

Half-Year report January-June 2021

# **Emcitate development program progressing according** to plan

# **Financial overview April-June**

- Quarterly net revenues MSEK 25.0 (21.7)
- Quarterly loss MSEK -34.3 (-36.2)
- Cash and cash equivalents MSEK 207.4 (184.5)
- Cash flow for the period MSEK-41.8 (-33.8)
- Loss per share before/after dilution SEK -0.2 (-0.7)

# Significant events during the period **April-June**

- Kristina Sjöblom Nygren, MD, joined Egetis Therapeutics as Chief Medical Officer (CMO) and Yilmaz Mahshid, PhD, joined Egetis Therapeutics as Chief Financial Officer (CFO).
- Dr Thomas Lönngren (Chairman) and Mats Blom were elected as new Directors of the Board at the Annual General Meeting on the 29th of April.

## **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.
- Continued 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 120 patients in total already getting access to Emcitate treatment.

## Financial overview January - June

- Net revenues for the period MSEK 28.8 (33.2)
- Loss for the period MSEK -53.6 (-79.0)
- Cash and cash equivalents MSEK 207.4 (184.5)
- Cash flow for the period MSEK -80.1 (-71.1)
- Loss per share before/after dilution SEK -0.3 (-1.5)

## **Aladote®**

- Aladote was presented at the scientific meeting of the American College of Medical Toxicology (ACMT) on April 14, under the heading Antidote
- Preparation for the pivotal Phase IIb/III study for Aladote continues targeting study start at the end of 2021, pending the COVID-19 pandemic situation.

## **PledOx**°

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

## Significant events after the reporting period

The results of the prematurely discontinued POLAR program with PledOx were presented at the ESMO World Congress on Gastrointestinal Cancer on July 2.

## Financial overview

	2021	2020	2021	2020	2020
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net revenues, KSEK	25,034	21,697	28,822	33,201	40,662
Result after tax, KSEK	-34,326	-36,164	-53,641	-78,983	-179,120
Cash flow, KSEK	-41,768	-33,802	-80,129	-71,063	34,223
Cash, KSEK	207,411	184,470	207,411	184,470	287,850
Equity ratio %	69%	86%	69%	86%	70%
Earnings per share, SEK	-0.2	-0.7	-0.3	-1.5	-2.7
Earnings per share after dilution, SEK	-0.2	-0.7	-0.3	-1.5	-2.7
Average number of employees	10	9	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 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.

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



## **Comments from the CEO**

The second quarter continued the positive momentum of integrating RTT (Rare Thyroid Therapeutics) and progressing the Emcitate development program. We have indeed sustained the good start to Egetis Therapeutics, dedicated to development and commercialization of therapies for rare diseases, with two important assets Emcitate and Aladote – both in late-stage clinical development. Our aim 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.

Patient recruitment to the TRIAC II study with Emcitate progressed well in the second quarter, and the recruitment is expected to be completed in Q4 2021 according to plan. I am gratified that we continue to recruit patients to the study according to plan despite the challenging Covid-19 situation. Interim results are targeted to be available in Q4 2022 and are 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 a continued 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 before market approval 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 120 patients in more than 20 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 is still making 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 at the end of this year.

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. At the scientific meeting of the American College of Medical Toxicology (ACMT) in April Professor James Dear from the University of Edinburgh, UK, presented Aladote as a novel emerging treatment of paracetamol overdose.

## Cash position

To continue the development of our clinical portfolio, we reported a cash position of approximately 207 million SEK on June 30, 2021, which is planned to finance the development of Emcitate and Aladote.

## Strengthened organization and board

We continued 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 our innovative drug candidates. In May, Kristina Sjöblom Nygren, MD, joined us as Chief Medical Officer (CMO). In June, Yilmaz Mahshid, PhD, joined the company as Chief Financial Officer (CFO). I worked with Yilmaz for three years at PledPharma and am pleased to renew this fruitful collaboration.

At the Annual General Meeting on April 29, Dr Thomas Lönngren (chairman) and Mats Blom were elected as new Board of Directors. We are grateful to have Thomas and Mats on the Board adding valuable

# EGETIS THERAPEUTICS

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 tenure as Head of the European Medicines Agency (EMA) will provide superior expertise of the regulatory framework in the life science sector.

