EGETIS THERAPEUTICS

Interim report January-March 2023

Emcitate® project progressing with focus on applications for market approvals in the EU and USA in 2023

Financial overview January-March

- Quarterly net revenue MSEK 6,8 (7,1)
- Quarterly loss MSEK -74,9 (-28,8)
- Cash flow for the period MSEK 115,8 (-37,8)
- Cash balances at the end of the quarter amounted to MSEK 243,5 (106,8)
- Loss per share before/after dilution SEK -0.3 (-0.2)

Significant events during the period

- Received MSEK 196 (net) through an oversubscribed directed share issue
- In light of existing rumors in the market the Board of Directors of Egetis made the following statement: Egetis has ongoing discussions with certain external parties regarding a potential acquisition of the company. There can be no certainty that a public take-over offer will be made, nor as to the terms of any such offer
- Recruited Katayoun Welin-Berger as Vice President Operations, responsible for designing and managing the supply chains for development candidates and commercial products. Katayoun joined from Calliditas Therapeutics in March
- Continued to strengthen the commercial organization with two general managers (GM): In January Raymond Francot joined as GM for Germany, Austria, Switzerland, and Central and Eastern European Cluster, and Sylvain Forget joined as GM for France and Southern European Cluster (Portugal, Spain, Italy, and Greece)

Emcitate

- Received approvals for the pivotal ReTRIACt study from the Institutional Review Boards at Children's Hospital of Philadelphia, USA, and Erasmus Medical Center in Rotterdam, The Netherlands

Significant events after the period

- Based on regulatory feedback on the documentation for the ReTRIACt study, certain clinical trial documentation has been updated, which necessitates renewed approvals from the ethics committees at the three participating hospitals, and if necessary, regulatory authorities. This work has started and is expected to result in the first patient being treated in the second quarter. In parallel, we have commenced the work to identify possible study participants, and so far we have identified >30 patients at the various trial sites. Therefore, our overall assessment is that this administrative delay of the start of the study will not significantly affect the timing of the submission of a marketing application in the USA
- Egetis plans to submit an NDA in the USA in the fourth quarter of 2023 under the 'Fast Track Designation' granted by the FDA. A marketing application in Europe is expected, as previously communicated, to be submitted during Q2 2023 and is not dependent on the ReTRIACt study

Financial overview

	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Net revenues, MSEK	6,8	7,1	22,6
Result after tax, MSEK	-74,9	-28,8	-193,8
Cash flow, MSEK	115,8	-37,8	-19,5
Cash, MSEK	243,5	106,8	127,7
Equity ratio %	93%	93%	90%
Earnings per share, SEK	-0.3	-0.2	-1.0
Earnings per share after dilution, SEK	-0.3	-0.2	-1.0
Average number of employees	20	13	15

Comments from the CEO

The ongoing quarter is very exciting and transformative for Egetis. We are approaching our first application for market approval in Europe for our lead drug candidate *Emcitate*.

I am also very pleased with our Directed Share Issue in the beginning of 2023. The Directed Issue was oversubscribed and Egetis received SEK 196 million after transaction costs. New investors comprise institutional international and Swedish sector specialist investors, including AXA Investment Managers, Handelsbanken Fonder AB through the investment fund Hälsovård Tema, and Medical Strategy GmbH, as well as existing investors including The Fourth Swedish National Pension Fund (AP4), Linc AB and Unionen. The net proceeds from the Directed Issue will primarily finance continued build-up of the Company's commercial infrastructure in Europe and the US and pre-launch activities for the planned commercialization of *Emcitate* in 2024, as well as general corporate purposes and financial flexibility.

The *Emcitate* project is progressing with focus on applications for market approvals in the US and EU in 2023

We work intensively to submit a marketing authorization application for *Emcitate* to the EMA in the second quarter of 2023, based on existing clinical data, after sufficient stability data has been obtained for the commercial product of *Emcitate*.

As previously communicated, Egetis will conduct a confirmatory randomized placebo-controlled trial in 16 patients to verify the results of previous clinical trials and publications regarding thyroid hormone T3 levels.

