

## Interim report January-March 2021

# Patient recruitment in the pivotal study with Emcitate progressing according to plan

### January March

- Quarterly net sales MSEK 3.8 (11.7)
- Quarterly result MSEK -19.3 (-42.8)
- Cash and cash equivalents MSEK 249.8 (221.1)
- Cash flow for the period MSEK -38.4 (-37.2)
- Loss per share before/after dilution SEK -0.1 (-0.8)

### Significant events during the period January-March

- The company has appointed Kristina Sjöblom Nygren, MD, as CMO, effective May 1, and will be member of the company's leadership team. The recruitment expands the orphan drug experience and expertise also to the clinical and medical function, further strengthening the company's alignment and strategic focus on this segment.
- Dr Thomas Lönngren was nominated as new Chairman of the Board at Egetis Therapeutics.
- Mats Blom was nominated as new board member at Egetis Therapeutics.

### Emcitate®

- Patient recruitment in the pivotal Phase IIb/III early intervention study with the drug candidate Emcitate progresses according to plan. Patient recruitment is expected to be completed in Q4 2021.
- Increased interest in the opportunity to treat MCT8 deficiency with Emcitate from physicians across the globe. Emcitate is supplied on a named patient basis in several countries, following special approval from the national regulatory authority with more than 100 MCT8 patients already getting access to Emcitate treatment.

### Aladote®

- An ODD application has been submitted to the European Medicines Agency (EMA).
- Preparation for the pivotal Phase IIb/III study for Aladote continues targeting study start in H2 2021, pending the COVID-19 pandemic situation.
- Aladote was presented as a novel emerging treatment of paracetamol overdose at the annual meeting of the Society of Toxicology (SOT) on March 16 under the heading Novel Emerging Treatments for Acetaminophen Toxicity.

### PledOx®

- No events to report.

### Significant events after the reporting period

- Aladote was presented at the scientific meeting of the American College of Medical Toxicology (ACMT) on April 14, under the heading Antidote Updates.
- The company has parked further PledOx development following the POLAR results. Our partner Solasia Pharma KK will continue the pre-clinical program in taxane induced peripheral neuropathy.
- Egetis Therapeutics appoints Yilmaz Mahshid, PhD as new CFO.

## Financial overview

### Key figures

	2021	2020	2020
	Jan-Mar	Jan-Mar	Jan-Dec
Net revenues, KSEK	3,787	11,712	40,662
Result after tax, KSEK	-19,315	-42,818	-179,120
Cash flow, KSEK	-38,361	-37,172	34,223
Cash, KSEK	249,775	221,141	287,850
Equity ratio %	72%	86%	70%
Earnings per share, SEK	-0.1	-0.8	-2.7
Earnings per share after dilution, SEK	-0.1	-0.8	-2.7
Average number of employees	10	9	9

### About Egetis Therapeutics

Egetis Therapeutics is an innovative, unique, and integrated pharmaceutical drug development company, focusing on projects in late-stage development for treatment of serious rare/niche diseases with significant unmet medical needs in the orphan drug segment. The drug candidate Emcitate is developed as the first potential treatment for patients with MCT8 deficiency, a rare disease with high unmet medical need and no available treatment. A Phase IIb clinical trial has been completed with significant and clinically relevant effects. A pivotal Phase IIb/III early intervention study has been initiated with the first patient dosed in Dec 2020 and interim results are expected in 2022. Emcitate holds Orphan Drug Designation (ODD) in the US and EU and was granted Rare Pediatric Disease Designation by the US FDA in November 2020. The drug candidate Aladote is a first in class drug candidate developed to reduce the risk

of acute liver injury associated with paracetamol poisoning. A proof of principle study has been successfully completed and the design of the upcoming pivotal Phase IIb/III study for Aladote has been finalized after completed interactions with FDA, EMA and MHRA. Aladote has been granted Orphan Drug Designation in the US and an application for ODD was submitted in Europe in Q1 2021. Results from the PledOx POLAR program in Dec 2020 showed that PledOx did not meet the efficacy endpoint. After discussion with our partner Solasia, Egetis Therapeutics has decided to park the development of PledOx following the POLAR results.

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

## Comments from the CEO

The first three months of the new year have indeed given a good start to Egetis Therapeutics, our new focused orphan drug development company with two important assets Emcitate and Aladote – both in late-stage clinical development. During this intense period, we have integrated Rare Thyroid Therapeutics, strengthened and further adapted the organization to the new strategic direction and thereby built a solid foundation for Egetis' future success as a sustainable orphan drug company dedicated to development and commercialization of therapies for rare diseases. Our goal is to offer medicines to patients with serious and rare diseases lacking adequate medical treatments and thereby create value for patients, shareholders and society.

### **Recruitment to the Phase IIb/III study TRIAC II with Emcitate is progressing well according to plan**

Emcitate, which has been granted Orphan Drug Designation (ODD) in both EU and the US and received a US Rare Pediatric Disease designation (RPD) in November 2020, is being developed for the treatment of MCT8 deficiency, a rare congenital disorder of thyroid hormone trafficking with detrimental natural history and no currently available therapy. Approximately 1 in 70,000 males are affected.

The first patient in the pivotal Phase IIb/III early intervention trial TRIAC II was dosed in December 2020, and the recruitment is progressing well and is expected to be completed in Q4 2021 as per plan. Interim results are targeted to be available in H2 2022 and expected to pave the way for regulatory approvals and commercial launch. TRIAC II is an international, open label, multi-center study in children younger than 30 months with MCT8 deficiency, conducted in both Europe and North America.

