 2023 Egetis participated at 12 international scientific and medical conferences. There is great interest among pediatric neurologists and pediatric endocrinologists to learn more about MCT8 deficiency, and general awareness of the disease is still limited. More information about MCT8 deficiency can be found at www.mct8deficiency.com

The Triac Trial II study with *Emcitate*

Triac Trial II is an ongoing international, open-label, multicentre study that investigates the effect of treatment with *Emcitate* on neurocognitive endpoints in young boys (≤ 30 months) with MCT8 deficiency. Patients will initially be treated for 96 weeks with *Emcitate*, after which they will be followed for an additional two years.

The recruitment target for Triac Trial II was achieved in the second quarter of 2022 where 22 patients have been included. Results from the study are expected in mid-2024. The design of the Triac Trial II study is available on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02396459) under the code [NCT02396459](https://clinicaltrials.gov/ct2/show/study/NCT02396459).

The pivotal study Albatross for *Aladote* in the US, EU and UK

The design of the pivotal Phase IIb/III study, called Albatross, has been agreed with the FDA, EMA and MHRA. The start of the study is now planned after completion of the *Emcitate* regulatory submissions in EU and the US.

Cash position

We reported a cash position of approximately SEK 85 million as of September 30, 2023. After the period, the Company received net proceeds of approximately SEK 161 million, after issuance costs, through an equity private placement. In addition, we have secured access to debt financing totalling approximately SEK 292 million.

The net proceeds from the private placement and the debt financing will fund the ongoing development of *Emcitate*, applications for marketing authorisations for *Emcitate* in the EU and the USA, as well as the continued establishment of a commercial and medical affairs organization, including pre-launch activities, and general corporate purposes as well as financial flexibility.

Looking ahead

Egetis is an innovative and integrated pharmaceutical company, focused on projects in late clinical development phase for commercialization within the orphan drug segment for the treatment of serious and rare diseases with significant unmet medical needs.

Our employees are now laser focused on the timely execution of the pivotal ReTRIACt study and on the regulatory interactions with the EMA during the review of the MAA. It is reassuring that we have been able to secure long-term financing for the Company and a stamp of quality to be able to attract a new major owner such as Frazier Life Sciences. I look forward to keeping you informed about the future developments of Egetis during the upcoming transformative year for the Company, as we head toward the launch of our lead product.

Nicklas Westerholm, CEO

About Egetis Therapeutics

Egetis Therapeutics is an innovative and integrated pharmaceutical company, focusing on projects in late-stage development for commercialization for treatments of serious diseases with significant unmet medical needs in the orphan drug segment.

The Company's lead drug candidate *Emcitate* is under development for the treatment of patients with monocarboxylate transporter 8 (MCT8) deficiency, a highly debilitating rare disease with no available treatment. In previous studies (Triac Trial I and a long-term real-life study) *Emcitate* has shown highly significant and clinically relevant results on serum thyroid hormone T3 levels and secondary clinical endpoints. Following successful regulatory interactions Egetis has submitted the marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) on October 9, 2023.

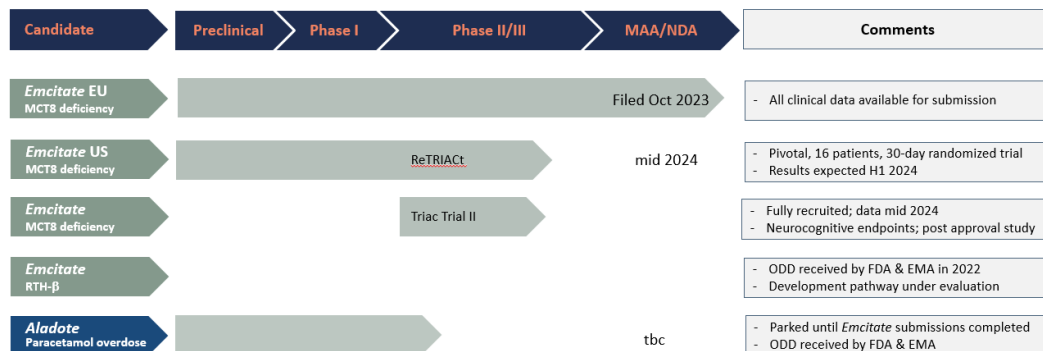
After a dialogue with the FDA, Egetis is conducting a small randomized, placebo-controlled pivotal study in 16 patients to verify the results on T3 levels seen in previous clinical trials and publications. Egetis intends to initiate the rolling submission of a new drug application (NDA) in the US for *Emcitate* in mid 2024 under the Fast-Track Designation granted by FDA.

Emcitate holds Orphan Drug Designation (ODD) for MCT8 deficiency and resistance to thyroid hormone type beta (RTH-beta) in the US and the EU. MCT8 deficiency and RTH-beta are two distinct indications, with no overlap in patient populations. *Emcitate* has been granted Rare Pediatric Disease Designation (RPDD) which gives Egetis the opportunity to receive a Priority Review Voucher (PRV) in the US, after approval. This voucher can be transferred or sold to another sponsor.

The drug candidate *Aladote* is a first in class drug candidate developed to reduce the risk of acute liver injury associated with paracetamol (acetaminophen) overdose. A proof of principle study has been successfully completed and the design of the upcoming pivotal Phase IIb/III study with the purpose of applying for market approval in the US and Europe for *Aladote* has been finalized following interactions with FDA, EMA and MHRA. The study start is planned after *Emcitate* submissions have been completed. *Aladote* has been granted ODD in the US and in the EU.

