

## **Interim report January-September 2021**

# **Emcitate® receives FDA Fast Track Designation**

## Financial overview July - September

- Quarterly net revenue MSEK 6.2 (2.6)
- Quarterly loss MSEK -22.5 (-24.7)
- Cash and cash equivalents MSEK 173.2 (159.4)
- Cash flow for the period MSEK-34.5 (-24.6)
- Loss per share before/after dilution SEK -0.1 (-0.5)

## Financial overview January - September

- Net revenue for the period MSEK 35.0 (35.8)
- Loss for the period MSEK -76.2 (-103.7)
- Cash and cash equivalents MSEK 173.2 (159.4)
- Cash flow for the period MSEK -115.4 (-95.8)
- Loss per share before/after dilution SEK -0.5 (-1.9)

# Significant events during the period July

## - September

#### **Emcitate®**

- Egetis receives approval in Turkey for compassionate use of Emcitate® for MCT8 deficiency.
- Egetis Therapeutics launches disease awareness initiatives to support identification of subjects with suspected MCT8 deficiency.

#### **Aladote®**

Preparation for the pivotal Phase IIb/III study for Aladote continues targeting study start early 2022, pending the COVID-19 pandemic situation.

#### Significant events after the reporting period

- Egetis Therapeutics receives FDA Fast Track Designation for Emcitate® for MCT8 deficiency.
- New data published confirms long-term efficacy and safety of Emcitate® (tiratricol) in MCT8 deficiency patients.

## **Financial overview**

	2021	2020	2021	2020	2020
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Net revenues, KSEK	6,210	2,572	35,032	35,772	40,662
Result after tax, KSEK	-22,530	-24,726	-76,171	-103,710	-179,120
Cash flow, KSEK	-34,491	-24,599	-115,400	-95,776	34,223
Cash, KSEK	173,150	159,424	173,150	159,424	287,850
Equity ratio %	71%	86%	71%	86%	70%
Earnings per share, SEK	-0.1	-0.5	-0.5	-1.9	-2.7
Earnings per share after dilution, SEK	-0.1	-0.5	-0.5	-1.9	-2.7
Average number of employees	11	9	11	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 has been

granted Rare Pediatric Disease Designation and Fast Track Designation by the US FDA. 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. There is an ongoing dialogue with EMA on the appropriate indication for an ODD in the EU.

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



#### **Comments from the CEO**

In the third quarter, Egetis Therapeutics continued its good progress with lead candidate Emcitate®, while the next clinical study with Aladote® is targeting study start early 2022, pending the COVID-19 pandemic situation.

## New data published confirms long-term efficacy and safety of Emcitate® in MCT8 deficiency patients

In October we announced that strong data from longterm treatment, up to 6 years, of 67 patients with the company's leading drug candidate Emcitate has been published in the Journal of Clinical Endocrinology & Metabolism. The data comes from an investigatorinitiated real-life cohort study at 33 sites conducted by the Erasmus Medical Center, Rotterdam, Netherlands, where the efficacy and safety of Emcitate (tiratricol) was investigated in 67 patients with MCT8 deficiency. These long-term data confirm the positive results from our previous trial with Emcitate, TRIAC Trial I, and indicate that the beneficial effects are maintained over time, up to six years. The consistent efficacy seen across several key clinical and biochemical parameters regardless of age, further supports the use of Emcitate in the treatment of MCT8 deficiency. We are currently evaluating how this data can be used as additional evidence in forthcoming regulatory submissions of a Marketing Authorisation Application (MAA) in Europe and a New Drug Application (NDA) in the US.

### **Fast Track Designation granted for Emcitate**

In early October, the U.S. Food and Drug Administration (FDA) granted Emcitate Fast Track Designation for the treatment of MCT8 deficiency. This designation is an acknowledgement from the FDA of the importance of Emcitate to address the significant unmet medical need in MCT8 deficiency. With a Fast Track Designation come opportunities to expedite both the NDA submission and FDA's review which can enable an earlier regulatory approval of Emcitate. Emcitate, has already been granted Orphan Drug Designation (ODD) in both EU and the US, as well as a US Rare Pediatric Disease designation (RPD).

## Patient recruitment to the TRIAC II study with Emcitate progressed well in the third quarter,

## and the recruitment is targeted to be completed in Q4 2021

We continue to recruit patients to the clinical phase IIb/III study TRIAC II despite the challenging Covid-19 situation. 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.