We also see an increased interest from physicians across the globe to treat patients that suffer from MCT8 deficiency with Emcitate. Emcitate is supplied on a named patient basis, following individual regulatory approval from the national regulatory

agency. Named patient access is a mechanism to allow for early access to important and life-saving medicines in situations with high unmet medical needs and where no available treatment alternatives exist or are suitable. Already more than 100 patients with MCT8 deficiency in several countries have been granted such named patient approval and are being treated with Emcitate, underlining the significant unmet medical need in this patient population.

### **Preparations for the Aladote pivotal Phase IIb/III study are ongoing**

Preparations for the planned Phase IIb/III study with Aladote are ongoing in the US, UK and EU together with the selected CRO. The Covid-19 pandemic makes it very challenging to start a clinical study in an emergency/intensive care setting. Therefore, pending how the situation evolves, we expect study start will likely take place in H2 2021.

We remain committed to the continued development of Aladote, which has the potential to be the first approved drug to benefit patients with an increased risk of liver injury, who are not adequately treated with NAC after a paracetamol overdose. Aladote has been granted ODD in the US, and an application for an ODD in the EU was submitted to the EMA in March.

We continue to see a strong interest in the scientific community for Aladote, which was presented by Professor James Dear from the University of Edinburgh, UK at two scientific conferences in March and April as a novel emerging treatment of paracetamol overdose.

### **PledOx**

After discussion with our partner Solasia, Egetis Therapeutics has decided to park the development of PledOx following the POLAR results. Solasia will further evaluate PledOx through a pre-clinical program in taxane-induced peripheral neuropathy.

# EGETIS THERAPEUTICS

## Cash position

To continue the development of our clinical portfolio, we reported a cash position of approximately 250 million SEK on March 31, 2021, which is planned to finance the development of Emcitate and Aladote towards market approval.

## Strengthened organization and board

We continue to strengthen the company, in order to adapt to our new strategic direction, prepare for the next steps of our clinical programs and ultimately launch of our innovative drug candidates. In February, Kristina Sjöblom Nygren, MD, was appointed Chief Medical Officer (CMO), effective May 1, and will be member of the company's leadership team. Kristina has more than 20 years' experience in the pharmaceutical industry from both large pharmaceutical companies and smaller biotech companies. She has an extensive experience in late-stage development and regulatory interactions in the rare disease and orphan drug segment in particular and will be instrumental in the execution of our development programs.

After the period, I was very pleased to announce that Yilmaz Mahshid, PhD, will join the company as Chief Financial Officer (CFO), starting in the second quarter this year. I worked with Yilmaz for three years at PledPharma and am very happy to renew this fruitful collaboration.

On the Board level, the nomination committee has nominated Dr Thomas Lönngren (chairman) and Mats

Blom to the Board of Directors. The decision is expected to be taken at the Annual General Meeting on April 29. We are grateful to be able to attract Thomas and Mats to the Board as they will add valuable experience, knowledge and expertise to Egetis when building the company with focus on orphan late-stage development, registration and commercialization for the future. Among other things, Thomas's ten-year mandate as Head of the European Medicines Agency (EMA) will provide an extra edge and understanding of the regulatory work in the complex life science sector.

## Looking ahead

Our focus on our clinical candidates with their opportunity to provide treatment for patients suffering from rare and serious diseases is firm as we shape the future of Egetis, our exciting company focusing on the orphan drug and rare disease segment. We continue to carefully monitor the impact of the Covid-19 pandemic and take every precaution to ensure that staff, collaborators, and study participants are safe and stay well, while progressing our clinical studies with high data quality.

I believe we are well positioned to deliver on our projects Emcitate and Aladote and their respective pivotal studies. I look forward to relaying news to you around the clinical studies and the progress of Egetis Therapeutics.

**Nicklas Westerholm, CEO**  
Egetis Therapeutics AB (publ.) Stockholm

## R&D Pipeline Projects



\*Egetis has decided to park the development of PledOx following the POLAR results.

## Project updates

### Emcitate

#### Events during the quarter

Patient recruitment in the pivotal Phase IIb/III early intervention study in young patients with the drug candidate Emcitate progresses according to plan. Patient recruitment is expected to be completed in Q4 2021.

Increased interest in the opportunity to treat MCT8 deficiency with Emcitate from physicians across the globe. Emcitate is supplied on a named patient basis

in several countries, following special approval from the national regulatory authority with more than 100 MCT8 patients already getting access to Emcitate treatment.

#### Significant events after the reporting period

There are no events to report.

#### About Emcitate

Emcitate is Egetis Therapeutics lead candidate drug in clinical development. It addresses MCT8 deficiency, which is a rare genetic disease with high unmet medical need and no available treatment, affecting 1:70,000 males.

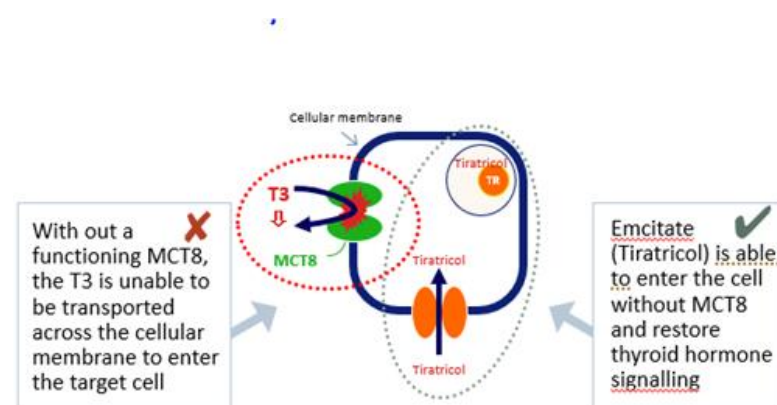
Thyroid hormone is crucial for the development and metabolic state of virtually all tissues. Thyroid hormone transport across the plasma membrane is required for the hormone's metabolism and intracellular action and is facilitated by thyroid hormone transporters, including monocarboxylate transporter 8 (MCT8). Mutations in the gene for MCT8, located at the X-chromosome, cause MCT8 deficiency, also called Allan-Herndon-Dudley syndrome (AHDS) in affected males. 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. 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 (RPD) in November 2020. Upon approval of the NDA, sponsors holding a RPD and meeting the criteria specified can apply to receive a US Rare Pediatric Disease 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.

