EGETIS THERAPEUTICS

Half-Year report January-June 2023

Egetis recruits first patients in the pivotal ReTRIACt trial for the US NDA for *Emcitate*

- **Egetis on track to submit Emcitate marketing authorisation application in EU on the by EMA predetermined date of October 9, 2023**

Financial overview April-June

- Quarterly Revenue MSEK 5.9 (4.7)
- Quarterly loss MSEK -79.5 (-33.2)
- Cash balances at the end of the quarter amounted to MSEK 179.2 (233.2)
- Cash flow for the quarter was MSEK -64.8 (124.3)
- Earnings per share before/after dilution SEK -0.3 (-0.2)

Financial overview January-June

- Revenue for the period MSEK 12.7 (11.8)
- Net loss for the period MSEK -154.4 (-62.1)
- Cash balances at the end of the period amounted to MSEK 179.2 (233.2)
- Cash flow for the period MSEK 51.0 (86.5)
- Earnings per share before/after dilution SEK -0.6 (-0.3)

Significant events during April-June

- Announced termination of discussions regarding a potential acquisition of the Company
- Board directors in Egetis acquired shares

Emcitate®

Announced site activation in the pivotal ReTRIACt trial for *Emcitate* and updated timeline for the US NDA submission

Significant events after the period

Emcitate®

- Announced first patient included and second site activated in the ReTRIACt trial, which is pivotal for the US NDA submission

Aladote®

- Announced that in-house development of *Aladote* will be parked, until *Emcitate* submissions have been completed

Financial overview

	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Net revenue, MSEK	5.9	4.7	12.7	11.8	22.6
Result after tax, MSEK	-79.5	-33.2	-154.4	-62.1	-193.8
Cash flow, MSEK	-64.8	124.3	51.0	86.5	-19.5
Cash, MSEK	179.2	233.2	179.2	233.2	127.7
Equity ratio, %	90%	96%	90%	96%	90%
Earnings per share, SEK	-0.3	-0.2	-0.6	-0.3	-1.0
Earnings per share after dilution, SEK	-0.3	-0.2	-0.6	-0.3	-1.0
Average number of employees	26	13	23	13	15

Comments from the CEO

I am delighted that the first patients have been included and that we now have two active sites in the ReTRIACt trial for *Emcitate*, which is pivotal for the New Drug Application (NDA) in the USA. I am also pleased that we are nearing our first marketing application for *Emcitate* in the EU, which is based on existing clinical data. These are important and transformative milestones for the Company.

The *Emcitate* project is progressing with focus on applications for market approvals in the EU in 2023 and the US in 2024

We are on track to submit a marketing authorisation application (MAA) for *Emcitate* to the EMA on October 9, 2023, based on existing clinical data.

As previously communicated, for the US NDA Egetis is conducting a confirmatory pivotal randomized placebo-controlled trial in 16 patients to verify the results of previous clinical trials and publications regarding thyroid hormone T3 levels.

We currently have two active sites in this pivotal ReTRIACt study for the NDA in the USA for *Emcitate* and the first patients have been recruited. The Company expects topline results from the ReTRIACt study during the first half of 2024 and estimates subsequent NDA submission in the USA in mid-2024, under the fast-track designation. The updated timelines announced in June are due to the substantial delay in the study start, and an anticipated higher number of treatment naïve patients, which implies a longer trial duration per patient, expected to be recruited in the trial compared to the original assumptions. In addition, there is lower-than-expected recruitment capacities per month at the participating sites.

The Company is working diligently with the ReTRIACt study sites to facilitate a smooth and efficient execution of the trial and more than 30 eligible patients have been identified across the three participating sites.

The design of the study is available on clinicaltrials.gov under the code NCT05579327.