Egetis Therapeutics (STO: EGTX) is listed on the Nasdaq Stockholm main market. For more information, see www.egetis.com

Pipeline overview



Project updates

Emcitate

Events during the quarter

- Announced first patient included and second site activated in the ReTRIACt trial, which is pivotal for the US NDA submission
- ReTRIACt trial design presented at the Annual Meeting of the European Society for Paediatric Endocrinology

Events after the reporting period

- Submitted marketing authorisation application for *Emcitate* for the treatment of MCT8 deficiency to the EMA

About *Emcitate*

Emcitate is Egetis' lead drug candidate in clinical development. It addresses monocarboxylate transporter 8 (MCT8) deficiency, also known as Allan-Herndon-Dudley Syndrome (AHDS), a rare genetic disease that affects 1 in 70,000 men with high unmet medical need with no available treatment.

Thyroid hormones are crucial for the development and metabolic state of virtually all tissues. Thyroid hormone transport across the plasma membrane is required for the hormones' metabolism and intracellular action and is facilitated by thyroid hormone transporters, including MCT8. Mutations in the gene for MCT8 cause MCT8 deficiency. The gene is located on the X chromosome and therefore mainly affects men, as men only have one X chromosome.

The resulting dysfunction of MCT8 leads to impaired transport of thyroid hormone into certain cells and across the blood-brain-barrier and disruption of normal thyroid hormone regulation. Patients with MCT8 deficiency therefore have low concentrations of thyroid hormone in the central nervous system, which signals that the body should produce more thyroid hormone. This leads to increased levels of active thyroid hormone T3 in peripheral tissues, also called thyrotoxicosis. This leads to a complex pattern of symptoms with neurological developmental delay and intellectual disability, accompanied by severely elevated circulating thyroid hormone concentrations which are toxic for tissues including the heart, muscle, liver and kidney and results in symptoms such as failure to thrive, cardiovascular stress, insomnia and muscle wasting.

Most patients will never develop the ability to walk or even sit independently. At present there is no approved therapy available for the treatment of MCT8 deficiency.

Emcitate was granted Orphan Drug Designation in the EU in 2017 and the US in 2019. *Emcitate* received US Rare Paediatric Disease Designation (RPDD) in 2020. Upon approval of the NDA, sponsors holding a RPDD and meeting the criteria specified can apply to receive a Priority Review Voucher (PRV). A PRV provides accelerated FDA review of a subsequent new drug application for any drug candidate, in any indication, shortening time to market in the US. The voucher may also be sold or transferred to another sponsor. During the last few years PRVs have been sold for around \$100 million.

A Phase IIb clinical trial (Triac Trial I) in MCT8 deficiency has been completed which showed significant and clinically relevant treatment effects on key aspects of the disease. In October 2021, strong data from long-term treatment in patients with MCT8 deficiency up to 6 years, with *Emcitate* was published in the *Journal of Clinical Endocrinology & Metabolism*. The data comes from an investigator-initiated real-life cohort study at 33 sites conducted by the Erasmus Medical Center, Rotterdam, The Netherlands, where the efficacy and safety of *Emcitate* was investigated in 67 patients with MCT8 deficiency.

Based on the new long-term data in 2021, Egetis had further interactions with the regulatory agencies in the US and Europe. In December 2021, the EMA concluded that the clinical data from the Triac Trial I, together

EGETIS THERAPEUTICS

with the published data from long-term treatment, is sufficient for a regulatory submission of a Marketing Authorisation Application (MAA) to the EMA for the treatment of MCT8 deficiency and Egetis has successfully completed the submission on October 9, 2023. The average review time for MAAs is generally 13-14 months.

FDA acknowledges that a treatment effect on T3 levels and the manifestations of chronic thyrotoxicosis in MCT8- deficiency could provide a basis for marketing approval also in the US. Egetis is conducting a small, randomized study in 16 patients for up to 30 days to verify the T3 results, seen in previous clinical trials and publications. The design of this study (ReTRIACt) is available on clinicaltrials.gov under the code NCT055793. It is well established that the T3 levels in untreated MCT8 patients are significantly elevated, and we have previously shown that *Emcitate* is able to normalize these levels rapidly and durably. Egetis is targeting the start of an US NDA rolling submission for *Emcitate* in mid 2024 under the Fast Track Designation granted by the FDA.

A Phase IIb/III early intervention study (Triac Trial II) was initiated in 2020. This study is an international, open label, multi-center study in boys younger than 30 months with MCT8 deficiency, conducted in both Europe and North America. The design of the Triac

Trial II study is available on clinicaltrials.gov under the code NCT02396459. The recruitment target was reached in April 2022, with 22 patients included in the study. Results from the Triac Trial II are expected in mid 2024.

Emcitate is already supplied to approximately 190 patients in Managed Access Programs, following individual regulatory approvals from national regulatory agencies in over 25 countries, the most recent program to open is the EAP in the USA, requested by the FDA. Managed Access Programs allow early access to a medicine prior to regulatory marketing approval, granted to pharmaceuticals under development for conditions with high unmet medical needs and where no available treatment alternatives exist.

Emcitate has been granted orphan drug designation (ODD) for RTH- β in the USA and the EU. RTH- β is an additional indication, without overlap in patient populations, to the previously obtained ODD for MCT8 deficiency. The ODD for RTH- β is a direct result of Egetis' work to extend the indications for the *Emcitate* program to related but distinct conditions.