A Phase IIb clinical trial in MCT8 deficiency has been completed which showed significant and clinically relevant treatment effects on key aspects of the disease. A pivotal Phase IIb/III early intervention study was initiated with the first patient dosed in Q4 2020. Patient recruitment is expected to be completed in Q4 2021. Results from an interim analysis following 12 months treatment are planned for H2, 2022 and is expected to pave the way for regulatory approvals in both EU and the US in 2023/24.



## Aladote

### Events during the quarter

An ODD application has been submitted to the EMA.

Preparation for the pivotal Phase IIb/III study for Aladote continues targeting study start in H2 2021, pending the COVID-19 pandemic situation.

Aladote was presented as a novel emerging treatment of paracetamol overdose at the annual meeting of the

Society of Toxicology (SOT) on March 16 under the heading Novel Emerging Treatments for Acetaminophen Toxicity.

### Significant events after the reporting period

Aladote was presented at the scientific meeting of the American College of Medical Toxicology (ACMT) on April 14, under the heading Antidote Updates.

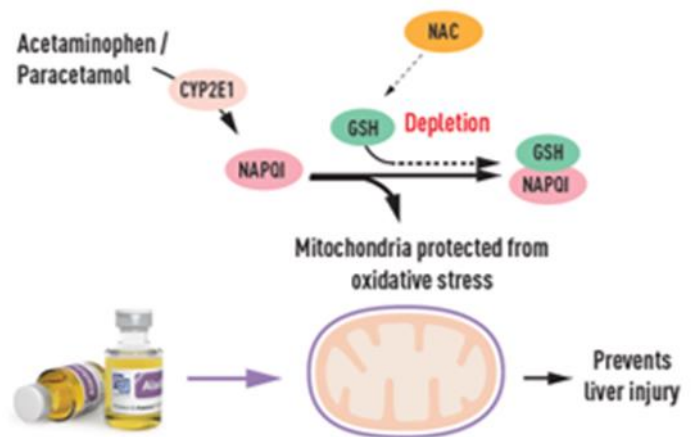
### About Aladote

Aladote is a “first-in-class” drug candidate with the potential to reduce the risk of acute liver injury associated with paracetamol/acetaminophen poisoning. Aladote has shown good effect in relevant preclinical models, even in the time-window when N-acetylcysteine (NAC) treatment no longer is effective. A proof of principle study in patients with paracetamol poisoning 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 liver injury in this patient population. Aladote has been granted Orphan Drug Designation in the US and is expected to be eligible for an ODD in the EU, for which an application has been submitted to the EMA in Q1 2021.

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 NAPQI is formed, which can cause acute liver injury. The current standard of care for paracetamol poisoning (NAC) is effective if the patient seeks medical care within 8 hours of ingestion. However, NAC is substantially less

effective if started more than 8 hours after the overdose.

The Phase IIb/III study is targeting patients with increased risk of liver injury, who arrive late at hospital, more than 8 hours after a paracetamol overdose, for which current standard of care, NAC, is substantially less effective. The total planned number of patients are 225, 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. Application for market approval for sales in the US, EU and UK is planned after successful completion of the study.



## PledOx

### Events during the quarter

There are no events to report.

### Significant events after the reporting period

The company has parked further PledOx development following the POLAR results. Our partner Solasia Pharma KK will continue the pre-clinical program in taxane induced peripheral neuropathy.

The POLAR study results will be presented at ESMO 23rd World Congress on Gastrointestinal Cancer to be held virtually from June 30 – July 3, 2021

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### About PledOx

PledOx is a “first in class” drug candidate aimed to provide patients that are treated adjuvantly or for metastatic colorectal cancer prevention against the nerve damage that can occur in conjunction with chemotherapy treatment. The global Phase III program for PledOx consisted of two double blind randomized placebo-controlled trials, POLAR-M and POLAR-A. POLAR-M was designed to include 420 patients undergoing chemotherapy treatment for metastatic colorectal cancer and was conducted in Asia, Europe and the US. The study aimed to compare PledOx at doses of 2  $\mu\text{mol}/\text{kg}$  and 5  $\mu\text{mol}/\text{kg}$  with placebo. POLAR-A was designed to include 280 patients undergoing adjuvant chemotherapy treatment for colorectal cancer and was conducted in Asia and Europe. The study aimed to compare PledOx at a dose of 5  $\mu\text{mol}/\text{kg}$  with placebo. In Q1 2020 US

Food and Drug and Administration (FDA) and French regulatory authority (ANSM) issued a clinical hold in the US and France, respectively, of the Phase III POLAR studies. The treatment of patients in the Phase III POLAR program was prematurely stopped in Q2 and the cut-off for data collection took place during Q3, 2020. The program was completed in December 2020, when the company announced that the efficacy endpoint was not met. The POLAR study results will be presented at ESMO 23rd World Congress on Gastrointestinal Cancer to be held virtually from June 30 – July 3, 2021. The company has parked further PledOx development following the POLAR results.