Based on regulatory feedback on the documentation for the ReTRIACt study, certain clinical trial documentation has been updated, which necessitates renewed approvals from the ethics committees at the three participating hospitals, and if necessary, regulatory authorities. This work has started and is expected to result in the first patient being treated in the second quarter. In parallel, we have commenced the work to identify possible study participants, and so far we have identified >30 patients at the various trial sites. Therefore, our overall assessment is that this administrative delay of the start of the study will not significantly affect the timing of the submission of a marketing application in the USA. Egetis plans to submit an NDA in the USA in the fourth quarter of 2023 under the 'Fast Track Designation' granted by the FDA. The design of the study is available on clinicaltrials.gov under the code NCT05579327.

As previously communicated, a marketing application in Europe is expected to be submitted during Q2 2023 and is not dependent on the ReTRIACt study.

Implementation ongoing for the Expanded Access Program for *Emcitate* in the USA

There is continued large and increasing interest from physicians all over the world to treat patients suffering from MCT8-deficiency with *Emcitate*, which is already prescribed on an individual license to patients in over 25 countries. In total, around 180 patients are now being treated with *Emcitate*, and we see more and more patients gaining access to treatment. This underlines the great medical need for a treatment for these patients.

On the request of the FDA Egetis submitted in the fourth quarter of 2022 an 'Expanded Access Program' in the USA, which is now being 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 will also be important for those patients finishing the ReTRIACt trial, enabling them to continue *Emcitate* treatment after the trial has ended.

Egetis continues the step-wise build-up of an organization in the US and Europe for the commercialization of *Emcitate* in 2024

The commercial organization was strengthened during the first quarter with three General Managers (GMs). In January Raymond Francot joined as GM for Germany, Austria, Switzerland and Central and Eastern European Cluster, and Sylvain Forget joined as GM for France and Southern European Cluster (Portugal, Spain, Italy and Greece). In April Nigel Nicholls joined as GM for the UK and Northern European Cluster (Ireland, Nordics and Baltics).

These key recruitments bring substantial experience and proven track records in successful launch preparations and commercialization of drugs in ultra-orphan diseases, including products such as Spinraza®, Brineura® and Tecfidera®, as well as experience from several successful rare-disease companies, such as BioMarin, Global Blood Therapeutics, SOBI and Vertex.

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

During the first quarter of 2023 Egetis participated at three 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. To increase awareness of the disease a new patient video has been created, which can be accessed here (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 and are planned to be submitted to regulatory authorities after market approvals have been obtained. The design of the Triac Trial II study is available on clinicaltrials.gov under the code NCT02396459.

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

There is a significant medical need for the approximately 25% of patients who reach hospital more than eight hours after paracetamol overdose. These patients have an increased risk of acute liver failure and need additional treatment options beyond the currently available N-acetylcysteine (NAC).

The design of the pivotal Phase IIb/III study, which is called Albatross, has been agreed with the FDA, EMA and MHRA. The start of the study is planned during 2023.

Cash position

During the period we raised net proceeds of SEK 196 million, after issuance costs, in a directed share issue. We reported a cash position of approximately SEK 244 million as of March 31, 2023.

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. With the recently strengthened balance sheet we can now continue to be focused on developing our drug candidates *Emcitate* and *Aladote* for all the patients who have a great need for these therapies I look forward to informing you about the future development of Egetis during this transformative year for the Company.

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. As a result of regulatory interaction Egetis intends to submit a marketing authorisation application (MAA) for *Emcitate* to the European Medicines Agency (EMA) during the second quarter of 2023 based on existing clinical data.

After a dialogue with the FDA, Egetis will conduct a small randomized, placebo-controlled study in 16 patients to verify the results on T3 levels seen in previous clinical trials and publications. Egetis intends to submit a new drug application (NDA) in the US for *Emcitate* in the fourth quarter of 2023 under the Fast-Track Designation granted by FDA.