Aladote

No events during the quarter

About *Aladote*

Aladote is a first-in-class drug candidate with the potential to reduce the risk of acute liver failure associated with paracetamol/acetaminophen poisoning. *Aladote* has shown a beneficial effect in relevant preclinical models, even in the time-window when N-acetylcysteine (NAC) treatment no longer is effective (>8 hours). A proof of principle study in patients with paracetamol poisoning to prevent acute liver injury has been successfully completed. The study results established the safety and tolerability of the combination of *Aladote* and NAC. Further, the results indicate that *Aladote* may reduce acute liver injury in this patient population.

Aladote has been granted Orphan Drug Designation (ODD) in the US and EU.

Paracetamol/acetaminophen is the most used drug in the world for the treatment of fever and pain, but also one of the most overdosed drugs –

intentionally or unintentionally. Paracetamol overdose is one of the most common methods in

suicide attempts. When excessive amounts of paracetamol are metabolized in the liver, the harmful metabolite N-acetyl-p-benzoquinone imine (NAPQI) is formed, which can cause acute liver failure. The current standard of care for paracetamol poisoning, NAC, is effective if the patient receives medical care within eight hours of ingestion.

A pivotal Phase IIb/III study, Albatross, has been parked until *Emcitate* submissions have been completed. This study will be targeting patients with increased risk of liver injury, who arrive late at hospital, more than eight hours after a paracetamol overdose, for which current standard of care, NAC, is substantially less effective. Study start is planned after *Emcitate* submissions have been completed.

Financial Information

Interim report January – September 2023

Revenue and results

Revenue

Revenue amounted to MSEK 12.2 (5.1) during the quarter and MSEK 25.0 (16.9) for the period from Emcitate “Managed Access Program” of MSEK 12.2 (5.0) during the quarter and MSEK 25.0 (16.3) during the period. The increase in revenue during the quarter is primarily attributed to higher demand and regional variations in orders. Revenue in the comparative period previous year included forwarding of expenses related to PledOx to Solasia Pharma K.K. (Solasia) with an amount of MSEK 0.6.

Expenses

Operating expenses amounted to MSEK -98.8 (-60.6) during the quarter and MSEK -266.7 (-136.8) during the period. The project expenses amounted to MSEK -51.2 (-41.1) during the quarter and MSEK -140.6 (-83.5) during the period. The project expenses consisted of expenses due to Emcitate of MSEK -50.9 (-35.2) and Aladote of MSEK -0.2 (-5.8), during the quarter and MSEK -139.0 (-74.7) for Emcitate and MSEK -1.6 (-7.8) for Aladote during the period.

Employee costs amounted to MSEK -22.1 (-11.8) during the quarter and MSEK -53.3 (-30.5) during the period. The cost increase is due to the increase of number of employees ahead of the anticipated commercial launch of Emcitate. These include among others, work related to the ongoing and upcoming submissions with major healthcare agencies around the world. The costs also include participants’ earnings in the employee stock option plans of MSEK -3.1 (-1.7) for the quarter and MSEK -4.2 (-3.8) for the period. Costs for the employee stock option plans will, to a certain extent, continue to vary with the share price development and do not impact cash flow.

Other external costs amounted to MSEK -19.3 (-5.5) during the quarter and MSEK -59.7 (-15.8) during the period. The increase is mainly due to higher

consultancy costs related to Egetis’ investments ahead of the planned commercial launch of Emcitate. These include among others, work related to the ongoing and upcoming submissions with major healthcare agencies in Europe and the USA. Depreciation amounted to MSEK -0.9 (-0.7) for the quarter and MSEK -2.7 (-2.0) during the period. The depreciation during the period derives from amortization of licences with MSEK -0.8 (-0.8), depreciation of right-of-use assets with MSEK -1.8 (-1.1) and depreciation of inventories with MSEK -0.1 (-0.1). Other operating expenses amounted to MSEK -2.6 (-) for the quarter and MSEK -4.1 (-) for the period and consists of exchange rate differences from operating income and operating expenses.

Results

Operating results amounted to MSEK -86.5 (-55.4) for the quarter and MSEK -241.7 (-119.8) for the period. Net financial items amounted to MSEK 0.3 (1.6) for the quarter and MSEK 1.1 (3.9) for the period. Results from net financial items are primarily related interest rate income on company held cash deposits. Results after financial items amounted to MSEK -86.2 (-53.9) for the quarter and MSEK -240.7 (-115.9) for the period. Results per share before and after dilution amounted to SEK -0.3 (-0.3) for the quarter and SEK -1.0 (-0.6) for the period both before and after dilution.

Financial position

Cash

Cash as of September 30, 2023, amounted to MSEK 85.0 (190.1).

Cash flow

Cash flow from operating activities amounted to MSEK -93.1 (-42.7) for the quarter and MSEK -236.7 (-111.1) for the period. Total Cash flow amounted to MSEK -94.2 (-43.2) for the quarter and MSEK -43.2 (43.3) for the period. Cash flow from operating

activities is driven by costs related to the ongoing clinical studies and the preparations ahead of the anticipated commercial launch of Emetate.

Cash flow from investment activities amounted to MSEK -0.5 (-1.7) during the period. The figures in the comparative period previous year included payment of deferred purchase price for the acquisition of Rare Thyroid Therapeutics International AB (RTTI AB). Cash flow from financing activities amounted to MSEK -0.6 (-0.5) for the quarter and MSEK 194.0 (156.1) for the period and derives mainly from the directed shares issue of 35,000,000 shares at SEK 6.00, that was completed during January 2023.

Equity and equity ratio

As of September 30, 2023, equity amounted to MSEK 466.9 (582.6). Shareholders' equity per average number of shares amounted to SEK 1.9 (2.9), at the end of the period. The company's equity ratio was 87 (94) %.