## Financial Information

### Interim report January-March 2021

#### Revenue, and results

##### Revenues

Revenues amounted to KSEK 3,787 (11,712) for the period. The revenue consisted of Emcitate sales of KSEK 2,539 (0) and forwarding of expenses related to PledOx to Solasia Pharma K.K (Solasia) of KSEK 1,248 (11,712).

##### Expenses

Operating expenses amounted to KSEK 23,401 (58,588) during the period. The project expenses amounted to KSEK 10,521 (49,932) during the period. The project expenses consisted of expenses due to Emcitate of KSEK 5,072 (0), Aladote KSEK 2,710 (881) and PledOx KSEK 2,739 (49,051).

Employee costs amounted to KSEK 6,386 (5,708) for the period.

Other external costs amounted to KSEK 4,490 (2,099) for the period. The increase is mainly due to higher consultancy and auditor expenses. Depreciation amounted to KSEK 437 (54) for the period. KSEK 276 of the depreciations derives from amortization of licences, KSEK 156 (54) derives from right-of-use assets according to IFRS 16 and KSEK 6 (0) derives from depreciation of inventories. Other operating expenses amounted to KSEK 56 (795) for the period and consists of exchange rate differences from operating income and operating expenses.

##### Results

Operating results amounted to KSEK -19,613 (-46,876) for the period. Net financial items amounted to KSEK 299 (4,058) for the period. Results from net financial items are related to unrealized revaluation of company's FX-accounts at the end of the period. Results after financial items amounted to KSEK -19,315 (-42,818) for the period. Result per share before and after dilution amounted to SEK -0.1 (-0.8) for the period both before and after dilution.

#### Financial position

##### Cash

Cash as of March 31, 2021 amounted to KSEK 249,775 (221,141).

##### Cash flow

Cash flow from operating activities amounted to KSEK -35,005 (-37,119) for the period. Total Cash flow amounted to KSEK -38,361 (-37,172) for the period. Cash flow from operating activities is driven by costs from the clinical studies. Cash flow from investment activities amounted to KSEK -1,317 (0) the period KSEK 1,250 are due to deferred purchase price of RTT and KSEK 67 are due to acquisition of inventories. Cash flow from financing activities amounted to KSEK -164 (-54) for the period and are mainly due to payment of office rent that is classified as IRFS 16 leases.

##### Equity and equity ratio

As of March 31, 2021, equity amounted to KSEK 610,509 (202,057). Shareholders' equity per share amounted to SEK 3.7 (3.8), at the end of the period. The company's equity ratio was 72 (86) %.

##### Debts and receivables

As of March 31, 2021, non-current liabilities amounted to KSEK 190,830 (29). Liabilities that derive from the acquisition of RTT is deferred tax liability of KSEK 119,847 and other long-term liabilities of KSEK 67,591 (0). Long-term lease liabilities amount to 3,221 (29) and long-term liabilities that are due to IFRS 2 amounts to KSEK 171 (0). Current lease liabilities amount to KSEK 1,297 (157), current liabilities from the acquisition of RTT amounted to KSEK 7,500 (0) and other non-current liabilities amounted to KSEK 41,919 (32,018). Account's receivables amounted to KSEK 2,688 (1,001) and non-current assets amounted to KSEK 593,727 (193).



# EGETIS THERAPEUTICS

## **Investments, tangible and intangible assets**

Due to the acquisition of RTT during 2020, KSEK 581,784 of the acquisition value were classified as research and development projects due to Emcitate. Amortisation will start when Emcitate has obtained market approval and the value is intended to be depreciated in line with the useful life.

SEK 7,301 are licences. The licences are amortised on a straight-line basis and was initially judged to have a useful life of 10 years in RTT.

## **Shares**

The number of shares as of March 31, 2021 were 165,068,560 (53,533,321). The number of shareholders were 3,167 as of March 31, 2021. The 20 largest shareholders owned 69.4 % of the shares. Egetis Therapeutics shares are listed on Nasdaq Stockholm's main market.

## **Stock option plan and warrant programs**

### **Information regarding previous warrant programs.**

The average share price during the period have been lower than the subscription prices of the programs and plans. Hence no dilution has been recognized to the shareholders.

Full utilization of granted options and warrants would increase the shares with 4,772,100 to a total of 169,790,660.

### **Stock option plan 2020/2024**

The 2020 Annual General Meeting resolved on a 2020/2024 stock option plan of 3,000,000 stock options for employees of Egetis Therapeutics.

To ensure the delivery of shares to participants in the company's incentive programs 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 PledPharma I AB, of which 2,900,000 warrants was allotted to the employees as of March 31, 2021.

## **Warrant program 2018/2021**

The 2018 Annual General Meeting resolved on a warrant program to the employees in Egetis Therapeutics of 779,500 warrants where each warrant entails the right to subscribe for one (1) new share in the company at a subscription price of SEK 26 per share. 779,500 warrants have been acquired by employees in the warrant program 2018/2021. The CEO holds 193,703 of the warrants in the warrant program 2018/2021.

## **Employees**

Number of employees as of March 1, 2021 were 10 (9) persons, 5 women and 5 men.

## **Parent company**

The parent company's revenues for the period amounted to KSEK 2,911 (11,712). KSEK 1,248 (11,712) of the revenues consists of forwarding of expenses related to PledOx to Solasia and KSEK 1,663 (0) are management fees invoiced to the subsidiary RTT.

Operating expenses amounted to KSEK 16,486 (58,588) during the period. The project expenses amounted to KSEK 5,775 (49,932) during the period. The project expenses consisted of expenses due to Emcitate of KSEK 326 (0), Aladote KSEK 2,710 (881) and PledOx KSEK 2,739 (49,051).