## Emcitate supplied on compassionate use and named patient basis

As we continue our clinical program with Emcitate, we see a continued interest from physicians across the globe to treat patients that suffer from MCT8 deficiency with our lead candidate drug. Emcitate is supplied on a named patient or compassionate use basis, following individual regulatory approval from the national regulatory agency. Compassionate use and named patient programs are mechanisms to allow early access to a medicine prior to regulatory marketing approval, granted to pharmaceuticals under development for conditions with high unmet medical needs and where no available treatment alternatives exist or are suitable.

More than 130 patients in more than 25 countries have been granted such named patient approval and are being treated with Emcitate, underlining the significant unmet medical need in this patient population and verifies the interest to treat patients that suffer from MCT8 deficiency.

In September, we received approval from the Turkish Medicines Agency for a compassionate use program of Emcitate.

## Launch of campaign to raise awareness of MCT8 deficiency

We are committed to help transforming and extending the lives of patients with rare diseases such as MCT8 deficiency. One important pillar in this commitment is raising disease awareness, and with this purpose we launched an awareness campaign, including the website www.mct8deficiency.com in September. In addition to other disease educational activities, e.g. at scientific and medical conferences targeting health care professionals, the website will be used for educational purposes through the expanding network



of key opinion leaders, physicians and patient advocacy groups focused on MCT8 deficiency.

With these activities, we aim to shorten the time toe diagnosis of MCT8 deficiency and relieve some of the heavy burden that MCT8 deficiency places on the affected individuals and the caregivers they are heavily dependent on.

## 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 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 early next 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. An application for an ODD in the EU was submitted in March, and we have an ongoing dialogue with EMA on the appropriate indication for an ODD in the EU.

#### **Cash position**

We reported a cash position of approximately 173 million SEK on September 30, 2021, which is planned to finance the continued clinical development of Emcitate and Aladote.

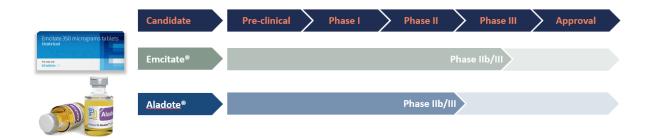
I am grateful to employees and directors for their support and strong belief in the company. This was illustrated among other things by executives in Egetis Therapeutics acquiring additional shares in late August.

#### **Looking ahead**

Our focus on our clinical candidates with their opportunity to provide treatment for patients suffering from rare and serious diseases remains firm as we shape the future of Egetis, our exciting company focusing on the orphan drug and rare disease segment. 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**





## **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 progressed in the third quarter despite challenging Covid-19 situation. Patient recruitment is targeted to be completed in Q4 2021.

There is continued interest in the opportunity to treat MCT8 deficiency with Emcitate from physicians across the globe. Egetis supplies Emcitate on a compassionate use or named patient basis in several countries, following special approval from the national regulatory authority with more than 130 patients in more than 25 countries already getting access to Emcitate treatment.

Egetis received approval from the Turkish Medicines Agency for compassionate use of Emcitate for MCT8 deficiency.

Egetis Therapeutics launched disease awareness initiatives to support diagnosis of MCT8 deficiency.

#### Significant events after the reporting period

The U.S. Food and Drug Administration (FDA) has granted Emcitate Fast Track Designation for the treatment of the rare genetic disease MCT8 deficiency.

Strong data from long-term treatment, up to 6 years, of 67 patients with Emcitate (tiratricol) has been published in the Journal of Clinical Endocrinology & Metabolism.

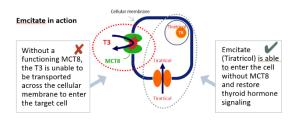
#### **About Emcitate**

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, resulting in significantly shortened life expectancy.

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 and Fast Track Designation in the US in October 2021. Upon approval of the NDA, sponsors holding an 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 early 2022, pending the COVID-19 pandemic situation.

#### Significant events after the reporting period

Aladote was presented at the scientific meeting of the North American Congress of Clinical Toxicology (NACCT) on October 18, by Professor James Dear from the University of Edinburgh, UK, under the heading Clinical studies with calmangafodipir in acetaminophen overdose.