Emcitate is currently being investigated in the Triac Trial II, a Phase II/III study in very young MCT8 deficiency patients (<30 months of age) exploring potential disease modifying effects of early intervention from a neurocognitive and neurodevelopmental perspective. The recruitment target was achieved in the second quarter 2022 and 22 patients have been included in the study. Results are expected in mid 2024 and are expected to be submitted post-approval to regulatory authorities shortly thereafter.

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 after completed interactions with FDA, EMA and MHRA and study start is planned during 2023. 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

- Received approvals for the pivotal ReTRIACt study from the Institutional Review Boards at Children's Hospital of Philadelphia, USA and Erasmus Medical Center in Rotterdam, The Netherlands

Events after the reporting period

- Based on regulatory feedback on the documentation for the ReTRIACt study, certain clinical trial documentation has been updated, which necessitates renewed approvals from the ethics committees at the three participating hospitals, and if necessary, regulatory authorities. This work has started and is expected to result in the first patient being treated in the second quarter. In parallel, we have commenced the work to identify possible study participants, and so far we have identified >30 patients at the various trial sites. Therefore, our overall assessment is that this administrative delay of the start of the study will not significantly affect the timing of the submission of a marketing application in the USA
- Egetis plans to submit an NDA in the USA in the fourth quarter of 2023 under the 'Fast Track Designation' granted by the FDA. A marketing application in Europe is expected, as previously communicated, to be submitted during Q2 2023 and is not dependent on the ReTRIACt study

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, 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 with the published data from long-term treatment, will suffice for a regulatory submission of a Marketing Authorisation Application (MAA) to the EMA for the treatment of MCT8 deficiency. Egetis plans to submit the MAA in the second quarter of 2023.

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 has agreed with the FDA to perform 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. The primary source of patients will be through our existing named patient program. Egetis is targeting an US NDA submission for *Emcitate* in the fourth quarter of 2023 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 now included in the study. Results from the Triac Trial II are expected in mid 2024 and are expected to be submitted post-approval to regulatory authorities.

Emcitate is already supplied to around 180 patients on a named patient or compassionate use basis, following individual regulatory approvals from national regulatory agencies in over 25 countries. Compassionate use and named patient programs are mechanisms to 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.

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, is expected to start in 2023 and is 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. The total planned number of patients is around 250, who will be enrolled in the US, UK and in at least one EU country. The study consists of two parts with an interim analysis which includes a futility analysis and dose selection where the most effective dose will be continued. Applications for market approval in the US, EU and UK are planned after successful completion of the study.

Financial Information

Interim report January – March 2023

Revenues and results

Revenues

Revenues amounted to MSEK 6,8 (7,1) for the period. The revenues consisted of "*Named Patient Use*" Emcitate sales of MSEK 6,8 (6,6) during the period. Revenues in the comparative period previous year included forwarding of expenses related to PledOx to Solasia Pharma K.K. (Solasia) with an amount of MSEK 0,5.

Expenses

Operating expenses amounted to MSEK -81,7 (-36,5) during the period. The project expenses amounted to MSEK -47,9 (-19,7) during the period. The project expenses consisted mainly of expenses due to Emcitate of MSEK -47,2 (-17,1) and Aladote MSEK -0,8 (-1,9), for the period.

Employee costs amounted to MSEK -15,4 (-8,5) during the period. The cost increase is due to the increase of number of employees ahead of the anticipated commercial launch of Emcitate. The costs also include participants' earnings in the employee stock option plans of MSEK -2,5 (-1,0) for the period.

Other external costs amounted to MSEK -14,9 (-5,4) for the period. The increase is mainly due to higher consultancy costs related to the Emcitate project. Depreciation amounted to MSEK -0,9 (-0,7) for the period. The depreciation during the period derives from amortization of licences with MSEK -0,3 (-0,3), depreciation of right-of-use assets with MSEK -0,6 (-0,4) and depreciation of inventories with MSEK -0,0 (-0,0). Other operating expenses amounted to MSEK -0,4 (-0,3) for the period and consists of exchange rate differences from operating income and operating expenses.