Egetis aligns the build-up of a commercial organization in the US with the updated NDA submission timelines for *Emcitate*

As a consequence of the delay with the expected submission of *Emcitate* in the US, the build-up of the commercial infrastructure in the US will be aligned with the updated NDA submission timelines and all resources will be focused on the Emcitate ReTRIACt study and the upcoming EU submission.

Implementation of 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, over 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 is also important for those patients finishing the ReTRIACt trial, enabling them to continue *Emcitate* treatment after the trial has ended.

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

During the second quarter of 2023 Egetis participated at six 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 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 now planned after completion of the Emcitate regulatory submissions in EU and the US.

Cash position

In January 2023 we raised net proceeds of SEK 196 million, after issuance costs, in a directed share issue. We reported a cash position of approximately SEK 179 million as of June 30, 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.

Our efforts are now focussed on the efficient execution of the pivotal ReTRIACt study, needed for the US NDA, and on the submission of the marketing application in the EU. 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) on October 9, 2023, based on existing clinical data.

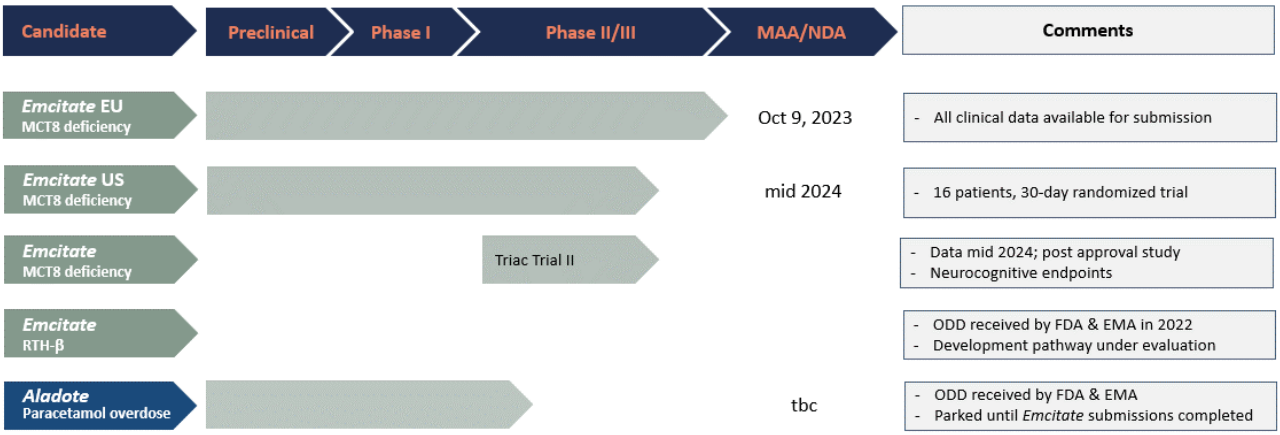
After a dialogue with the FDA, Egetis is conducting a small randomized, placebo-controlled pivotal study in 16 patients to verify the results on T3 levels seen in previous clinical trials and publications. Egetis intends to submit a new drug application (NDA) in the US for *Emcitate* in mid 2024 under 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 after completed interactions with FDA, EMA and MHRA and 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 site activation in the pivotal ReTRIACt trial for *Emcitate* and updated timeline for the US NDA submission

Events after the reporting period

- Announced first patient included and second site activated in the ReTRIACt trial, which is pivotal for the US NDA submission

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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 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 on October 9, 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. Egetis is targeting an US NDA 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 over 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.

Aladote

Events after the reporting period

- Announced that in-house development of *Aladote* will be parked, until *Emcitate* submissions have been completed

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. 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.

Financial Information

Half-Year report January – June 2023

Revenue and results

Revenue

Revenue amounted to MSEK 5,9 (4,7) during the quarter and MSEK 12,7 (11,8) for the period. The Revenue consisted of "*Named Patient Use*" Emcitate sales of MSEK 5,9 (4,7) during the quarter and MSEK 12,7 (11,2) during the period. 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 0,5.