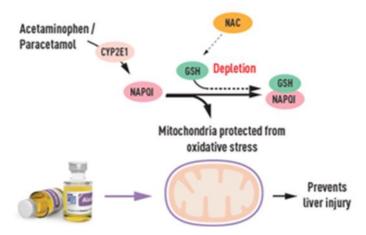
#### **About Aladote**

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. An application for an ODD in the EU was submitted in March, and we have an ongoing dialogue with EMA on the appropriate indication for an ODD in the EU.

Paracetamol/acetaminophen is the most used drug in the world for the treatment of fever and pain, but also one of the most overdosed drugs - intentionally or unintentionally. Paracetamol overdose is one of the most common methods in suicide attempts. When excessive amounts of paracetamol are metabolized in the liver, the harmful metabolite 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.





## **Financial Information**

## **Interim report January - September 2021**

#### Revenue, and results

#### Revenue

Revenue amounted to KSEK 6,210 (2,572) during the quarter and 35,032 (35,772) for the period. Revenues consisted of Emcitate sales of KSEK 6,210 (-) during the quarter and KSEK 12,441 (-) during the period and forwarding of expenses related to PledOx to Solasia Pharma K.K (Solasia) of KSEK - (2,572) during the quarter and KSEK 22,591 (35,772) during the period.

#### **Expenses**

Operating expenses amounted to KSEK 25,801 (26,893) during the quarter and KSEK 108,093 (140,771) during the period. The project expenses amounted to KSEK 13,745 (19,292) during the quarter and KSEK 70,166 (117,418) during the period. The project expenses consisted mainly of expenses due to Emcitate of KSEK 9,522 (-) and Aladote KSEK 2,700 (7,891) for the quarter and Emcitate KSEK 22,069 (-) and Aladote KSEK 16,016 (11,738) for the period. Lower projects costs in the quarter and period are due to delayed initiation of the Aladote study and the parked PledOx project.

Employee costs amounted to KSEK 6,798 (4,608) during the quarter and KSEK 19,633 (15,963) for the period.

Other external costs amounted to KSEK 2,316 (2,884) for the quarter and KSEK 10,728 (6,590) for the period. The increase is mainly due to higher auditor expenses and consultancy costs. Depreciation amounted to KSEK 669 (53) for the quarter and KSEK 1,783 (159) for the period. The depreciation during the period derives from amortization of licences with KSEK 825 (-), depreciation of right-of-use assets with KSEK 930 (159) and depreciation of equipment with KSEK 28 (-). Other operating expenses amounted to KSEK 353 (56) for the quarter and 425 (643) for the period.

#### **Results**

Operating results amounted to KSEK -19,591 (-24,322) for the quarter and KSEK -73,061 (-104,999) for the period. Net financial items amounted to KSEK -2,939 (-404) for the quarter and KSEK -3,110 (1,289) for the period and consists mainly of fair value changes to the

RTT contingent consideration due to changes in exchange rates and discount period. The booked higher amount is a non-cash item. Results after financial items amounted to KSEK -22,530 (-24,726) for the quarter and KSEK -76,171 (-103,710) for the period. Result per share before and after dilution amounted to SEK -0.1 (-0.5) for the quarter and SEK -0.5 (-1.9) for the period both before and after dilution.

## **Financial position**

#### Cash

Cash as of September 30, 2021, amounted to KSEK 173,150 (159,424).

#### **Cash flow**

Cash flow from operating activities amounted to KSEK -30,951 (-24,546) for the quarter and KSEK -104,131 (-95,616) for the period. Total Cash flow amounted to KSEK -34,491 (-24,599) for the quarter and KSEK -115,400 (-95,776) for the period. Cash flow from operating activities is driven by costs related to the projects. Cash flow from investment activities amounted to KSEK -4,651 (-) during the period of which KSEK 3,750 are due to deferred purchase price of RTT and KSEK 116 are due to acquisition of equipment. Cash flow from financing activities amounted to KSEK -6,617 (-160) for the period and are mainly due to amortization of loans.

### **Equity and equity ratio**

As of September 30, 2021, equity amounted to KSEK 554,410 (141,433). Shareholders' equity per share amounted to SEK 3.4 (2.6), at the end of the period. The company's equity ratio was 71 (86) %.