I am grateful to employees and directors for their support and strong belief in the company. This was illustrated amongst others by executives in Egetis Therapeutics acquiring shares. We have proactively continued to promote the company's equity story and participated at a number of conferences during the period, including ABG Life Science Summit, Erik Penser Bank Commercialization of Pharmaceuticals, and Redeve Orphan Drugs event.

## 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 development programs. I look forward to relaying news to you around the projects and the progress of Egetis Therapeutics.

Nicklas Westerholm, CEO

# **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 (TRIAC II) in young patients with the drug candidate Emcitate progresses according to plan. Patient recruitment is expected to be completed in Q4 2021.

Continued 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 120 patients already getting access to Emcitate treatment.

# Significant events after the reporting period

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.

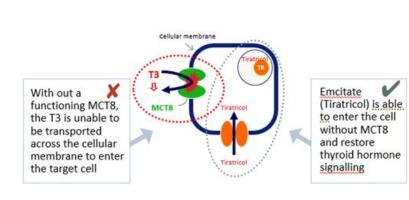
Thyroid hormone is crucial for the development and metabolic state of virtually all tissues. Thyroid hormone transport across the plasma membrane is required for the hormone's metabolism and intracellular action and is facilitated by thyroid hormone transporters, including monocarboxylate transporter 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 (TRIAC I) 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 (TRIAC II) was initiated with the first patient dosed in Q4 2020. 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. Patient recruitment is expected to be completed in Q4 2021. Results from an interim analysis following 12 months treatment are planned Q4 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**

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

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

# Significant events after the reporting period

No events to report.

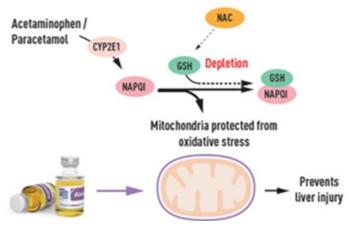
## **About Aladote**

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 Nacetylcysteine (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.

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 in the US, EU and UK is planned after successful completion of the study.





# **PledOx**

## **Events during the quarter**

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.

## Significant events after the reporting period

The results of the prematurely discontinued POLAR program with PledOx were presented at the ESMO World Congress on Gastrointestinal Cancer on July 2. By end of August, results will be available at clinicaltrials.gov. Work has been initiated on a publication together with the coordinating investigators. Submission to a peer-reviewed journal is targeted later in the year and will complete the PledOx POLAR program.

## **About PledOx**

PledOx was 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 μmol/kg and 5 μmol/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 μmol/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 company has parked further PledOx development following the POLAR results.



# **Financial Information**

## Half-Year report January-June 2021

## Revenue, and results

## **Revenues**

Revenues amounted to KSEK 25,034 (21,488) during the guarter and 28,822 (33,201) for the period. The revenue consisted of Emcitate sales of KSEK 3,691 (-) during the quarter and KSEK 6,230 (-) (during the period) and forwarding of expenses related to PledOx to Solasia Pharma K.K (Solasia) of KSEK 21,343 (21,488) during the quarter and KSEK 22,591 (33,201) during the period.

## **Expenses**

Operating expenses amounted to KSEK 58,891 (55,499) during the quarter and KSEK 82,292 (113,878) during the period. The project expenses amounted to KSEK 45,900 (48,194) during the quarter and KSEK 56,421 (98,126) during the period. The project expenses consisted of expenses due to Emcitate of KSEK 7,475 (-), Aladote KSEK 10,606 (2,967) and PledOx KSEK 27,819 (45,227) for the quarter and KSEK 12,547 (-), Aladote KSEK 13,316 (3,848) and PledOx KSEK 30,558 (94,278) for the period. The higher PledOx costs in the quarter are due to the final payment for the POLAR studies. Of the quarterly costs of KSEK 27,819, KSEK 21,343 was forwarded to Solasia.

Employee costs amounted to KSEK 6,449 (5,646) during the quarter and KSEK 12,834 (11,354) for the period.

Other external costs amounted to KSEK 3,922 (1,607) for the quarter and KSEK 8,412 (3,706) for the period. The increase is mainly due to higher auditor expenses and consultancy costs. Depreciation amounted to KSEK 678 (52) for the quarter and KSEK 1,114 (106) for the period. The depreciation during the period derives from amortization of licences with KSEK 541 (-), depreciation of right-of-use assets with KSEK 548 (106) and depreciation of inventories with KSEK 25 (-). Other operating expenses amounted to KSEK 16 (-) for the quarter and 72 (586) for the period and consists of exchange rate differences from operating income and operating expenses.