Expenses

Operating expenses amounted to MSEK -86,2 (-40,0) during the quarter and MSEK -167,9 (-76,2) during the period. The project expenses amounted to MSEK -41,5 (-22,6) during the quarter and MSEK -89,4 (-42,3) during the period. The project expenses consisted of expenses due to Emcitate of MSEK -41,0 (-22,4) and Aladote of MSEK -0,6 (-0,1), during the quarter and MSEK -88,1 (-39,5) for Emcitate and MSEK -1,3 (-2,0) for Aladote during the period.

Employee costs amounted to MSEK -15,8 (-10,2) during the quarter and MSEK -31,2 (-18,7) 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 1,4 (-1,1) for the quarter and MSEK -1,1 (-2,1) for the period. Costs for the employee stock option plans will continue to vary with the share price development and do not impact cash flow.

Other external costs amounted to MSEK -25,5 (-5,0) during the quarter and MSEK -40,4 (-10,3) 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 upcoming submissions with major healthcare agencies around the world. Depreciation amounted to MSEK -0,9 (-0,7) for the quarter and MSEK -1,8 (-1,3) during the period. The depreciation during the period derives from amortization of licences with MSEK -0,5 (-0,5), depreciation of right-of-use assets with MSEK -1,2 (-0,8) and depreciation of inventories with MSEK -0,1 (-0,0). Other operating expenses amounted to MSEK -1,1 (-) for the quarter and MSEK -1,5 (-) for the period and consists of exchange rate differences from operating income and operating expenses.

Results

Operating results amounted to MSEK -80,3 (-35,0) for the quarter and MSEK -155,2 (-64,4) for the period. Net financial items amounted to MSEK 0,8 (1,7) for the quarter and MSEK 0,8 (2,3) 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 -79,5 (-33,2) for the quarter and MSEK -154,4 (-62,1) for the period. Results per share before and after dilution amounted to SEK -0.3 (-0.2) for the quarter and SEK -0.6 (-0.3) for the period both before and after dilution.

Financial position

Cash

Cash as of June 30, 2023, amounted to MSEK 179,2 (233,2).

Cash flow

Cash flow from operating activities amounted to MSEK -64,2 (-35,3) for the quarter and -143,6 (-68,4) for the period. Total Cash flow amounted to MSEK -64,8 (124,3) for the quarter and MSEK 51,0 (86,5) 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 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 AB (RTTI AB). Cash flow from financing activities amounted to MSEK -0,6 (159,5) for the quarter and MSEK 194,7 (156,6) 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 June 30, 2023, equity amounted to MSEK 550,9 (635,0). Shareholders' equity per average number of shares amounted to SEK 2.3 (3.4), at the end of the period. The company's equity ratio was 90 (96) %.

Debts and receivables

As of June 30, 2023, non-current liabilities amounted to MSEK 5,8 (2,6). These consist mainly of liabilities that derive from right of use liabilities according to IFRS 16 of MSEK 3,3 (1,9) and provisions for social security contributions relating to stock option plans of MSEK 2,5 (0,7). Current liabilities amount to MSEK 52,1 (23,6) of which other liabilities and accrued expenses amount to MSEK 30,9 (18,7) and accounts payable amount to MSEK 21,2 (4,9).

Investments in tangible and intangible assets

As of June 30, 2023, non-current intangible assets amounted to MSEK 415,1 (414,1). No significant investments were allocated to tangible assets during the period.

Shares

The number of shares as of June 30, 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 7,488 as of June 30, 2023. The 10 largest shareholders hold 62.0 % 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 June 30, 2023, were 28 (15) persons, 17 women and 11 men (8 women and 7 men).