#### **Debt and receivables**

As of September 30, 2021, non-current liabilities amounted to KSEK 188,167 (86). 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 68,320 (86). Current liabilities amount to KSEK 34,800 (22,481) of which other liabilities amount to KSEK 15,194 (856) and accounts payable amount to KSEK 8,795 (3,904).



#### Investments, tangible and intangible assets

As of September 30, 2021, non-current assets amounted to KSEK 593,949 (81). 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 September 30, 2021, were 165,068,560 (53,533,321). The number of shareholders were 6,777 as of September 30, 2021. The ten largest shareholders hold 64.15 % 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, of which 4,900,000 ESOPs were granted to the employees as of September 30, 2021.

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.

### 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), of which 2,900,000 ESOPs were granted to the employees as of September 30, 2021 and 2,400,000 are outstanding.

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).

#### 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 September 30, 2021, were 12 (7) persons, 7 women and 5 men.

### **Parent company**

The parent company's revenues for the quarter amounted to KSEK 5,645 (2,572) and for the period to KSEK 32,552 (35,772). Sales during the period consist of KSEK 22,591 (35,772) due to forwarding of expenses related to PledOx to Solasia. Other income for the quarter amounted to KSEK 5,645 (-) and for the period to KSEK 9,961 (-). Other income for the period consisted of KSEK 7,133 (-) management fees invoiced to the subsidiary RTT and KSEK 2,828 (-) are forwarding of expenses to RTT.

Operating expenses amounted to KSEK 14,791 (26,094) during the quarter and KSEK 81,655 (139,972) for the period. The project expenses amounted to KSEK 5,211 (19,292) for the quarter and KSEK 50,956 (117,418) during the period. Lower projects costs in the quarter and period are due to delayed initiation of the Aladote study and the parked PledOx project.

The parent company's result after financial net amounted to KSEK -12,151 (-23,925) for the quarter and -52,223 (-102,906) for the period.

Financial non-current assets amount to KSEK 490,952 (50) and other non-current liabilities amount to KSEK 63,152 (86). Increases in comparison to prior period



are due to the acquisition of RTT during 2020. Increases to previous quarter are due to fair value changes of the RTT acquisition.



## **Consolidated statement of comprehensive income**

KSEK	2021	2020	2021	2020	2020
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Revenue					
Revenues	6,210	2,572	35,032	35,772	40,662
Other operating income	-	-	-	-	-
	6,210	2,572	35,032	35,772	40,662
Operating expenses					
Costs of sales of goods	-1,921	-	-5,358	-	-1,895
Project costs	-13,745	-19,292	-70,166	-117,418	-183,276
Other external costs	-2,316	-2,884	-10,728	-6,590	-11,097
Employee costs	-6,798	-4,608	-19,633	-15,963	-22,151
Depreciation and impairment	-669	-53	-1,783	-159	-395
Other operating expenses	-353	-56	-425	-643	-243
Sum operating expenses	-25,801	-26,893	-108,093	-140,771	-219,057
Operating results	-19,591	-24,322	-73,061	-104,999	-178,395
Financial items					
Finance income	748	44	577	1,298	163
Finance expense	-3,687	-448	-3,687	-9	-888
Sum financial items	-2,939	-404	-3,110	1,289	-725
Results after financial net	-22,530	-24,726	-76,171	-103,710	-179,120
Tax	-	-	-	-	-
Results after tax	-22,530	-24,726	-76,171	-103,710	-179,120
Statement of comprehensive income					
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	-22,530	-24,726	-76,171	-103,710	-179,120
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		53,533,321	165,068,560	53,533,321	67,391,206
Earnings per share before dilution (SEK)		-0.5	-0.5	-1.9	-2.7
Earnings per share after dilution (SEK)	-0.1	-0.5	-0.5	-1.9	-2.7
Equity per average number of shares	3.4	2.6	3.4	2.6	9.3
Equity per average number of shares	3.4	2.6	3.4	2.6	9.3
after dilution					