## **Results**

Operating results amounted to KSEK -33,857 (-33,802) for the quarter and KSEK -53,470 (-80,677) for the period. Net financial items amounted to KSEK -469 (-2,363) for the quarter and KSEK -170 (1,695) for the period. Results from net financial items are related to unrealized revaluation of company's FX-accounts. Results after financial items amounted to KSEK -34,326 (-36,164) for the quarter and KSEK -53,641 (-78,983) for the period. Result per share before and after dilution amounted to SEK -0.2 (-0.7) for the quarter and SEK -0.3 (-1.5) for the period both before and after dilution.

## **Financial position**

Cash as of June 30, 2021, amounted to KSEK 207,411 (184,470).

## **Cash flow**

Cash flow from operating activities amounted to KSEK -38,174 (-33,749) for the quarter and KSEK -73,180 (-70,957) for the period. Total Cash flow amounted to KSEK -41,767 (-33,802) for the quarter and KSEK -80,129 (-71,063) for the period. Cash flow from operating activities is driven by costs related to the projects. Cash flow from investment activities amounted to KSEK -2,616 (-) during the period of which KSEK 2,500 are due to deferred purchase price of RTT and KSEK 116 are due to acquisition of inventories. Cash flow from financing activities amounted to KSEK -4,333 (-105) for the period and are mainly due to amortization of loans.

## **Equity and equity ratio**

As of June 30, 2021, equity amounted to KSEK 576,406 (165,995). Shareholders' equity per share amounted to SEK 3.5 (3.1), at the end of the period. The company's equity ratio was 69 (86) %.

## **Debts and receivables**

As of June 30, 2021, non-current liabilities amounted to KSEK 187,950 (34). These consists mainly of liabilities that derive from the acquisition of RTT as



deferred tax liability of KSEK 119,847 (-) and other long-term liabilities of KSEK 67,874 (34). Current liabilities amount to KSEK 67,153 (27,174) of which other liabilities amount to KSEK 14,896 (989) and accounts payable amount to KSEK 34,751 (10,089).

## Investments, tangible and intangible assets

As of June 30, 2021, non-current intangible assets amounted to KSEK 593,667 (134). The major difference vs prior period is the acquisition of RTT during 2020 where KSEK 581,784 of the acquisition value were classified as non-current intangible assets. No significant investments were allocated to tangible assets.

### Shares

The number of shares as of June 30, 2021, were 165,068,560 (53,533,321). The number of shareholders were 6,822 as of June 30, 2021. The 20 largest shareholders hold 68.4 % of outstanding shares. Egetis Therapeutics shares are listed on Nasdaq Stockholm's main market.

# Stock option plan and warrant programs Information regarding existing incentive programs.

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 options and warrants approved by the AGM would increase the number of shares with 11,293,100 to a total of 176,361,660.

## Employee Stock option plan 2021/2025

The 2021 Annual General Meeting resolved on a 2021/2025 stock option plan of 5,000,000 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 6,571,000 warrants to its subsidiary Egetis Therapeutics Incentive AB, of which 4,900,000 ESOPs were granted to the employees as of June 30, 2021.

## Employee 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 PledPharma (previous company name).

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 (previous company name), of which 2,900,000 warrants was granted to the employees as of June 30, 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 granted to 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 June 30, 2021, were 11 (9) persons, 6 women and 5 men.

## **Parent company**

The parent company's revenues for the quarter amounted to KSEK 21,343 (21,488) and for the period to KSEK 22,591 (33,201). Sales during the period consist of KSEK 22,591 (33,201) due to forwarding of expenses related to PledOx to Solasia. Other income for the quarter amounted to KSEK 2,668 (209) and for the period to KSEK 4,316 (-). Other income for the period consisted of KSEK 3,451 (-) management fees invoiced to the subsidiary RTT and KSEK 865 (-) are forwarding of expenses to RTT.

Operating expenses amounted to KSEK 50,393 (55,499) during the quarter and KSEK 66,864 (113,879) for the period. The project expenses amounted to KSEK 39,990 (48,194) for the quarter and KSEK 45,745 (98,126) during the period.