Parent company

The parent company's Revenue for the quarter amounted to MSEK - (-) and MSEK - (0,5) 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 22,8 (10,1) and MSEK 42,3 (16,6) for the period. Other income for the period consisted of MSEK 19,9 (12,3) management fees invoiced to the subsidiaries RTTI AB and Egetis US Inc., MSEK 22,3 (4,3) for forwarding of expenses to RTTI AB and MSEK 0,1 (0,1) as exchange rate gains.

Operating expenses amounted to MSEK -15,7 (-21,0) for the quarter and MSEK -32,0 (-39,0) for the period. The project expenses amounted to MSEK -12,3 (-5,6) for the quarter and MSEK -23,6 (-9,5) during the period.

The parent company's results amounted to MSEK -94,8 (-34,2) for the quarter and MSEK -131,1 (-44,4) for the period.

Financial non-current assets amount to MSEK 434,1 (433,5) and other long-term liabilities amount to MSEK 2,5 (0,7).

Consolidated statement of income

MSEK	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Revenue					
Revenue	5.9	4.7	12.7	11.8	22.6
Other operating income	0.0	0.4	0.0	0.1	-
	5.9	**5.0**	**12.7**	**11.8**	**22.6**
Operating expenses					
Costs of sales of goods	-1.3	-1.5	-3.6	-3.5	-6.3
Project costs	-41.5	-22.6	-89.4	-42.3	-136.3
Other external costs	-25.5	-5.0	-40.4	-10.3	-22.3
Employee costs	-15.8	-10.2	-31.2	-18.7	-52.0
Depreciation and impairment	-0.9	-0.7	-1.8	-1.3	-2.7
Other operating expenses	-1.1	-	-1.5	-	-1.1
Sum operating expenses	**-86.2**	**-40.0**	**-167.9**	**-76.2**	**-220.6**
Operating results	**-80.3**	**-35.0**	**-155.2**	**-64.4**	**-198.1**
Financial items					
Interest income and similar items	0.8	1.8	0.9	2.4	5.0
Interest expense and similar items	-0.0	-0.0	-0.1	-0.1	-0.7
Sum financial items	**0.8**	**1.7**	**0.8**	**2.3**	**4.3**
Results after financial net	**-79.5**	**-33.2**	**-154.4**	**-62.1**	**-193.8**
Tax	-	-	-	-	-
Net loss for the period	**-79.5**	**-33.2**	**-154.4**	**-62.1**	**-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	198,292,502	244,561,504	189,099,479	194,238,210
Average number of shares during period, after dilution	255,537,608	198,292,502	249,612,356	189,099,479	194,238,210
Earnings per share before dilution (SEK)	-0.3	-0.2	-0.6	-0.3	-1.0
Earnings per share after dilution (SEK)	-0.3	-0.2	-0.6	-0.3	-1.0
Equity per average number of shares	2.2	3.2	2.3	3.4	2.6
Equity per average number of shares after dilution	2.2	3.2	2.3	3.4	2.6

Statement of comprehensive income

MSEK	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Net loss for the period	**-79.5**	**-33.2**	**-154.4**	**-62.1**	**-193.8**
Translation exchange rate differences	0.2	-	0.2	-	0.0
Comprehensive income for the period	**-79.3**	**-33.2**	**-154.2**	**-62.1**	**-193.8**

Consolidated statement of financial position

MSEK	30/06/2023	30/06/2022	31/12/2022
ASSETS			
Non-current assets			
Research and development costs	404.8	404.8	404.8
Licences	4.9	5.9	5.4
Right-of-use assets	5.4	3.3	2.6
Equipment	0.1	0.1	0.1
Financial non-current assets	0.8	0.8	0.8
Total non-current assets	**416.0**	**415.0**	**413.7**
Current assets			
Inventories	0.1	0.2	0.6
Accounts receivables	4.2	4.2	3.8
Other receivables	6.6	3.3	6.4
Prepaid expenses and accrued income	2.6	5.1	8.9
Cash and bank balance	179.2	233.2	127.7
Total current assets	**192.7**	**246.1**	**147.4**
Total assets	**608.8**	**661.1**	**561.1**