Employee costs amounted to KSEK 6,429 (5,708) for the period. Other external costs amounted to KSEK 4,226 (2,152) for the period. Depreciation amounted to KSEK 6 (0) for the period. Other operating expenses amounted to KSEK 70 (795) for the period and consists of exchange rate differences from operating income and operating expenses.

The parent company's result amounted to KSEK -13,280 (-42,817) for the period.

Financial non-current assets amount to KSEK 493,256 (50) the increase is due to the acquisition of RTT during 2020. Other-long term liabilities amounts to KSEK 63,387 (0).

## Consolidated statement of comprehensive income

KSEK	2021	2020	2020
	Jan-Mar	Jan-Mar	Jan-Dec
<b>Revenue</b>			
Sales	3,787	11,712	40,662
	<b>3,787</b>	<b>11,712</b>	<b>40,662</b>
<b>Operating expenses</b>			
Costs of sales of goods	-1,511	-	-1,895
Project costs	-10,521	-49,932	-183,276
Other external costs	-4,490	-2,099	-11,097
Employee costs	-6,386	-5,708	-22,151
Depreciation and impairment	-437	-54	-395
Other operating expenses	-56	-795	-243
<b>Operating results</b>	<b>-19,613</b>	<b>-46,876</b>	<b>-178,395</b>
<b>Financial items</b>			
Interest income and similar items	315	4,059	163
Interest expense and similar items	-17	-1	-888
<b>Results after financial net</b>	<b>-19,315</b>	<b>-42,818</b>	<b>-179,120</b>
Tax	-	-	-
<b>Results after tax</b>	<b>-19,315</b>	<b>-42,818</b>	<b>-179,120</b>
<b>Statement of comprehensive income</b>			
Other comprehensive income	-	-	-
<b>Comprehensive income for the period</b>	<b>-19,315</b>	<b>-42,818</b>	<b>-179,120</b>
Net earnings and comprehensive income is entirely attributable to parent company shareholders			
<b>Share Data</b>			
Number of shares at the end of period	165,068,560	53,533,321	165,068,560
Average number of shares during period	165,068,560	53,533,321	67,391,206
Earnings per share before dilution (SEK)	-0.1	-0.8	-2.7
Earnings per share after dilution (SEK)	-0.1	-0.8	-2.7
Equity per average number of shares	3.7	3.8	9.3
Equity per average number of shares after dilution	3.7	3.8	9.3

# EGETIS THERAPEUTICS

## Consolidated statement of financial position

KSEK	3/31/2021	3/31/2020	12/31/2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Research and development costs	581,784	-	581,784
Licences	7,301	-	7,571
Right-of-use assets	4,511	193	4,666
Equipment	131	-	75
<b>Total non-current assets</b>	<b>593,727</b>	<b>193</b>	<b>594,097</b>
<b>Current assets</b>			
Inventories	2,074	-	3,138
Accounts receivables	2,688	1,001	3,883
Other receivables	1,123	2,563	2,960
Prepaid expenses and accrued income	1,371	9,207	2,039
Cash and bank balance	249,775	221,141	287,850
<b>Total current assets</b>	<b>257,031</b>	<b>233,912</b>	<b>299,871</b>
<b>Total assets</b>	<b>850,758</b>	<b>234,104</b>	<b>893,967</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	8,688	2,818	8,688
Other capital contributions	1,262,837	705,278	1,262,837
Reserves	645	-	448
Accumulated loss including net loss	-661,661	-506,038	-642,346
<b>Total equity</b>	<b>610,509</b>	<b>202,057</b>	<b>629,627</b>
<b>Long-term liabilities</b>			
Deferred tax liabilities	119,847	-	119,847
Other long-term liabilities	70,812	29	74,242
Provisions for social security contributions	171	-	109
<b>Total Long-term liabilities</b>	<b>190,830</b>	<b>29</b>	<b>194,198</b>
<b>Current liabilities</b>			
Accounts payable	3,716	13,264	15,611
Other liabilities	14,658	980	14,542
Accrued expenses and deferred income	31,045	17,774	39,988
<b>Total current liabilities</b>	<b>49,419</b>	<b>32,018</b>	<b>70,141</b>
<b>Total equity and liabilities</b>	<b>850,758</b>	<b>234,104</b>	<b>893,967</b>

# EGETIS THERAPEUTICS

## Consolidated statement of cash flows

KSEK	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
<b>OPERATING ACTIVITIES</b>			
Result after financial net	-19,315	-42,818	-179,120
Adjustments for non-cash items	425	-3,158	2,430
Tax paid	-	-	-
<b>Cash flow from operating activities before changes in working capital</b>	<b>-18,890</b>	<b>-45,977</b>	<b>-176,690</b>
<b>Cash flow from changes in working capital</b>			
Increase/decrease in operating receivables	607	2,078	16,428
Increase/decrease in operating liabilities	-16,723	6,780	25,624
<b>Cash flow from changes in working capital</b>	<b>-16,115</b>	<b>8,858</b>	<b>42,052</b>
<b>Cash flow from operating activities</b>	<b>-35,005</b>	<b>-37,119</b>	<b>-134,639</b>
<b>INVESTING ACTIVITIES</b>			
Acquisition of subsidiaries	-1,250	-	-59,520
Purchase of property, plant and equipment	-67	-	-24
<b>Cash flow from investing activities</b>	<b>-1,317</b>	<b>-</b>	<b>-59,543</b>
<b>FINANCING ACTIVITIES</b>			
New share issue	-	-	250,750
Cost new share issue	-	-	-22,130
Repayment of loans	-1,875	-	-
Cash outflow lease agreements	-164	-54	-215
<b>Cash flow from financing activities</b>	<b>-2,039</b>	<b>-54</b>	<b>228,405</b>
<b>Cash flow for the period</b>	<b>-38,361</b>	<b>-37,172</b>	<b>34,223</b>
Balance at beginning of period	287,850	255,101	255,101
Change in cash	-38,361	-37,172	34,223
Exchange rate difference in cash	286	3,212	-1,473
<b>CASH BALANCE AT THE END OF THE PERIOD</b>	<b>249,775</b>	<b>221,141</b>	<b>287,850</b>