Debts and receivables

As of September 30, 2023, non-current liabilities amounted to MSEK 6.0 (2.4). These consist mainly of liabilities that derive from right of use liabilities according to IFRS 16 of MSEK 2.7 (1.5) and provisions for social security contributions relating to stock option plans of MSEK 3.3 (1.0). Current liabilities amount to MSEK 61.1 (32.6) of which other liabilities and accrued expenses amount to MSEK 49.8 (25.6) and accounts payable amount to MSEK 11.3 (7.0). Accrued expenses increase are reservations due to assessed industry standard rebate scheme settled on an annual basis and with final settlement within five years.

Investments in tangible and intangible assets

As of September 30, 2023, non-current intangible assets amounted to MSEK 414.3 (413.4). No significant investments were allocated to tangible assets during the period.

Shares

The number of shares as of September 30, 2023, were 249,589,128. The number of shares has increased with 35,000,000 shares as a result of a directed new share issue during January. The number of shareholders

were 7,275 as of June 30, 2023. The 10 largest shareholders hold 73.4 % of outstanding shares. Egetis Therapeutics shares are listed on Nasdaq Stockholm's main market.

Stock option plan and warrant programs

Information regarding existing incentive programs

For information about current and previous employee stock option programs please see note 6.

Employees

Number of employees as of September 30, 2023, were 29 (17) persons, 17 women and 12 men (10 women and 7 men).

Parent company

The parent company's Revenue for the quarter amounted to MSEK - (-) and MSEK - (0.6) for the period. Revenue in the prior period were due to forwarding of expenses related to PledOx to Solasia. Other income for the quarter amounted to MSEK 23.3 (15.0) and MSEK 65.6 (31.6) for the period. Other income for the period consisted of MSEK 31.0 (20.1) management fees invoiced to the subsidiaries RTTI AB and Egetis Therapeutics US Inc., MSEK 34.2 (11.3) for forwarding of expenses to RTTI AB and MSEK 0.4 (0.2) as exchange rate gains.

Operating expenses amounted to MSEK -42.8 (-32.4) for the quarter and MSEK -117.2 (-71.4) for the period. The project expenses amounted to MSEK -13.7 (-15.2) for the quarter and MSEK -37.4 (-24.7) during the period.

The parent company's results amounted to MSEK -89.2 (-45.8) for the quarter and MSEK -220.3 (-90.2) for the period.

Financial non-current assets amount to MSEK 434.9 (433.7) and other long-term liabilities amount to MSEK 3.3 (-).

Consolidated statement of income

MSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Revenue					
Revenue	12.2	5.1	25.0	16.9	22.6
Other operating income	0.0	0.1	0.0	0.1	-
	12.2	5.2	25.0	17.0	22.6
Operating expenses					
Costs of sales of goods	-2.7	-1.5	-6.3	-5.0	-6.3
Project costs	-51.2	-41.1	-140.6	-83.5	-136.3
Other external costs	-19.3	-5.5	-59.7	-15.8	-22.3
Employee costs	-22.1	-11.8	-53.3	-30.5	-52.0
Depreciation and impairment	-0.9	-0.7	-2.7	-2.0	-2.7
Other operating expenses	-2.6	-	-4.1	-	-1.1
Sum operating expenses	-98.8	-60.6	-266.7	-136.8	-220.6
Operating results	-86.5	-55.4	-241.7	-119.8	-198.1
Financial items					
Interest income and similar items	0.5	1.6	1.4	4.0	5.0
Interest expense and similar items	-0.2	0.0	-0.4	-0.1	-0.7
Sum financial items	0.3	1.6	1.1	3.9	4.3
Results after financial net	-86.2	-53.9	-240.7	-115.9	-193.8
Tax	-	-	-	-	-
Net loss for the period	-86.2	-53.9	-240.7	-115.9	-193.8
Net earnings and comprehensive income is entirely attributable to parent company shareholders					
Share Data					
Number of shares at the end of period	249,589,128	214,589,128	249,589,128	214,589,128	214,589,128
Average number of shares during period, before dilution	249,589,128	214,589,128	246,255,795	204,223,484	194,238,210
Average number of shares during period, after dilution	249,689,618	214,589,128	249,595,085	204,223,484	194,238,210
Earnings per share before dilution (SEK)	-0.3	-0.3	-1.0	-0.6	-1.0
Earnings per share after dilution (SEK)	-0.3	-0.3	-1.0	-0.6	-1.0
Equity per average number of shares	1.9	2.7	1.9	2.9	2.6
Equity per average number of shares after dilution	1.9	2.7	1.9	2.9	2.6

Statement of comprehensive income

MSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Net loss for the period	-86.2	-53.9	-240.7	-115.9	-193.8
Translation exchange rate differences	-0.1	-	0.1	-	0.0
Comprehensive income for the period	-86.3	-53.9	-240.5	-115.9	-193.8