The parent company's result after financial net amounted to KSEK -26,792 (-36,164) for the quarter and -40,072 (-78,981) for the period.

Financial non-current assets amount to KSEK 490,295 (50) and other long-term liabilities amount to KSEK 60,716 (34). Increases in comparison to prior period are due to the acquisition of RTT during 2020.



# **Consolidated statement of comprehensive income**

KSEK	2021	2020	2021	2020	2020
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Revenue					
Revenues	25,034	21,488	28,822	33,201	40,662
Other operating income	-	209	-	-	-
	25,034	21,697	28,822	33,201	40,662
Operating expenses					
Costs of sales of goods	-1,926	-	-3,437	-	-1,895
Project costs	-45,900	-48,194	-56,421	-98,126	-183,276
Other external costs	-3,922	-1,607	-8,412	-3,706	-11,097
Employee costs	-6,449	-5,646	-12,834	-11,354	-22,151
Depreciation and impairment	-678	-52	-1,114	-106	-395
Other operating expenses	-16	-	-72	-586	-243
Sum operating expenses	-58,891	-55,499	-82,292	-113,878	-219,057
Operating results	-33,857	-33,802	-53,470	-80,677	-178,395
Financial items					
Interest income and similar items	-	43	72	1,702	163
Interest expense and similar items	-469	-2,406	-242	-7	-888
Sum financial items	-469	-2,363	-170	1,695	-725
Results after financial net	-34,326	-36,164	-53,641	-78,983	-179,120
Tax	-	-	-	-	-
Results after tax	-34,326	-36,164	-53,641	-78,983	-179,120
Statement of comprehensive income					
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	-34,326	-36,164	-53,641	-78,983	-179,120
Not cornings and comprehensive income is					
Net earnings and comprehensive income is entirely attributable to parent company					
shareholders					
Share Data					
Number of shares at the end of period	165,068,560	53,533,321	165,068,560	53,533,321	165,068,560
Average number of shares during period	165,068,560	53,533,321	165,068,560	53,533,321	67,391,206
Earnings per share before dilution (SEK)	-0.2	-0.7	-0.3	-1.5	-2.7
Earnings per share after dilution (SEK)	-0.2	-0.7	-0.3	-1.5	-2.7
Equity per average number of shares	3.5	3.1	3.5	3.1	9.3
Equity per average number of shares after	3.5	3.1	3.5	3.1	9.3
dilution					



# **Consolidated statement of financial position**

KSEK	6/30/2021	6/30/2020	12/31/2020
ASSETS			
Non-current assets			
Research and development costs	581,784	-	581,784
Licences	7,031	-	7,571
Right-of-use assets	4,853	134	4,666
Equipment	166	_	75
Total non-current assets	593,832	134	594,097
Current assets			
Inventories	1,637	_	3,138
Accounts receivables	25,889	6,130	3,883
Other receivables	1,642	922	2,960
Prepaid expenses and accrued income	1,099	1,547	2,039
Cash and bank balance	207,411	184,470	287,850
Total current assets	237,678	193,069	299,871
Total assets	831,510	193,204	893,967
KSEK	30/06/2021	30/06/2020	31/12/2020
Equity			
Share capital	8,688	2,818	8,688
Other capital contributions	1,262,837	705,387	1,262,837
Reserves	868	-	448
Accumulated loss including net loss	-695,986	-542,210	-642,346
Total equity	576,406	165,995	629,627
Non-current liabilities			
Deferred tax liabilities	119,847	-	119,847
Other long-term liabilities	67,874	34	74,242
Provisions	229	_	109
Total non-current liabilities	187,950	34	194,198
Current liabilities			
Accounts payable	34,751	10,089	15,611
Other liabilities	14,896	989	14,542
Accrued expenses and deferred income	17,506	16,096	39,988
Total current liabilities	67,153	27,174	70,141
Total equity and liabilities	831,510	193,204	893,967