## Consolidated statement of changes in equity

KSEK	Share capital	Other capital	Accumulated loss incl. net	Other reserves	Total equity
<b>Opening balance 20210101</b>	<b>8,688</b>	<b>1,262,837</b>	<b>-642,346</b>	<b>448</b>	<b>629,627</b>
Comprehensive income for the period	-	-	-19,315	-	-19,315
Transactions with shareholders	-	-	-	-	-
Costs due to share-based payments of employee stock option plan	-	-	-	197	197
<b>Closing balance 20210331</b>	<b>8,688</b>	<b>1,262,837</b>	<b>-661,661</b>	<b>645</b>	<b>610,509</b>
<b>Opening balance 20200101</b>	<b>2,818</b>	<b>705,278</b>	<b>-463,220</b>	<b>-</b>	<b>244,876</b>
Comprehensive income for the period	-	-	-42,818	-	-42,818
<b>Closing balance 20200331</b>	<b>2,818</b>	<b>705,278</b>	<b>-506,038</b>	<b>-</b>	<b>202,057</b>
<b>Opening balance 20200101</b>	<b>2,818</b>	<b>705,278</b>	<b>-463,220</b>	<b>-</b>	<b>244,876</b>
Comprehensive income for the period	-	-	-179,120	-	-179,120
Transactions with shareholders	-	-	-	-	-
Issue in kind	3,356	331,454	-	-	334,810
New share issue	2,514	248,236	-	-	250,750
Cost new share issue	-	-22,130	-	-	-22,130
Costs due to share-based payments of employee stock option plan	-	-	-	448	448
<b>Closing balance 20201231</b>	<b>8,688</b>	<b>1,262,837</b>	<b>-642,346</b>	<b>448</b>	<b>629,627</b>

## 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.

KSEK	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Equity	610,509	202,057	629,627
Equity ratio %	72%	86%	70%
Return on equity %	neg.	neg.	neg.
Number of shares at the end of the period	165,068,560	53,533,321	165,068,560
Number of shares at the end of the period after dilution	165,068,560	53,533,321	165,068,560
Average number of shares during the period	165,068,560	53,533,321	67,391,206
Average number of shares during the period after dilution	165,068,560	53,533,321	67,391,206

### Share Data

Earnings per share	-0.1	-0.8	-2.7
Earnings per share after dilution	-0.1	-0.8	-2.7
Cash flow from operating activities per shares, SEK	-0.2	-0.7	-2.0
Equity per average number of shares	3.7	3.8	9.3
Equity per average number of shares after dilution	3.7	3.8	9.3
Dividend	-	-	-
Average number of employees	10	9	9

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

# EGETIS THERAPEUTICS

## Parent company - income statement

KSEK	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
<b>Revenue</b>			
Sales	1,248	11,712	38,935
Other operating income	1,663	-	332
	<b>2,911</b>	<b>11,712</b>	<b>39,267</b>
<b>Operating expenses</b>			
Project costs	-5,755	-49,932	-169,422
Other external costs	-4,226	-2,152	-9,806
Employee costs	-6,429	-5,708	-22,152
Depreciation and impairment	-6	-	-1
Other operating expenses	-70	-795	-290
<b>Operating results</b>	<b>-13,575</b>	<b>-46,876</b>	<b>-162,403</b>
<b>Financial items</b>			
Interest income and similar items	295	4,059	163
Interest expense and similar items	-1	-	-885
<b>Results after financial net</b>	<b>-13,280</b>	<b>-42,817</b>	<b>-163,125</b>
Tax	-	-	-
<b>Results after tax</b>	<b>-13,280</b>	<b>-42,817</b>	<b>-163,125</b>
<b>Statement of comprehensive income</b>			
Other comprehensive income	-	-	-
<b>Comprehensive income for the period</b>	<b>-13,280</b>	<b>-42,817</b>	<b>-163,125</b>

# EGETIS THERAPEUTICS

## Parent company - balance sheet

KSEK	3/31/2021	3/31/2020	12/31/2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Equipment	84	-	23
Financial non-current assets	493,172	50	490,172
<b>Total non-current assets</b>	<b>493,256</b>	<b>50</b>	<b>490,195</b>
<b>Current assets</b>			
Receivables from group companies	2,078	-	-
Accounts receivables	788	1,001	2,470
Other receivables	507	2,563	2,266
Prepaid expenses and accrued income	982	9,207	1,135
Cash and bank balance	235,000	220,841	285,830
<b>Total current assets</b>	<b>239,355</b>	<b>233,612</b>	<b>291,701</b>
<b>Total assets</b>	<b>732,611</b>	<b>233,662</b>	<b>781,896</b>