MSEK	30/06/2023	30/06/2022	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	9.1	3.1	6.1
Accumulated loss including net loss	-1,093.9	-807.9	-939.6
Total equity	**550.9**	**635.0**	**506.2**
Non-current liabilities			
Other non-current liabilities	3.3	1.9	1.1
Provisions	2.5	0.7	4.4
Total non-current liabilities	**5.8**	**2.6**	**5.5**
Current liabilities			
Accounts payable	21.2	4.9	20.0
Other liabilities	8.1	4.3	5.7
Accrued expenses and deferred income	22.8	14.4	23.7
Total current liabilities	**52.1**	**23.6**	**49.4**
Total equity and liabilities	**608.8**	**661.1**	**561.1**

Consolidated statement of cash flows

MSEK	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-79.5	-33.2	-154.4	-62.1	-193.8
Adjustments for non-cash items	-0.3	0.3	3.3	1.4	9.4
Tax paid	-	-	-	-	-
Cash flow from operating activities before changes in working capital	**-79.8**	**-32.9**	**-151.1**	**-60.6**	**-184.4**
Cash flow from changes in working capital					
Increase/decrease in operating receivables	2.1	-0.5	6.1	-3.9	-10.7
Increase/decrease in operating liabilities	13.6	-1.8	1.3	-3.9	21.6
Cash flow from changes in working capital	**15.6**	**-2.4**	**7.5**	**-7.8**	**10.9**
Cash flow from operating activities	**-64.2**	**-35.3**	**-143.6**	**-68.4**	**-173.5**
INVESTING ACTIVITIES					
Acquisition of subsidiaries, net cash required	-	-	-	-1.7	-1.7
Investment in financial assets	-0.0	-	-0.0	-	0.0
Purchase of property, plant and equipment	-0.0	-	-0.0	-	-
Cash flow from investing activities	**-0.0**	**-**	**-0.0**	**-1.7**	**-1.7**
FINANCING ACTIVITIES					
New share issue	-	177.4	210.0	177,4	177.4
Cost of new share issue	-	-12.6	-14.0	-12.6	-12.6
Repayment of loans	-	-5.0	-	-7.5	-7.5
Repayment of leases	-0.6	-0.3	-1.3	-0.7	-1.6
Cash flow from financing activities	**-0.6**	**159.5**	**194.7**	**156.6**	**155.7**
Cash flow for the period	**-64.8**	**124.3**	**51.0**	**86.5**	**-19.5**
Balance at beginning of period	243.5	106.8	127.7	144.0	144.0
Change in cash	-64.8	124.2	51.0	86.4	-19.5
Exchange rate difference in cash	0.5	2.2	0.4	2.8	3.2
CASH BALANCE AT THE END OF THE PERIOD	**179.2**	**233.2**	**179.2**	**233.2**	**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**
Rights issue	1.8	208.2	-	-	210.0
Costs, rights issue	-	-14.0	-	-	-14.0
Comprehensive income for the period	-	-	-154.2	-	-154.2
Transactions with shareholders					
Costs due to share-based payments of employee stock option plan	-	-	-	2.9	2.9
Closing balance 30/06/2023	**13.1**	**1,622.6**	**-1,093.8**	**9.0**	**550.9**
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
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-Jun	2022 Jan-Jun	2022 Jan-Dec
Equity	550.9	635.0	506.2
Equity ratio %	90%	96%	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	244,561,504	189,099,479	194,238,210
Average number of shares during the period after dilution	249,612,356	189,099,479	194,238,210
Share Data			
Earnings per share	-0.6	-0.3	-1.0
Earnings per share after dilution	-0.6	-0.3	-1.0
Cash flow from operating activities	-0.6	-0.4	-0.9
Equity per average number of shares	2.3	3.4	2.6
Equity per average number of shares after dilution	2.3	3.4	2.6
Dividend	-	-	-
Average number of employees	23	13	15