# **Consolidated statement of cash flows**

KSEK	2021	2020	2021	2020	2020
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-34,326	-36,164	-53,641	-78,983	-179,120
Adjustments for non-cash items	1,603	3,066	2,028	-182	2,430
Tax paid	-	-	-	-	-
Cash flow from operating activities before changes	-32,723	-33,098	-51,613	-79,165	-176,690
in working capital					
Cash flow from changes in working capital					
Increase/decrease in operating receivables	-18,854	4,171	-18,247	6,250	16,428
Increase/decrease in operating liabilities	13,402	-4,822	-3,320	1,958	25,624
Cash flow from changes in working capital	-5,452	-651	-21,567	8,208	42,052
Cash flow from operating activities	-38,174	-33,749	-73,180	-70,957	-134,639
INVESTING ACTIVITIES					
Acquisition of subsidiaries, net cash required	-1,250	-	-2,500	-	-59,520
Investment in financial assets	_	-	_	-	_
Purchase of property, plant and equipment	-49	-	-116	-	-24
Cash flow from investing activities	-1,299	-	-2,616	-	-59,543
FINANCINGACTIVITIES					
New share issue	-	-	-	-	250,750
Cost new share issue	-	-	-	-	-22,130
Repayment of loans	-1,875	-	-3,750	-	-
Repayment of leases	-418	-53	-583	-105	-215
Cash flow from financing activities	-2,293	-53	-4,333	-105	228,405
Cash flow for the period	-41,767	-33,802	-80,129	-71,063	34,223
	0.42 ===	001.11	00= 0=	057.45	055.40
Balance at beginning of period	249,775	221,141	287,850	255,101	255,101
Change in cash	-41,767	-33,802	-80,129	-71,063	34,223
Exchange rate difference in cash	-597	-2,869	-311	431	-1,473
CASH BALANCE AT THE END OF THE PERIOD	207,411	184,470	207,411	184,470	287,850



# Consolidated statement of changes in equity

KSEK	Share capital	Other capital contributions	Accumulated loss incl. net results for the period	Other reserves	Total equity
Opening balance 20210101	8,688	1,262,837	-642,346	448	629,627
Comprehensive income for the period	-	-	-53,641	-	-53,641
Costs due to share-based payments of					
employee stock option plan	-	-	-	420	420
Closing balance 20210630	8,688	1,262,837	-695,986	868	576,406
Opening balance 20200101	2,818	705,278	-463,227	-	244,876
Incentive program/New share issue	-	109		-	109
Comprehensive income for the period	-	-	-78,983_	-	-78,983
Closing balance 20200630	2,818	705,387	-542,210	-	165,995
Opening balance 20200101	2,818	705,278	-463,220	-	244,876
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
Closing balance 20201231	8,688	1,262,837	-642,346	448	629,627

# **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	2020	2020
	Jan-Jun	Jan-Jun	Jan-Dec
Equity	576,406	165,995	629,627
Equity ratio %	69%	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	-0.3	-1.5	-2.7
Earnings per share after dilution	-0.3	-1.5	-2.7
Cash flow from operating activities	-0.5	-1.3	0.2
Equity per average number of shares	3.5	3.1	9.3
Equity per average number of shares after dilution	3.5	3.1	9.3
Dividend	-	-	-
Average number of employees	10	9	9



# **Parent company - income statement**

KSEK	2021	2020	2021	2020	2020
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Revenue					
Revenues	21,343	21,488	22,591	33,201	38,935
Other operating income	2,668	209	4,316	-	332
	24,011	21,697	26,907	33,201	39,267
Operating expenses					
Project costs	-39,990	-48,194	-45,745	-98,126	-169,422
Other external costs	-3,944	-1,660	-8,170	-3,812	-9,806
Employee costs	-6,449	-5,646	-12,877	-11,354	-22,152
Depreciation and impairment	-11	-	-17	-	-1
Other operating expenses	-	-	-55	-586	-290
Sum operating expenses	-50,393	-55,499	-66,864	-113,879	-201,670
Operating results	-26,382	-33,802	-39,957	-80,678	-162,403
Financial items					
Interest income and similar items	-	43	52	1,702	163
Interest expense and similar items	-410	-2,405	-167	-6	-885
Sum financial items	-410	-2,363	-115	1,697	-722
Results after financial net	-26,792	-36,164	-40,072	-78,981	-163,125
Appropriations	-	-	-23,000	-	-
Tax	-	-	-	-	-
Results after tax	-26,792	-36,164	-63,072	-78,981	-163,125