KSEK	3/31/2021	3/31/2020	12/31/2020
<b>EQUITY AND LIABILITES</b>			
<b>Equity</b>			
<i>Restricted Equity</i>			
Share capital	8,688	2,818	8,688
<i>Non-restricted equity</i>			
Share premium reserve	636,235	241,801	799,360
Reserves	645	-	448
Net profit for the year	-13,280	-42,817	-163,125
<b>Total equity</b>	<b>632,288</b>	<b>201,802</b>	<b>645,371</b>
<b>Long-term liabilities</b>			
Other long-term liabilities	63,216	-	63,216
Provisions for social security contributions	171	-	109
<b>Total Long-term liabilities</b>	<b>63,387</b>	<b>-</b>	<b>63,325</b>
<b>Current liabilities</b>			
Liabilities to group company	-	-	19,209
Accounts payable	2,251	13,264	10,755
Other liabilities	5,799	823	5,840
Accrued expenses and deferred income	28,887	17,774	37,396
<b>Total current liabilities</b>	<b>36,937</b>	<b>31,861</b>	<b>73,199</b>
<b>Total equity and liabilities</b>	<b>732,611</b>	<b>233,662</b>	<b>781,896</b>

## Notes

### Note 1 - Accounting principles

Egetis Therapeutics 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 Therapeutics consolidated financial statements for the year ended December 31, 2020. 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 2020. No new accounting principles or policies is being implemented by the Group during 2021. The parent company and the Groups accounting currency is SEK. All the numbers in this interim report are, if nothing else is stated, stated in thousands.

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 2020 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. Leasing costs are charged to profit and do not impact the balance sheet. Lease payments are recognized on a straight-line basis over the term of the lease. The parent company accounts the acquisition costs of group entities as participation in group entities under financial non-current assets and not through the income statement.

### 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 Group's risk exposure is included in Egetis Therapeutics 2020 Annual Report.

There are no major changes in the Group's risk exposure in 2021 compared with 2020.

### COVID-19 uncertainties

The impact of the coronavirus outbreak for Egetis Therapeutics and its operations has so far been limited. Egetis Therapeutics is closely monitoring the developments and is evaluating the extent to which this may affect operations in the short and long term. Therefore, Egetis Therapeutics continue to carefully monitor the impact of the Covid-19 pandemic and take every precaution to ensure that staff, collaborators, and study participants are safe and stay well, while progressing our clinical studies with high data quality. Due to the ongoing Covid-19 pandemic, it is challenging to start a clinical study in an emergency/intensive care setting. Other risks and uncertainties that the company currently have identified are recruitment of patients in the ongoing Ecmicate study.

### Note 2 - Additional information

Other information in accordance with IAS 34.16A are found on pages before the income statement and statement of comprehensive income. Information on earnings, cash flow and financial position, see page 8. For events after the period, see page 1.



# EGETIS THERAPEUTICS

## Note 3 – Financial assets and liabilities

All financial assets and liabilities are measured at amortized costs except liability due to additional purchase price. Liability due to additional purchase price are classified as level 3 in the fair value hierarchy. The liability due to additional purchase price is valued as net present value of estimated future net sales of Emcitate. The weighted average cost of capital (WACC) used is 10%.

KSEK	Non-current	Current	Total
<b>Group March, 2021</b>			
FINANCIAL ASSETS MEASURED AT AMORTISIED COST			
Accounts receivable	-	2,688	2,688
Cash	-	249,775	249,775
<b>Total financial assets</b>	-	<b>252,463</b>	<b>252,463</b>
FINANCIAL LIABLITIES MEASURED AT FINANCIAL COST THROUGH PROFIT AND LOSS			
Contingent consideration	58,216	-	58,216
<b>Total</b>	<b>58,216</b>	-	<b>58,216</b>
FINANCIAL LIABLITIES MEASURED AT AMORTISIED COST			
Lease liabilities	3,221	1,297	4,519
Accounts payable	-	3,716	3,716
Deferred purchase price	3,750	5,000	8,750
Other liabilities	5,625	7,500	13,125
<b>Total</b>	<b>12,596</b>	<b>17,513</b>	<b>30,110</b>
<b>Total financial liabilities</b>	<b>70,812</b>	<b>17,513</b>	<b>88,325</b>
<b>Group March 31, 2020</b>			
FINANCIAL ASSETS MEASURED AT AMORTISIED COST			
Accounts receivable	-	1,001	1,001
Cash	-	221,141	221,141
<b>Total financial assets</b>	-	<b>222,142</b>	<b>222,142</b>
FINANCIAL LIABLITIES MEASURED AT AMORTISIED COST			
Lease liabilities	29	157	186
Accounts payable	-	13,264	13,264
Other liabilities	-	1	1
<b>Total</b>	<b>29</b>	<b>13,422</b>	<b>13,452</b>
<b>Total financial liabilities</b>	<b>29</b>	<b>13,422</b>	<b>13,452</b>

No significant changes have been made due to valuation methods, input data or assumptions since December 31, 2020. No financial assets or liabilities have been reclassified between the valuation categories. The fair value of financial assets and liabilities that are valued at amortised cost is deemed to essentially correspond to their fair value.

# EGETIS THERAPEUTICS

## Note 4 – Segments

As of April 1, 2019, the group has categorized and identified two independent segments of development for calmagangfodipir, PledOx and Aladote. As a result of the acquisition of RTT the segment report has been expanded with the develop area Emcitate. These three segments are independent R&D projects for which the chief operating decision maker in the company allocates company resources. The PledOx revenues consists of forwarding of expenses for the Asian part of the POLAR studies.

The table below specify revenues and costs attributed to PledOx and Aladote and Emcitate.