Consolidated statement of financial position

MSEK	30/09/2023	30/09/2022	31/12/2022
ASSETS			
Non-current assets			
Research and development costs	404.8	404.8	404.8
Licences	4.6	5.7	5.4
Right-of-use assets	4.9	2.9	2.6
Equipment	0.1	0.1	0.1
Financial non-current assets	1.3	0.8	0.8
Total non-current assets	415.6	414.4	413.7
Current assets			
Inventories	0.4	0.8	0.6
Accounts receivables	21.6	4.6	3.8
Other receivables	6.0	4.0	6.4
Prepaid expenses and accrued income	5.5	3.8	8.9
Cash and bank balance	85.0	190.1	127.7
Total current assets	118.5	203.2	147.4
Total assets	534.1	617.6	561.1
MSEK	30/09/2023	30/09/2022	31/12/2022
Equity			
Share capital	13.1	11.3	11.3
Other capital contributions	1,622.6	1,428.4	1,428.4
Reserves	11.4	4.6	6.1
Accumulated loss including net loss	-1,180.1	-861.7	-939.6
Total equity	466.9	582.6	506.2
Non-current liabilities			
Other non-current liabilities	2.7	1.5	1.1
Provisions	3.3	1.0	4.4
Total non-current liabilities	6.0	2.4	5.5
Current liabilities			
Accounts payable	11.3	7.0	20.0
Other liabilities	6.6	6.2	5.7
Accrued expenses and deferred income	43.2	19.4	23.7
Total current liabilities	61.1	32.6	49.4
Total equity and liabilities	534.1	617.6	561.1

Consolidated statement of cash flows

MSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-86.2	-53.9	-240.7	-115.9	-193.8
Adjustments for non-cash items	4.8	2.6	8.1	4.0	9.4
Tax paid	-	-	-	-	-
Cash flow from operating activities before changes in working capital	-81.5	-51.3	-232.6	-111.9	-184.4
Cash flow from changes in working capital					
Increase/decrease in operating receivables	-20.0	-0.2	-13.9	-4.1	-10.7
Increase/decrease in operating liabilities	8.4	8.8	9.7	5.0	21.6
Cash flow from changes in working capital	-11.6	8.7	-4.2	0.8	10.9
Cash flow from operating activities	-93.1	-42.7	-236.7	-111.1	-173.5
INVESTING ACTIVITIES					
Acquisition of subsidiaries, net cash required	-	-	-	-1.7	-1.7
Investment in financial assets	-0.5	0.0	-0.4	0.0	0.0
Purchase of property, plant and equipment	-	-	0.0	-	-
Cash flow from investing activities	-0.5	0.0	-0.5	-1.7	-1.7
FINANCING ACTIVITIES					
New share issue	-	-	210.0	177.4	177.4
Cost new share issue	-	-	-14.0	-12.6	-12.6
Repayment of loans	-	-	-	-7.5	-7.5
Repayment of leases	-0.6	-0.5	-1.9	-1.2	-1.6
Cash flow from financing activities	-0.6	-0.5	194.0	156.1	155.7
Cash flow for the period	-94.2	-43.2	-43.2	43.3	-19.5
Balance at beginning of period	179.2	233.2	127.7	144.0	144.0
Change in cash	-94.2	-43.2	-43.2	43.3	-19.5
Exchange rate difference in cash	0.0	0.1	0.4	2.9	3.2
CASH BALANCE AT THE END OF THE PERIOD	85.0	190.1	85.0	190.1	127.7

Consolidated statement of changes in equity

MSEK	Share capital	Other capital contributions	Accumulated loss incl. net results for the period	Other reserves	Total equity
Opening balance 01/01/2023	11.3	1,428.4	-939.6	6.1	506.2
Directed share issue	1.8	208.2	-	-	210.0
Costs, directed share issue	-	-14.0	-	-	-14.0
Comprehensive income for the period	-	-	-240.5	-	-240.5
<i>Transactions with shareholders</i>					
Costs due to share-based payments of employee stock option plan	-	-	-	5.3	5.3
Closing balance 30/09/2023	13.1	1,622.6	-1,180.1	11.3	466.9
Opening balance 01/01/2022	8.7	1,262.8	-745.8	1.3	527.0
Rights issue	2.6	178.1	-	-	180.8
Costs, rights issue	-	-12.6	-	-	-12.6
Comprehensive income for the period	-	-	-193.8	-	-193.8
<i>Transactions with shareholders</i>					
Costs due to share-based payments of employee stock option plan	-	-	-	4.8	4.8
Closing balance 31/12/2022	11.3	1,428.4	-939.6	6.1	506.2

Consolidated key ratios

The key ratios below are useful to those who read the financial statements and a complement to other performance targets in evaluating strategic investment implementation and the Group's ability to achieve financial goals and commitments.

MSEK	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Equity	466.9	582.6	506.2
Equity ratio %	87%	94%	90%
Number of shares at the end of the period	249,589,128	214,589,128	214,589,128
Average number of shares during the period	246,255,795	204,223,484	194,238,210
Average number of shares during the period after dilution	249,595,085	204,223,484	194,238,210

Share Data

Earnings per share	-1.0	-0.6	-1.0
Earnings per share after dilution	-1.0	-0.6	-1.0
Cash flow from operating activities	-1.0	-0.5	-0.9
Equity per average number of shares	1.9	2.9	2.6
Equity per average number of shares after dilution	1.9	2.9	2.6
Dividend	-	-	-
Average number of employees	25	14	15

*Effect from dilution is not considered when result is negative.