# Parent company - balance sheet

KSEK	6/30/2021	6/30/2020	12/31/2020
ASSETS			
Non-current assets			
Equipment	123	_	23
Financial non-current assets	490,172	50	490,172
Total non-current assets	490,295	50	490,195
Current assets			
Accounts receivables	22,124	6,130	2,470
Other receivables	266	922	2,266
Prepaid expenses and accrued income	774	1,547	1,135
Cash and bank balance	184,075	184,170	285,830
Total current assets	207,239	192,770	291,701
Total assets	697,533	192,820	781,896
KSEK	30/06/2021	30/06/2020	31/12/2020
Equity			
Restricted Equity			
Share capital	8,688	2,818	8,688
Non-restricted equity			
Share premium reserve	636,235	198,984	799,360
Reserves	868	109	448
Net loss for the period	-63,072	-36,164	-163,125
Total equity	582,719	165,747	645,371
Non-current liabilities			
Other non-current liabilities	60,716	34	63,216
Provisions	229		109
Total non-current liabilities	60,944	34	63,325
Current liabilities			
Liabilities to group company	-	-	19,209
Accounts payable	32,416	10,089	10,755
Other liabilities	5,862	854	5,840
Accrued expenses and deferred income	15,592	16,096	37,396
Total current liabilities	53,870	27,039	73,199
Total equity and liabilities	697,533	192,820	781,896



## **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. Some amendments to existing standards became applicable from January 1, 2021, 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 thousands 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 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, note 3. 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 Emcitate 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.

## Note 3 - Financial assets and liabilities

All financial assets and liabilities are measured at amortized costs except liability due to contingent considerations. Liability due to contingent considerations price are classified as level 3 in the fair value hierarchy. The liability due to contingent considerations is based on the market and sector practice methodology, net present valuation of pharmaceutical projects in research and development phase. The valuation is based on several different assumptions such as pricing, growth rate, exchange rates, market share, probabilities and discount rate.

KSEK	Non-current	Current	Total
Group June 30, 2021			
FINANCIAL ASSETS MEASURED AT			
AMORTISIED COST			
Accounts receivable	-	25,889	25,889
Cash Total financial assets	-	207,411 <b>233,300</b>	207,411 <b>233,300</b>
i otai iiilaiiciai assets	_	233,300	233,300
FINANCIAL LIABLILITIES MEASURED AT FAIR			
VALUE THROUGH PROFIT AND LOSS			
Contingent consideration	58,216	-	58,216
Total	58,216	-	58,216
FINANCIAL LIABILITIES MEASURED AT			
AMORTISIED COST Lease liabilities	3,409	1,473	4,881
Accounts payable	3,409	34,751	34,751
Deferred purchase price	2,500	5,000	7,500
Other liabilities	3,750	7,500	11,250
Total	9,659	48,723	58,382
Total financial liabilities	67,874	48,723	116,598
Group June 30, 2020			
FINANCIAL ASSETS MEASURED AT			
AMORTISIED COST			
Accounts receivable	_	6,130	6,130
Cash	-	184,470	184,470
Total financial assets	-	190,600	190,600
FINANCIAL LIABILITIES MEASURED AT			
AMORTISIED COST			
Lease liablilities	_	136	136
Accounts payable	-	10,089	10,089
Other liabilities	-	-	-
Total	-	10,224	10,224
Total financial liabilities	-	10,224	10,224

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.



## Note 4 - Segments

As of April 1, 2019, the group has categorized and identified two independent segments of development for calmangafodipir, PledOx and Aladote. As a result of the acquisition of RTT the segment report has been expanded with 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. Emcitate revenues are due to Named Patient Use (NPU) of the drug candidate.

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

2021						2020				
Apr-Jun						Apr-Jun				
KSEK	PledOx	Aladote	Emcitate	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	21,343	-	3,691	-	25,034	Revenues	21,488	-	-	21,488
Costs of sales of goods	-	-	-1,926	-	-1,926	Costs of sales of goods	-	-	-	-
Project costs	-27,819	-10,606	-7,475	-	-45,900	Project costs	-45,227	-2,967	-	-48,194
Other	-	-	-	-11,064	-11,064	Other	-10	-	-7,086	-7,096
Operating results	-6,476	-10,606	-5,710	-11,064	-33,857	Operating results	-23,749	-2,967	-7,086	-33,802
Net financial items					-469	Net financial items				-2,363
Pretax profit				-	-34,326	Pretax profit				-36,164
2021						2020				
Jan-Jun						Jan-Jun				