## **Consolidated statement of financial position**

KSEK	9/30/2021	9/30/2020	12/31/2020
ASSETS			
Non-current assets			-01-01
Research and development costs	581,784	-	581,784
Licences	6,760	-	7,571
Right-of-use assets	4,470	81	4,666
Equipment	150	-	75
Financial non-current assets	785	=	-
Total non-current assets	593,949	81	594,097
Current assets			
Inventories	964	-	3,138
Accounts receivables	4,903	471	3,883
Other receivables	1,784	803	2,960
Prepaid expenses and accrued income	2,627	3,221	2,039
Cash and bank balance	173,150	159,424	287,850
Total current assets	183,428	163,918	299,871
Total assets	777,377	164,000	893,967
KSEK	9/30/2021	9/30/2020	12/31/2020
Equity			
Share capital	8,688	2,818	8,688
Other capital contributions	1,262,837	705,551	1,262,837
Reserves	1,402	, -	448
Accumulated loss including net loss	-718,516	-566,936	-642,346
Total equity	554,410	141,433	629,627
	00.,0	,	020,021
Non-current liabilities			
Deferred tax liabilities	119,847	-	119,847
Other non-current liabilities	67,933	86	74,242
Provisions	387	-	109
Total non-current liabilities	188,167	86	194,198
Current liabilities			
Accounts payable	8,795	3,904	15,611
Other liabilities	15,194	856	14,542
Accrued expenses and deferred income	10,811	17,721	39,988
Total current liabilities	34,800	22,481	70,141
Total equity and liabilities	777,377	164,000	893,967



## **Consolidated statement of cash flows**

KSEK	2021	2020	2021	2020	2020
	Jul-Sep_	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-22,530	-24,726	-76,171	-103,710	-179,120
Adjustments for non-cash items	4,084	715	6,112	421	2,430
Tax paid	-	-	-	-	-
Cash flow from operating activities before changes in working capital	-18,446	-24,012	-70,058	-103,289	-176,690
Cash flow from changes in working capital					
Increase/decrease in operating receivables	19,989	4,105	1,742	10,355	16,428
Increase/decrease in operating liabilities	-32,494	-4,640	-35,815	-2,682	25,624
Cash flow from changes in working capital	-12,506	-535	-34,073	7,673	42,052
Cash flow from operating activities	-30,951	-24,546	-104,131	-95,616	-134,639
INVESTING ACTIVITIES					
Acquisition of subsidiaries, net cash required	-1,250		-3,750		-59,520
Investment in financial assets	-1,230 -5		-3,730 -785		-55,520
Purchase of property, plant and equipment	-5		-116		-24
Cash flow from investing activities	-1,255	_	-4,651		-59,543
cash now from investing activities	1,233		4,031		-33,343
FINANCING ACTIVITIES					
New share issue	_	-	-	-	250,750
Cost new share issue	_	-	-	-	-22,130
Repayment of loans	-1,875	-	-5,625	-	_
Repayment of leases	-410	-53	-992	-160	-215
Cash flow from financing activities	-2,285	-53	-6,617	-160	228,405
Cash flow for the period	-34,491	-24,599	-115,400	-95,776	34,223
Balance at beginning of period	206,631	184,470	287,850	255,101	255,101
Change in cash	-34,491	-24,599	-115,400	-95,776	34,223
Exchange rate difference in cash	1,010	-446	699	99	-1,473
CASH BALANCE AT THE END OF THE PERIOD	173,150	159,424	173,150	159,424	287,850



## Consolidated statement of changes in equity

KSEK	Share capital	Other capital	Accumulated loss incl. net	Other reserves	Total equity
		contributions	results for the period		
Opening balance 20210101	8,688	1,262,837	-642,346	448	629,627
Comprehensive income for the period	-	-	-76,171	-	-76,171
Costs due to share-based payments of					
employee stock option plan	-	-	-	954	954
Closing balance 20210930	8,688	1,262,837	-718,516	1,402	554,410
Opening balance 20200101	2,818	705,278	-463,227	-	244,876
Incentive program/New share issue	-	273		-	273
Comprehensive income for the period	-	-	-103,710	-	-103,710
Closing balance 20200930	2,818	705,551	-566,936	-	141,433
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-sep	jan-sep	jan-dec
Equity	554,410	141,433	629,627
Equity ratio %	71%	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	-0.5	-1.9	-2.7
Earnings per share after dilution	-0.5	-1.9	-2.7
Cash flow from operating activities	-0.6	-1.8	-0.8
Equity per average number of shares	3.4	2.6	9.3
Equity per average number of shares after dilution	3.4	2.6	9.3
Dividend	-	-	-
Average number of employees	11	9	9
*Effect from dilution is not considered when results are ne	gative.		