Parent company - income statement

MSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Revenue					
Revenue	-	0.1	-	0.6	0.6
Other operating income	23.3	15.0	65.6	31.6	53.6
	23.3	15.0	65.6	32.2	54.2
Operating expenses					
Project costs	-13.7	-15.2	-37.4	-24.7	-42.4
Other external costs	-10.7	-5.1	-31.3	-15.7	-22.4
Employee costs	-18.3	-11.8	-48.0	-30.5	-52.0
Depreciation and impairment	0.0	0.0	-0.1	0.0	-0.1
Other operating expenses	-0.1	-0.3	-0.6	-0.4	-0.6
Sum operating expenses	-42.8	-32.4	-117.2	-71.4	-117.4
Operating results	-19.5	-17.4	-51.6	-39.2	-63.2
Financial items					
Interest income and similar items	0.4	1.6	1.4	4.0	3.7
Interest expense and similar items	0.0	-	-0.1	-	0.0
Sum financial items	0.4	1.6	1.3	4.0	3.7
Results after financial net	-19.2	-15.8	-50.3	-35.2	-59.5
Appropriations	-70.0	-30.0	-170.0	-55.0	-135.0
Tax	-	-	-	-	-
Net loss for the period	-89.2	-45.8	-220.3	-90.2	-194.5

Parent company - balance sheet

MSEK	30/09/2023	30/09/2022	31/12/2022
ASSETS			
Non-current assets			
Equipment	0.1	0.1	0.1
Financial non-current assets	434.9	433.7	433.8
Total non-current assets	435.0	433.8	433.9
Current assets			
Receivables from Group companies	0.6	-	0.1
Other receivables	0.1	0.0	0.6
Prepaid expenses and accrued income	7.5	3.0	3.8
Cash and bank balance	76.8	183.6	120.0
Total current assets	85.0	186.6	124.4
Total assets	520.0	620.4	558.3
MSEK	30/09/2023	30/09/2022	31/12/2022
Equity			
<i>Restricted Equity</i>			
Share capital	13.1	11.3	11.3
<i>Non-restricted equity</i>			
Share premium reserve	673.5	673.8	673.8
Reserves	11.3	4.6	6.1
Net loss for the period	-220.3	-90.2	-194.5
Total equity	477.6	599.5	496.7
Non-current liabilities			
Provisions	3.3	1.0	4.4
Total non-current liabilities	3.3	1.0	4.4
Current liabilities			
Liabilities to group company	18.0	5.5	33.1
Accounts payable	5.5	3.6	7.8
Other liabilities	4.3	4.5	3.9
Accrued expenses and deferred income	11.3	6.3	12.4
Total current liabilities	39.1	19.9	57.2
Total equity and liabilities	520.0	620.4	558.3

Notes

Note 1 - Accounting principles

Egetis applies International Financial Reporting Standards (IFRS) as adopted by the EU. This report is prepared in accordance with IAS 34 Interim Financial Reporting and the Annual Accounts Act and should be read together with the Egetis consolidated financial statements for the year ended December 31, 2022. The interim report does not include all disclosures that would otherwise be required in a complete set of financial statements. Applied accounting principles and calculation methods are the same as in the latest annual report for 2022. Some amendments to existing standards became applicable from January 1, 2023, however none of these have a material impact on the consolidated financial statements or accounting policies. The parent company and the Group's accounting currency is SEK. All the numbers in this interim report are, if nothing else is stated, presented in million SEK.

The preparation of interim reports requires certain critical accounting estimates to be made. Furthermore, company management is required to make assessments when applying accounting principles. During the year assessed industry standard rebate scheme which are settled on an annual basis and with final settlement within five years has been added. These assessments are in large based on the judgement from external expertise. See the Group's accounting principles in the annual report 2022 regarding more information on estimates and assessments.

Parent company

The parent company Egetis Therapeutics AB (publ) prepares financial reports in accordance with the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and the Swedish Annual Accounts Act. The parent company applies the exception from application of IFRS 16 Leases.

Operating risks

All business operations involve risk. Risks may be company specific or due to events in the external environment and may affect a certain industry or market. The group is, among others, exposed to the following operational and financial risks.

Operational risks:

Pharmaceutical development, Manufacturing, Regulatory, Commercialization, Competition and Market Acceptance and Intellectual property.

Financial risks:

Foreign currency, Need of working capital, General market risk, Credit and Interest rate risks.

A more detailed description of the Group's risk exposure is included in Egetis 2022 Annual Report, *Risks and Risk Management* section and Note 3. There are no major changes in the Group's risk exposure in 2023 compared with 2022.

External risk factors

Egetis Therapeutics is dependent on the efficient and uninterrupted operation of various IT systems to run its business. A significant breakdown or other disruption in the IT systems (for example as a result of a virus attack or network congestion attacks) can affect the ability to conduct business in general and can lead to delays and increased costs in the Company's research and development work.

There is a risk that the Company, as a result of such as viral pandemics, will not succeed in recruiting participants for its clinical studies, either because participants do not want, or due to restrictions should not, visit hospitals to avoid infection. There is also a risk that new variants of different microorganisms will lead to lockdowns in Sweden or in other countries, which could mean that the Company or its partners cannot conduct research and development work according to the existing clinical development plan. There is also a risk that caregivers need to allocate resources to meet the effects of different pandemics, which can lead to limited resources to participate in the Company's clinical trials.

Continued and/or escalating tension between Russia and Ukraine led to Russia's full-scale military invasion of Ukraine, middle eastern conflicts and current inflationary situation in the society could have a significant negative impact on the global macroeconomic situation and the Swedish economy. It could result in the Company or its partners not being able to conduct R&D efforts according to plan.

A more detailed description of the Group's risk exposure is included in Egetis 2022 Annual Report, *Risks and Risk Management* section and Note 3. There are no major changes in the Group's risk exposure in 2023 compared with 2022.

Note 2 – Additional information

Other information in accordance with IAS 34.16A are found on the pages before the income statement and statement of comprehensive income. For information on earnings, cash flow and financial position, see page 9. For events after the period, see page 1.