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

Parent company - income statement

MSEK	2023 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Revenue					
Revenue	-	-	-	0.5	0.6
Other operating income	22.8	10.1	42.3	16.6	53.6
	22.8	**10.1**	**42.3**	**17.2**	**54.2**
Operating expenses					
Project costs	-12.3	-5.6	-23.6	-9.5	-42.4
Other external costs	-11.6	-5.1	-20.6	-10.6	-22.4
Employee costs	-14.3	-10.2	-29.7	-18.7	-52.0
Depreciation and impairment	0.0	0.0	0.0	0.0	-0.1
Other operating expenses	-0.2	-0.1	-0.4	-0.1	-0.6
Sum operating expenses	-38.5	-21.0	-74.4	-39.0	-117.4
Operating results	**-15.7**	**-10.9**	**-32.0**	**-21.8**	**-63.2**
Financial items					
Interest income and similar items	0.9	1.8	0.9	2.4	3.7
Interest expense and similar items	0.0	-	0.0	-	0.0
Sum financial items	0.9	1.8	0.9	2.4	3.7
Results after financial net	**-14.8**	**-9.2**	**-31.1**	**-19.4**	**-59.5**
Group contributions	-80.0	-25.0	-100.0	-25.0	-135.0
Tax	-	-	-	-	-
Results after tax	**-94.8**	**-34.2**	**-131.1**	**-44.4**	**-194.5**

Parent company - balance sheet

MSEK	30/06/2023	30/06/2022	31/12/2022
ASSETS			
Non-current assets			
Equipment	0.1	0.1	0.1
Financial non-current assets	434.1	433.5	433.8
Total non-current assets	**434.2**	**433.6**	**433.9**
Current assets			
Receivables from Group companies	0.5	-	0.1
Other receivables	0.5	0.0	0.6
Prepaid expenses and accrued income	4.4	2.6	3.8
Cash and bank balance	161.7	220.9	120.0
Total current assets	**167.1**	**223.4**	**124.4**
Total assets	**601.3**	**657.0**	**558.3**

MSEK	30/06/2023	30/06/2022	31/12/2022
Equity			
Restricted Equity			
Share capital	13.1	11.3	11.3
Non-restricted equity			
Share premium reserve	673.5	673.8	673.8
Reserves	9.0	3.1	6.1
Net loss for the period	-131.1	-44.4	-194.5
Total equity	**564.5**	**643.8**	**496.7**
Non-current liabilities			
Provisions	2.5	0.7	4.4
Total non-current liabilities	**2.5**	**0.7**	**4.4**
Current liabilities			
Liabilities to group company	14.1	1.6	33.1
Accounts payable	5.2	2.4	7.8
Other liabilities	5.6	2.5	3.9
Accrued expenses and deferred income	9.4	6.1	12.4
Total current liabilities	**34.3**	**12.5**	**57.2**
Total equity and liabilities	**601.3**	**657.0**	**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 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. 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 Apr-Jun MSEK	**Emcitate**	**Aladote**	**Common***	**Sum**
Revenue	5.9	-	-	**5.9**
Costs of sales of goods	-1.3	-	-	**-1.3**
Project costs	-41.0	-0.6	-	**-41.5**
Other	-	-	-43.3	**-43.3**
Operating results	**-36.4**	**-0.6**	**-43.3**	**-80.3**
Net financial items				**0.8**
Pretax profit				**-79.5**

2022 Apr-Jun MSEK	**Emcitate**	**Aladote**	**Common***	**Sum**
Revenue	4.7	-	-	**4.7**
Costs of sales of goods	-1.5	-	-	**-1.5**
Project costs	-22.4	-0.1	-0.1	**-22.6**
Other	-	-	-15.5	**-15.5**
Operating results	**-19.3**	**-1.9**	**-15.6**	**-35.0**
Net financial items				**1.7**
Pretax profit				**-33.2**