Results

Operating results amounted to MSEK -74,9 (-29,4) for the period. Net financial items amounted to MSEK 0,0 (0,6) for the period. Results from net financial items are related to unrealized revaluation of company's FX-accounts. Results after financial items amounted to MSEK -74,9 (-28,8) for the period. Results per share before and after dilution amounted to SEK -0.3 (-0.2) for the period both before and after dilution.

Financial position

Cash

Cash as of March 31, 2023, amounted to MSEK 243,5 (106,8).

Cash flow

Cash flow from operating activities amounted to MSEK -79,5 (-33,2) for the period. Total Cash flow amounted to MSEK 115,8 (-37,8) for the period. Cash flow from operating activities is driven by costs related to the clinical studies and the preparations ahead of the anticipated commercial launch of Emcitate.

Cash flow from investment activities amounted to MSEK -0,0 (-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 (RTT). Cash flow from financing activities amounted to MSEK 195,3 (-2,9) for the period and derives mainly from the directed rights issue, of 35,000,000 shares at SEK 6.00, that was completed during January 2023. The figures in the comparative period previous year included re-payment of loans related to the acquisition of RTT.

Equity and equity ratio

As of March 31, 2023, equity amounted to MSEK 628,7 (499,1). Shareholders' equity per share amounted to SEK 2.6 (2.8), at the end of the period. The company's equity ratio was 93 (93) %.

Debts and receivables

As of March 31, 2023, non-current liabilities amounted to MSEK 9,3 (2,8). These consist mainly of liabilities

that derive from right of use liabilities according to IFRS 16 of MSEK 3,8 (2,3) and provisions for social security contributions relating to stock option plans of MSEK 5,5 (0,5). Current liabilities amount to MSEK 38,1 (33,0) of which other liabilities and accrued expenses amount to MSEK 30,9 (27,3) and accounts payable amount to MSEK 7,2 (5,7).

Investments in tangible and intangible assets

As of March 31, 2023, non-current intangible assets amounted to MSEK 416,0 (414,7). No significant investments were allocated to tangible assets.

Shares

The number of shares as of March 31, 2023, were 249,589,128. The number of shares has increased with 35,000,00 shares as a result of a directed new share issue during January. The number of shareholders were 7,533 as of March 31, 2023. The 10 largest shareholders hold 61.4 % 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 March 31, 2023, were 20 (13) persons, 13 women and 7 men (7 women and 6 men).

Parent company

The parent company's revenues for the period amounted to MSEK 0,0 (0,5). Revenues in the prior period were due to forwarding of expenses related to PledOx to Solasia. Other income for the period amounted to MSEK 19,5 (6,6). Other income for the period of MSEK 8,7 (5,2) consisted of management fees invoiced to the subsidiaries RTT and Egetis US Inc., MSEK 10,7 (1,3) are forwarding of expenses to RTT and MSEK 0,1 (0,1) exchange rate gains.

Operating expenses amounted to MSEK -35,9 (-18,0) for the period. The project expenses amounted to MSEK -11,3 (-3,9) for the period.

The parent company's results amounted to MSEK -36,3 (-10,2) for the period.

Financial non-current assets amount to MSEK 434,0 (433,4) and long-term liabilities amount to MSEK 5,5 (0,5).