2021 Jan-Mar						2020 Jan-Mar					
KSEK	PledOx	Aladote	Emcitate	Common	Sum	KSEK	PledOx	Aladote	Common	Sum	
Revenues	1,248	-	2,539	-	3,787	Revenues	11,712	-	-	11,712	
Costs of sales of goods	-	-	-1,511	-	-1,511	Costs of sales of goods	-	-	-	-	
Project costs	-2,739	-2,710	-5,072	-	-10,521	Project costs	-49,051	-881	-	-49,932	
Other	0	-	-	-11,369	-11,369	Other	-10	-	-8,646	-8,656	
Operating results	<b>-1,491</b>	<b>-2,710</b>	<b>-4,043</b>	<b>-11,369</b>	<b>-19,613</b>	Operating results	<b>-37,349</b>	<b>-881</b>	<b>-8,646</b>	<b>-46,876</b>	
Net financial items					299	Net financial items				4,057	
Pretax profit					-19,315	Pretax profit				-42,818	

2020 Jan-Dec					
KSEK	PledOx	Aladote	Emcitate	Common	Sum
Revenues	38,935	-	1,727	-	40,662
Costs of sales of goods	-	-	-1,895	-	-1,895
Project costs	-153,692	-15,730	-13,854	-	-183,276
Other	-53	-	-	-33,834	-33,887
Operating results	<b>-114,809</b>	<b>-15,730</b>	<b>-14,022</b>	<b>-33,834</b>	<b>-178,395</b>
Net financial items					-725
Pretax profit					-179,120

## Turnover by country area

Sales to Japan are attributable to the segment PledOx och sales to other countries are attributable to the segment Emcitate. The PledOx segment has a customer for whom revenues relate to more than 10% of the segment's revenues. The revenue from this customer amounts to KSEK 1,248 (11,712) for the period.

Country	2021	2020	2020
	Jan-Mar	Jan-Mar	Jan-Dec
Japan	1,248	11,712	38,935
Europe	1,972	-	1,342
Sweden	342	-	87
Other countries	225	-	298
<b>Total</b>	<b>3,787</b>	<b>11,712</b>	<b>40,662</b>

## Turnover by type of revenue

	2021	2020	2020
	Jan-Mar	Jan-Mar	Jan-Dec
Re-invoicing of costs to Solasia	1,248	11,712	38,935
Sales of goods	2,539	-	1,727
<b>Total</b>	<b>3,787</b>	<b>11,712</b>	<b>40,662</b>

## Note 5 – Changes in financial liabilities due to financing activities

The below table presents a reconciliation of changes in liabilities divided by cash-flow and noncash- flow activities due to lease liabilities and other liabilities that are classifieds financing activities.

	12/31/2020		No affect on cash flow		3/31/2021
	Cash flow		Acquisition of business	New lease agreements	
Lease liabilities	4,666	-164	-	-	4,502
Other liabilities	15,000	-1,875	-	-	13,125
<b>Closing balance</b>	<b>19,666</b>	<b>-2,039</b>	<b>-</b>	<b>-</b>	<b>17,627</b>

	12/31/2018		No affect on cash flow		3/31/2020
	Cash flow		Acquisition of business	Transition to IFRS 16	
Lease liabilities	-	-54	-	240	186
<b>Closing balance</b>	<b>-</b>	<b>-54</b>	<b>-</b>	<b>240</b>	<b>186</b>

## Note 6 – Related party transactions

There are no transactions to be reported with related parties.

## 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.

## 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 ratio Equity 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.

**Return on equity, %** Net income divided by shareholders' equity. The company uses the alternate key figure Return on equity, % because the company believes that the key ratio gives investors a better understanding of the return generated on the total capital that the shareholders have invested in the Company.

**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

		2021	2020	2020
		Oct-Dec	Oct-Dec	Jan-Dec
A	Equity, KSEK	610,509	202,057	629,627
B	Balance sheet total, KSEK	850,758	234,104	893,967
<b>A/B</b>	<b>Equity ratio %</b>	<b>72%</b>	<b>86%</b>	<b>70%</b>
A	Net result, KSEK	-19,315	-42,818	-179,120
B	Equity, KSEK	610,509	202,057	629,627
<b>A/B</b>	<b>Return on equity, %</b>	<b>neg.</b>	<b>neg.</b>	<b>neg.</b>
A	Cash flow from operating activities, KSEK	-35,005	-37,119	-134,639
B	Average number of shares under the period, before dilution, thousand	165,069	53,533	67,391
<b>A/B</b>	<b>Cash flow from operating activities per shares, SEK</b>	<b>-0.2</b>	<b>-0.7</b>	<b>-2.0</b>
A	Equity, KSEK	610,509	202,057	629,627
B	Average number of shares at the end of the period before dilution, thousand	165,069	53,533	67,391
<b>A/B</b>	<b>Equity per average number of shares before dilution, SEK</b>	<b>3.7</b>	<b>3.8</b>	<b>9.3</b>
A	Equity, KSEK	610,509	202,057	629,627
B	Average number of shares at the end of the period after dilution, thousand	165,069	53,533	67,391
<b>A/B</b>	<b>Equity per average number of shares after dilution, SEK</b>	<b>3.7</b>	<b>3.8</b>	<b>9.3</b>

# EGETIS THERAPEUTICS

## Other information

### Next reports

Annual General Meeting April 29, 2021.

Interim report April 1- June 30, August 19, 2021.

Interim report July 1- September 30, 2021, November 4, 2021.

This report, and further information is available on the website, [www.egetis.com](http://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 22, 2021 at 8.00 am (CET).

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ABGSC, Viktor Sundberg

# EGETIS THERAPEUTICS

## Certification

This report provides a true and fair overview of the company's business activities, financial position, and results of operations, and describes significant risks and uncertainties to which the company is exposed.

Stockholm, April 22, 2021.

Håkan Åström

*Chairman of the board*

Elisabeth Svanberg

Board member

Sten Nilsson

Board member

Gunilla Osswald

Board member

Peder Walberg

Board member

Nicklas Westerholm

CEO