Note 3 – Segments

The Group applies segment reporting with mainly two independent development areas, Emcitate and Aladote. The highest executive decision-maker in the Company allocates the Company's resources between these two R&D projects. The Aladote project has been parked since June 2023. Revenue for Emcitate is attributable to the "Named Patient Use" use of the drug candidate.

Revenue and expenses attributable to Emcitate and Aladote are reported below.

2023 Jul-Sep MSEK	Emcitate	Aladote	Common*	Sum
Revenue	12.2	-	-	12.2
Costs of sales of goods	-2.7	-	-	-2.7
Project costs	-50.9	-0.2	-	-51.2
Other	-	-	-44.9	-44.9
Operating results	-41.4	-0.2	-44.9	-86.5
Net financial items				0.3
Pretax profit				-86.2

2023 Jan-Sep MSEK	Emcitate	Aladote	Common*	Sum
Revenue	25.0	-	-	25.0
Costs of sales of goods	-6.3	-	-	-6.3
Project costs	-139.0	-1.6	-	-140.6
Other	-	-	-119.7	-119.7
Operating results	-120.4	-1.6	-119.7	-241.7
Net financial items				1.1
Pretax profit				-240.7

2022 Jul-Sep MSEK	Emcitate	Aladote	Common*	Sum
Revenue	5.0	-	0.1	5.1
Costs of sales of goods	-1.5	-	-	-1.5
Project costs	-35.2	-5.8	-0.2	-41.1
Other	-	-	-17.9	-17.9
Operating results	-31.7	-5.8	-18.0	-55.4
Net financial items				1.6
Pretax profit				-53.9

2022 Jan-Sep MSEK	Emcitate	Aladote	Common	Sum
Revenue	16.3	-	0.6	16.9
Costs of sales of goods	-5.0	-	-	-5.0
Project costs	-74.7	-7.8	-1.0	-83.5
Other	-	-	-48.2	-48.2
Operating results	-63.4	-7.8	-48.7	-119.8
Net financial items				3.9
Pretax profit				-115.9

2022 Jan-Dec				
MSEK	Emciteate	Aladote	Common *	Sum
Revenue	21.9	-	0.6	22.6
Costs of sales of goods	-6.3	-	-	-6.3
Project costs	-124.6	-10.6	-1.1	-136.3
Other	-	-	-78.0	-78.0
Operating results	-109.0	-10.6	-78.5	-198.1
Net financial items				4.3
Pretax profit				-193.8

*) Revenue and project costs attributable to the parked PledOx project are provided in the "Common" column in the comparative period.

Turnover by type of revenue

KSEK	2023	2022	2023	2022	2022
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Re-invoicing of costs to Solasia	-	0.1	-	0.6	0.6
Sales of goods	12.2	5.0	25.0	16.3	21.9
Total	12.2	5.1	25.0	16.9	22.6

Note 4 – Contingent liabilities

Egetis has a contractual obligation, on future net sales from Emciteate, to provide royalty payments to the previous owners of Rare Thyroid Therapeutics International AB and Erasmus Medical Center corresponding to a low double-digit percentage of net sales of the product.

Note 5 – Related party transactions

Peder Walberg has been providing consultancy services to the company, invoicing MSEK 1,5 (0,9) during the period.

Note 6 – Employee Stock Option Plan

During the first nine months of 2023, the average share price exceeded the exercise price of the majority of the employee stock option plan (ESOP) 2022 why a dilution effect is reported in the number of shares after dilution. However, as earnings per share are negative, no dilution is reported in the key ratio earnings per share after dilution. As of September 30, 2023, the company has four ESOPs outstanding. Full utilization of the granted stock options would increase the number of shares in the company by 24,123,364. The total number of granted stock options have during the period increased with the granting of ESOP 2023.

Employee Stock option plan 2023

The 2023 Annual General Meeting resolved on a 2023/2026 stock option plan of 9,000,000 stock options for employees at Egetis Therapeutics, of which 8,706,204 were granted to employees and key consultants, as of September 30, 2023. The CEO and the rest of the management team (eight individuals) were granted 1,313,869 and 4,653,285 employee stock options, respectively. To ensure the delivery of shares to participants in the incentive plans as well as to cover social security contributions when the share awards and employee options are exercised, the Parent Company has issued 10,350,000 warrants to its subsidiary Egetis Therapeutics Incentive AB.

The ESOP is implemented for employees and key consultants. The options were allotted free of charge to participants of the program. The options have a three-year vesting period calculated from the allotment date, provided that, with customary exceptions, the participants remain as employees of, or continue to provide services to Egetis. Once the options are vested, they can be exercised within a six-month period. Each vested option entitles the holder to acquire one share in Egetis at a predetermined price. The price per share is to be equivalent to 120% of the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the allotment date, however, the price per share shall not be lower than SEK 7.2. The options have, at the time of issue, been valued according to the Black & Scholes valuation models. The exercise price is SEK 7.2 per option.

Employee Stock option plan 2022

The 2022 Annual General Meeting resolved on a 2022/2026 stock option plan of 7,300,000 stock options for employees at Egetis Therapeutics, of which 7,300,000 were granted to employees and key consultants, as of March 31, 2023. The CEO and the rest of the management team (eight individuals) were granted 1,430,463 and 4,033,776 employee stock options, respectively. To ensure the delivery of shares to participants in the incentive plans as well as to cover social security contributions when the share awards and employee options are exercised, the Parent Company has issued 9,592,200 warrants to its subsidiary Egetis Therapeutics Incentive AB.