Consolidated statement of comprehensive income

MSEK	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Revenue			
Revenues	6,8	7,1	22,6
Other operating income	0,0	0,0	0,0
	6,8	**7,1**	**22,6**
Operating expenses			
Costs of sales of goods	-2,3	-2,0	-6,3
Project costs	-47,9	-19,7	-136,3
Other external costs	-14,9	-5,4	-22,3
Employee costs	-15,4	-8,5	-52,0
Depreciation and impairment	-0,9	-0,7	-2,7
Other operating expenses	-0,4	-0,3	-1,1
Sum operating expenses	**-81,7**	**-36,5**	**-220,6**
Operating results	**-74,9**	**-29,4**	**-198,1**
Financial items			
Interest income and similar items	0,3	0,6	5,0
Interest expense and similar items	-0,3	0,0	-0,7
Sum financial items	**0,0**	**0,6**	**4,3**
Results after financial net	**-74,9**	**-28,8**	**-193,8**
Tax	-	-	-
Results after tax	**-74,9**	**-28,8**	**-193,8**
Statement of comprehensive income			
Other comprehensive income	0,0	-	0,0
Comprehensive income for the period	**-74,9**	**-28,8**	**-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	179 906 457	214 589 128
Average number of shares during period, before dilution	239 478 017	179 906 457	194 238 210
Average number of shares during period, after dilution	243 674 783	179 906 457	194 238 210
Earnings per share before dilution (SEK)	-0.3	-0.2	-1.0
Earnings per share after dilution (SEK)	-0.3	-0.2	-1.0
Equity per average number of shares	2.6	2.8	2.6
Equity per average number of shares after dilution	2.6	2.8	2.6

*) The comparative figures in the table have been adjusted for the share issue in May 2022.

Consolidated statement of financial position

MSEK	31/03/2023	31/03/2022	31/12/2022
ASSETS			
Non-current assets			
Research and development costs	404,8	404,8	404,8
Licences	5,1	6,2	5,4
Right-of-use assets	6,0	3,7	2,6
Equipment	0,1	0,2	0,1
Financial non-current assets	0,8	0,8	0,8
Total non-current assets	**417,0**	**415,7**	**413,7**
Current assets			
Inventories	0,4	0,4	0,6
Accounts receivables	4,1	4,0	3,8
Other receivables	5,5	2,1	6,4
Prepaid expenses and accrued income	5,6	5,8	8,9
Cash and bank balance	243,5	106,8	127,7
Total current assets	**259,1**	**119,1**	**147,4**
Total assets	**676,1**	**534,8**	**561,1**

MSEK	31/03/2023	31/03/2022	31/12/2022
Equity			
Share capital	13,1	8,7	11,3
Other capital contributions	1 622,6	1 262,8	1 428,4
Reserves	7,5	2,1	6,1
Accumulated loss including net loss	-1 014,5	-774,6	-939,6
Total equity	**628,7**	**499,1**	**506,2**
Non-current liabilities			
Other non-current liabilities	3,8	2,3	1,1
Provisions	5,5	0,5	4,4
Total non-current liabilities	**9,3**	**2,8**	**5,5**
Current liabilities			
Accounts payable	7,2	5,7	20,0
Other liabilities	6,6	11,9	5,7
Accrued expenses and deferred income	24,3	15,4	23,7
Total current liabilities	**38,1**	**33,0**	**49,4**
Total equity and liabilities	**676,1**	**534,8**	**561,1**