2023 Jan-Jun MSEK	**Emcitate**	**Aladote**	**Common***	**Sum**
Revenue	12.7	-	-	**12.7**
Costs of sales of goods	-3.6	-	-	**-3.6**
Project costs	-88.1	-1.3	-	**-89.4**
Other	-	-	-74.9	**-74.9**
Operating results	**-79.0**	**-1.3**	**-74.9**	**-155.2**
Net financial items				**0.8**
Pretax profit				**-154.4**

2022 Jan-Jun MSEK	**Emcitate**	**Aladote**	**Common**	**Sum**
Revenue	11.2	-	0.5	**11.8**
Costs of sales of goods	-3.5	-	-	**-3.5**
Project costs	-39.5	-2.0	-0.9	**-42.3**
Other	-	-	-30.3	**-30.3**
Operating results	**-31.8**	**-2.0**	**-30.7**	**-64.4**
Net financial items				**2.3**
Pretax profit				**-62.1**

2022 Jan-Dec MSEK	Emcitate	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 Apr-Jun	2022 Apr-Jun	2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
Re-invoicing of costs to Solasia	-	-	-	0.5	0.6
Sales of goods	5.9	4.7	12.7	11.2	21.9
Total	**5.9**	**4.7**	**12.7**	**11.8**	**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 1,0 (0,6) during the period.

Note 6 – Employee Stock Option Plan

During the first half 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 June 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 June 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 7.20 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.

		2023 Jan-Jun	2022 Jan-Jun	2022 Jan-Dec
A	Equity, MSEK	550.9	635.0	506.2
B	Balance sheet total, MSEK	608.8	661.1	561.1
A/B	**Equity ratio %**	**90%**	**96%**	**90%**
A	Net result, MSEK	-154.2	-62.1	-193.8
B	Equity, MSEK	550.9	635.0	506.2
A/B	**Return on equity, %**	**neg.**	**neg.**	**neg.**
A	Cash flow from operating activities, MSEK	-143.6	-68.4	-173.5
B	Average number of shares during the period, before dilution, thousand	244,562	189,099	194,238
A/B	**Cash flow from operating activities per share, SEK**	**-0.6**	**-0.4**	**-0.9**
A	Equity, MSEK	550.9	635.0	506.2
B	Average number of shares at the end of the period before dilution, thousand	244,562	189,099	194,238
A/B	**Equity per average number of shares before dilution, SEK**	**2.3**	**3.4**	**2.6**
A	Equity, MSEK	550.9	635.0	506.2
B	Average number of shares at the end of the period after dilution, thousand	249,612	189,099	194,238
A/B	**Equity per average number of shares after dilution, SEK**	**2.3**	**3.4**	**2.6**

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

Other information

Next reports

Interim report January 1- September 30: November 8, 2023.
Full year results January 1- December 31: February 24, 2024.

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.

For further information, please contact:

Nicklas Westerholm, CEO
E-mail: nicklas.westerholm@egetis.com

Yilmaz Mahshid, CFO
E-mail: yilmaz.mahshid@egetis.com

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 August 22, 2023, at 7.00 am (CEST).

Egetis Therapeutics AB (publ)
Klara Norra kyrkogata 26, 111 22 Stockholm, Sweden
Org.nr. 556706-6724
Phone: +46(0)8-679 72 10
www.egetis.com

Analysts who follow Egetis Therapeutics

ABGSC: Gonzalo Artiach
Bryan, Garnier & Co: Alex Cogut
Carnegie: Arvid Necander & Erik Hultgård
Erik Penser Bank: Ludvig Svensson
Pareto Securities: Chien-Hsun Lee & Dan Akschuti
Redeye: Fredrik Thor
Rx Securities: Joseph Hedden

Certification

This Half-Year report for January-June 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, August 22, 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
Behshad Sheldon	
Board member	