The ESOP is implemented for employees and key consultants. The options were allotted free of charge to participants of the program. The options have a three-year vesting period calculated from the allotment date, provided that, with customary exceptions, the participants remain as employees of, or continue to provide services to Egetis. Once the options are vested, they can be exercised within a one-year period. Each vested option entitles the holder to acquire one share in Egetis at a predetermined price. The price per share is to be equivalent to 120% of the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the allotment date. The options have, at the time of issue, been valued according to the Black & Scholes valuation models. The exercise prices are in the interval of SEK 4.22-7.15 per option.

Employee Stock option plan 2021

The 2021 Annual General Meeting resolved on a 2021/2025 stock option plan for employees at Egetis Therapeutics AB. The number of outstanding and granted stock options are 5,000,000. To ensure the delivery of shares to participants in the Company's incentive plans as well as to cover social security contributions when the share awards and employee options are exercised, the Parent Company has issued 6,571,000 warrants to its subsidiary Egetis Therapeutics Incentive AB. After re-calculation, according to the terms and conditions for the ESOP, for the May 2022 rights issue, every stock option is eligible to 1.02 shares and the updated exercise price is SEK 9.33 per option.

Employee Stock option plan 2020

The 2020 Annual General Meeting resolved on a 2020/2024 stock option plan for employees at PledPharma (previous company name for Egetis Therapeutics AB). The number of granted stock options are 2,900,000. To ensure the delivery of shares to participants in the Company's incentive plans as well as to cover social security contributions when the share awards and employee options are exercised, the Parent Company has issued 3,942,600 warrants to its subsidiary Egetis Therapeutics Incentive AB. After re-calculation, according to the terms and conditions for the ESOP, for the November 2020 and May 2022 rights issues, the numbers of shares each stock option is entitled to is 1.0404 shares and the updated exercise price is SEK 11.71 per option.

Note 7 –Key ratios definitions

Ratios that have been calculated according to IFRS

Earnings per share. Net income divided by average number of shares before dilution.

Number of shares at end of period. The number of outstanding shares before dilution at the end of the period.

Number of shares after dilution. The number of issued shares after dilution effect of potential shares at end of period.

Average number of shares during the period. Average number of outstanding shares before dilution for the period.

Average number of shares during the period after dilution. Average number of issued shares after dilution effect of potential shares.

Project costs Refer to external costs that are directly attributable to the Group's costs regarding research and development of drug candidates.

Ratios that have not been calculated in accordance with IFRS

The company defines the below ratios as follows.

Equity ratio, % The period's closing equity divided by the period's closing balance sheet. The Company uses the alternate Equity ratio as it shows the proportion of total assets represented by shareholders' equity and has been included to allow investors to assess the Company's capital structure.

Cash flow from operations per share. Cash flow from operating activities divided by the average number of shares outstanding at the end of the period. The Company uses the alternate key figure Cash flow from operations per share because the Company believes that the key ratio gives investors a better understanding of the Company's cash flow in relation to its number of shares adjusted for changes in the number of shares outstanding during the period.

Equity per share. Equity divided by number of shares outstanding at the end of the period. Outstanding stock options and warrants are only considered if they are "in the money". The Company uses the alternate key ratio equity per share because the Company believes that the key ratio gives investors a better understanding of the historical return per share adjusted for changes in the number of shares outstanding during the period.

Number of employees (average). The average number of employees at the end of each period.

EGETIS THERAPEUTICS

		2023	2022	2022
		Jan-Sep	Jan-Sep	Jan-Dec
A	Equity, MSEK	466.9	582.6	506.2
B	Balance sheet total, MSEK	534.1	617.6	561.1
A/B	Equity ratio %	87%	94%	90%
A	Net result, MSEK	-240.5	-115.9	-193.8
B	Equity, MSEK	466.9	582.6	506.2
A/B	Return on equity, %	neg.	neg.	neg.
A	Cash flow from operating activities, MSEK	-236.7	-111.1	-173.5
B	Average number of shares under the period, before dilution, thousand	246,256	204,223	194,238
A/B	Cash flow from operating activities per shares, SEK	-1.0	-0.5	-0.9
A	Equity, MSEK	466.9	582.6	506.2
B	Average number of shares at the end of the period before dilution, thousand	246,256	204,223	194,238
A/B	Equity per average number of shares before dilution, SEK	1.9	2.9	2.6
A	Equity, MSEK	466.9	582.6	506.2
B	Average number of shares at the end of the period after dilution, thousand	249,595	204,223	194,238
A/B	Equity per average number of shares after dilution, SEK	1.9	2.9	2.6

Other information

Next reports

Full year results January 1- December 31: February 22, 2024

Interim report January 1- March 31: May 3, 2024

Annual General Meeting: May 6, 2024

This report, and further information is available on the website, www.egetis.com

This report has been reviewed by the Company's auditor. This is a translation of the Swedish interim report.

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This information is such information as Egetis Therapeutics AB (publ) is obliged to disclose in accordance with EU market abuse regulation and the Securities Markets Act. The information was submitted, through the above contact persons, for publication on November 8, 2023, at 7.00 am (CET).

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Redeye: Fredrik Thor

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Certification

This Interim report for January-September 2023 period provides a true and fair overview of the parent's and group's business activities, financial position, and results of operations, and describes significant risks and uncertainties to which the companies in the group are exposed.

Stockholm, November 8, 2023

Thomas Lönngren

Chairman of the board

Mats Blom

Board member

Gunilla Osswald

Board member

Elisabeth Svanberg

Board member

Peder Walberg

Board member

Behshad Sheldon

Board member

Nicklas Westerholm

CEO