Consolidated statement of cash flows

MSEK	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
OPERATING ACTIVITIES			
Result after financial net	-74,9	-28,8	-193,8
Adjustments for non-cash items	3,7	1,1	9,4
Tax paid	-	-	-
Cash flow from operating activities before changes in working capital	**-71,3**	**-27,7**	**-184,4**
Cash flow from changes in working capital			
Increase/decrease in operating receivables	4,0	-3,4	-10,7
Increase/decrease in operating liabilities	-12,2	-2,0	21,6
Cash flow from changes in working capital	**-8,2**	**-5,4**	**10,9**
Cash flow from operating activities	**-79,5**	**-33,2**	**-173,5**
INVESTING ACTIVITIES			
Acquisition of subsidiaries, net cash required	-	-1,7	-1,7
Investment in financial assets	-	-	0,0
Purchase of property, plant and equipment	0,0	-	-
Cash flow from investing activities	**0,0**	**-1,7**	**-1,7**
FINANCING ACTIVITIES			
New share issue	210,0	-	177,4
Cost new share issue	-14,0	-	-12,6
Repayment of loans	-	-2,5	-7,5
Repayment of leases	-0,6	-0,4	-1,6
Cash flow from financing activities	**195,3**	**-2,9**	**155,7**
Cash flow for the period	**115,8**	**-37,8**	**-19,5**
Balance at beginning of period	127,7	144,0	144,0
Change in cash	115,8	-37,8	-19,5
Exchange rate difference in cash	-0,1	0,6	3,2
CASH BALANCE AT THE END OF THE PERIOD	**243,5**	**106,8**	**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	-	-	-74,9	-	-74,9
Transactions with shareholders					
Costs due to share-based payments of employee stock option plan	-	-	-	1,4	1,4
Closing balance 31/03/2023	**13,1**	**1 622,6**	**-1 014,5**	**7,5**	**628,7**
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
Transactions with shareholders					
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-Mar	2022 Jan-Mar	2022 Jan-Dec
Equity	628,7	499,1	506,2
Equity ratio %	93%	93%	90%
Number of shares at the end of the period**	249 589 128	179 906 457	214 589 128
Average number of shares during the period**	239 478 017	179 906 457	194 238 210
Average number of shares during the period after dilution**	243 674 783	179 906 457	194 238 210
Share Data			
Earnings per share**	-0.3	-0.2	-1.0
Earnings per share after dilution**	-0.3	-0.2	-1.0
Cash flow from operating activities**	-0.3	-0.2	-0.9
Equity per average number of shares**	2.6	2.8	2.6
Equity per average number of shares after dilution**	2.6	2.8	2.6
Dividend	-	-	-
Average number of employees	20	13	15

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

**The comparative figures in the table have been adjusted for the share issue in May 2022.

Parent company - income statement

MSEK	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Revenue			
Revenues	0,0	0,5	0,6
Other operating income	19,5	6,6	53,6
	19,5	**7,1**	**54,2**
Operating expenses			
Project costs	-11,3	-3,9	-42,4
Other external costs	-9,0	-5,5	-22,4
Employee costs	-15,4	-8,5	-52,0
Depreciation and impairment	0,0	0,0	-0,1
Other operating expenses	-0,2	0,0	-0,6
Sum operating expenses	**-35,9**	**-18,0**	**-117,4**
Operating results	**-16,4**	**-10,9**	**-63,2**
Financial items			
Interest income and similar items	0,3	0,6	3,7
Interest expense and similar items	-0,2	0,0	0,0
Sum financial items	**0,0**	**0,6**	**3,7**
Results after financial net	**-16,3**	**-10,2**	**-59,5**
Group contributions	-20,0	-	-135,0
Tax	-	-	-
Results after tax	**-36,3**	**-10,2**	**-194,5**

Parent company - balance sheet

MSEK	31/03/2023	31/03/2022	31/12/2022
ASSETS			
Non-current assets			
Equipment	0,1	0,1	0,1
Financial non-current assets	434,0	433,4	433,8
Total non-current assets	**434,1**	**433,5**	**433,9**
Current assets			
Receivables from Group companies	6,0	-	0,1
Accounts receivables	-	0,0	-
Other receivables	0,0	0,0	0,6
Prepaid expenses and accrued income	3,1	1,4	3,8
Cash and bank balance	235,8	89,5	120,0
Total current assets	**244,9**	**91,0**	**124,4**
Total assets	**679,0**	**524,5**	**558,3**

MSEK	31/03/2023	31/03/2022	31/12/2022
Equity			
Restricted Equity			
Share capital	13,1	8,7	11,3
Non-restricted equity			
Share premium reserve	673,5	508,3	673,8
Reserves	7,5	2,1	6,1
Net loss for the period	-36,3	-10,2	-194,5
Total equity	**657,7**	**508,8**	**496,7**
Non-current liabilities			
Provisions	5,5	0,5	4,4
Total non-current liabilities	**5,5**	**0,5**	**4,4**
Current liabilities			
Liabilities to group company	-	1,8	33,1
Accounts payable	4,9	2,0	7,8
Other liabilities	4,1	5,2	3,9
Accrued expenses and deferred income	6,9	6,0	12,4
Total current liabilities	**15,8**	**15,1**	**57,2**
Total equity and liabilities	**679,0**	**524,5**	**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. 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 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 10. 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. Revenue for Emcitate is attributable to the "*Named Patient Use*" use of the drug candidate.