2021 Jan-Jun						2020 Jan-Jun				
KSEK	PledOx	Aladote	Emcitate	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	22,591	-	6,230	-	28,822	Revenues	33,201	-	-	33,201
Costs of sales of goods	-	-	-3,437	-	-3,437	Costs of sales of goods	-	-	-	-
Project costs	-30,558	-13,316	-12,547	-	-56,421	Project costs	-94,278	-3,848	-	-98,126
Other	-	-	-	-22,433	-22,433	Other	-20	-	-15,732	-15,752
Operating results Net financial items Pretax profit	-7,967	-13,316	-9,753	-22,433 -	-53,470 -170 -53,641	Operating results Net financial items Pretax profit	-61,098	-3,848	-15,732	-80,677 1,695 -78,983

2020					
Jan-Dec					
KSEK	PledOx	Aladote	<b>Emcitate</b>	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	-114,809	-15,730	-14,022	-33,834	-178,395
Net financial items				_	-725
Pretax profit				•	-179,120



## Revenues by country area

Revenues to Japan are attributable to the segment PledOx and revenues to other countries are attributable to the segment Emcitate. The PledOx segment has only a single customer who account for all revenues reported. Revenues from this single customer amounts to KSEK 22,591 (33,201) for the period. In the Emcitate segment revenues from two countries account for more than 10% of the segment's sales.

KSEK	2021	2020	2021	2020	2020
Country	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Japan	21,343	21,488	22,591	33,201	38,935
France	833	-	1,398	-	-
Spain	1,076	-	1,704	-	-
Sweden	558	-	899	-	87
Other countries	1,225	-	2,229	-	1,640
Total	25,034	21,488	28,822	33,201	40,662

## Turnover by type of revenue

	2021	2020	2021	2020	2020
KSEK	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Re-invoicing of					
costs to Solasia	21,343	21,488	22,591	33,201	38,935
Sales of goods	3,691	-	6,230	-	1,727
Total	25,034	21,488	28,822	33,201	40,662



## 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 non-cash flow activities due to lease liabilities and other liabilities that are classifieds financing activities.

		No affect on cash flow			
	31/12/2020	Cash flow	Acquisition of business	New lease agreements	30/06/2021
Lease liablilities	4,666	-583	-	798	4,881
Other liabilities	15,000	-3,750	-	· -	11,250
Closing balance	19,666	-4,333		-	15,333
		No affect on cash flow			
	31/12/2019	Cash flow	Acquisition of business	Transition to IFRS 16	30/06/2020
Lease liablilities	-	-105	-	241	136
Closing balance	-	-105	-	241	136

## Note 6 - Related party transactions

Peder Wahlberg is consulting the company and has invoiced the company KSEK 1,234, during 2021.

## 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

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
		Jan-Jun	Jan-Jun	Jan-Dec
Α	Equity, KSEK	576,406	165,995	629,627
В	Balance sheet total, KSEK	831,510	193,204	893,967
A/B	Equity ratio %	69%	86%	70%
Α	Net result, KSEK	-53,641	-78,983	-179,120
В	Equity, KSEK	576,406	165,995	629,627
A/B	Return on equity, %	neg.	neg.	neg.
Α	Cash flow from operating activities, KSEK	-80,129	-71,063	34,223
В	Average number of shares under the period, before dilution,	165,069	53,533	67,391
A/B	Cash flow from operating activities per shares, SEK	-0.5	-1.3	0.5
Α	Equity, KSEK	576,406	165,995	629,627
В	Average number of shares at the end of the period before	165,069	53,533	67,391
A/B	Equity per average number of shares before dilution, SEK	3.5	3.1	9.3
Α	Equity, KSEK	576,406	165,995	629,627
В	Average number of shares at the end of the period after	165,069	53,533	67,391
A/B	Equity per average number of shares after dilution, SEK	3.5	3.1	9.3



## Other information

## **Next report**

Interim report January – September 2021, November 4, 2021.

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:

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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 August 19, 2021, at 8.00 am (CET).

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## **Analysts who follow Egetis Therapeutics**

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## Certification

This interim report for the January-June 2021 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 19, 2021.	
Thomas Lönngren Chairman of the board	Elisabeth Svanberg Board member
Gunilla Osswald Board member	Mats Blom Board member
Peder Walberg Board member	Nicklas Westerholm CEO