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

2023 Jan-Mar MSEK	**Emcitate**	**Aladote**	**Common***	**Sum**
Revenues	6,8	-	-	**6,8**
Costs of sales of goods	-2,3	-	-	**-2,3**
Project costs	-47,2	-0,8	-	**-47,9**
Other	-	-	-31,5	**-31,5**
Operating results	**-42,6**	**-0,8**	**-31,5**	**-74,9**
Net financial items				**0,0**
Pretax profit				**-74,9**

2022 Jan-Mar MSEK	**Emcitate**	**Aladote**	**Common***	**Sum**
Revenues	6,6	-	0,5	**7,1**
Costs of sales of goods	-2,0	-	-	**-2,0**
Project costs	-17,1	-1,9	-0,8	**-19,7**
Other	-	-	-14,8	**-14,8**
Operating results	**-12,5**	**-1,9**	**-15,1**	**-29,4**
Net financial items				**0,6**
Pretax profit				**-28,8**

2022 Jan-Dec MSEK	**Emcitate**	**Aladote**	**Common***	**Sum**
Revenues	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**

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

Turnover by type of revenue

MSEK	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Re-invoicing of costs to Solasia	0,0	0,5	0,6
Sales of goods	6,8	6,6	21,9
Total	**6,8**	**7,1**	**22,6**

Note 4 – Contingent liabilities

Egetis has a contractual obligation, on future net sales from Emcitate, 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 0,5 (0,3) during the period.

Note 6 – Employee Stock Option Plan

During the first quarter 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 March 31, 2023, the company has three ESOPs outstanding. Full utilization of the granted stock options would increase the number of shares in the company by 15,417,160. The total number of granted stock options is unchanged during the period.

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.

		2023 Jan-Mar	2022* Jan-Mar	2022 Jan-Dec
A	Equity, MSEK	628,7	499,1	506,2
B	Balance sheet total, MSEK	676,1	534,8	561,1
A/B	**Equity ratio %**	**93%**	**93%**	**90%**
A	Net result, MSEK	-74,9	-28,8	-193,8
B	Equity, MSEK	628,7	499,1	506,2
A/B	**Return on equity, %**	**neg.**	**neg.**	**neg.**
A	Cash flow from operating activities, MSEK	-79,5	-33,2	-173,5
B	Average number of shares under the period, before dilution, thousand	239 478	179 906	194 238
A/B	**Cash flow from operating activities per shares, SEK**	**-0.3**	**-0.2**	**-0.9**
A	Equity, MSEK	628,7	499,1	506,2
B	Average number of shares at the end of the period before dilution, thousand	239 478	179 906	194 238
A/B	**Equity per average number of shares before dilution, SEK**	**2.6**	**2.8**	**2.6**
A	Equity, MSEK	628,7	499,1	506,2
B	Average number of shares at the end of the period after dilution, thousand	243 675	179 906	194 238
A/B	**Equity per average number of shares after dilution, SEK**	**2.6**	**2.8**	**2.6**

*) The comparative figures in the table have been adjusted for the share issue in May 2022.

Other information

Next reports

Annual General Meeting: April 27, 2023.
Half-year report January 1- June 30: August 22, 2023.
Interim report January 1- September 30: November 8, 2023.

This report, and further information is available on the website, www.egetis.com
This report has not 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 April 26, 2023, at 7.00 am (CEST).

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Pareto Securities: Dan Akschuti
Redeye: Fredrik Thor
Rx Securities: Joseph Hedden

Certification

This Interim report for the January-March 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, April 26, 2023

Thomas Lönngren	Mats Blom
Chairman of the board	Board member
Gunilla Osswald	Elisabeth Svanberg
Board member	Board member
Peder Walberg	Nicklas Westerholm
Board member	CEO