## **Parent company - income statement**

KOEK	2024	2020	2024	2020	2020
KSEK	2021	2020	2021	2020	2020
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Revenue					
Revenues	-	2,572	22,591	35,772	38,935
Other operating income	5,645	-	9,961	-	332
	5,645	2,572	32,552	35,772	39,267
Operating expenses					
Project costs	-5,211	-19,292	-50,956	-117,418	-169,422
Other external costs	-2,456	-2,137	-10,626	-5,949	-9,806
Employee costs	-6,798	-4,608	-19,676	-15,963	-22,152
Depreciation and impairment	-12	-	-28	-	-1
Other operating expenses	-315	-56	-370	-643	-290
Sum operating expenses	-14,791	-26,094	-81,655	-139,972	-201,670
Operating results	-9,146	-23,522	-49,104	-104,199	-162,403
Financial items					
Finance income	683	44	568	1,298	163
Finance expense	-3,687	-448	-3,687	-6	-885
Sum financial items	-3,004	-404	-3,119	1,293	-722
Results after financial net	-12,151	-23,925	-52,223	-102,906	-163,125
Appropriations	-	-	-23,000	-	-
Tax	-	-	-	-	-
Results after tax	-12,151	-23,925	-75,223	-102,906	-163,125



## Parent company - balance sheet

KSEK	9/30/2021	9/30/2020	12/31/2020
ACCETC			
ASSETS			
Non-current assets	444		00
Equipment	111	-	23
Financial non-current assets	490,952	50	490,172
Total non-current assets	491,063	50	490,195
Current assets			
Accounts receivables	-	471	2,470
Other receivables	581	802	2,266
Prepaid expenses and accrued income	2,356	4,022	1,135
Cash and bank balance	158,551	159,125	285,830
Total current assets	161,489	164,420	291,701
Total assets	652,552	164,470	781,896
KSEK	9/30/2021	9/30/2020	12/31/2020
Equity			
Restricted Equity			
Share capital	8,688	2,818	8,688
	-,	,	-,
Non-restricted equity			
Share premium reserve	636,235	162,820	799,360
Reserves	1,402	273	448
Net loss for the period	-75,223	-23,925	-163,125
Total equity	571,102	141,986	645,371
Non-current liabilities			
Other non-current liabilities	63,153	86	63,216
Provisions	387		109
Total non-current liabilities	63,540	86	63,325
Current liabilities			
Liabilities to group company	-	-	19,209
Accounts payable	6,417	3,904	10,755
Other liabilities	5,905	773	5,840
Accrued expenses and deferred income	5,588	17,721	37,396
Total current liabilities	17,910	22,399	73,199
Total equity and liabilities	652,552	164,470	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 September 30, 2021			
FINANCIAL ASSETS MEASURED AT			
AMOR TISIED COST			
Financial non-current assets	785	-	785
Accounts receivable	-	4,903	4,903
Cas h	-	173,150	173,150
Total financial assets	785	178,053	178,838
FINANCIAL LIABLILITIES MEASURED AT FAIR			
VALUE THROUGH PROFIT AND LOSS			
Contingent consideration	61,903	-	61,903
Total	61,903	-	61,903
FINANCIAL LIABILITIES MEASURED AT AMORTISIED COST			
Leas e liablilities	2,905	1,614	4,519
Accounts payable	-	8,795	8,795
Deferred purchas e price	1,250	5,000	6,250
Other liabilities	1,875	7,500	9,375
Total	6,030	22,909	28,939
Total financial liabilities	67,933	22,909	90,842
Group September 30, 2020			
FINANCIAL ASSETS MEASURED AT			
AMORTISIED COST			
Accounts receivable	-	471	471
Cash	-	159,424	
Total financial assets	•	159,895	159,895
FINANCIAL LIABILITIES MEASURED AT			
AMORTISIED COST			
Leas e liablilities		82	82
Accounts payable		3,904	3,904
Other liabilities		-	-,
Total	-	3,987	3,987
Total financial liabilities	-	3,987	3,987

Contingent consideration (see page 7)- expected future values are discounted to present value. No significant changes to the valuation methods, input data or assumptions have been made during 2021. The most critical valuation parameters are forecasted sales growth, future operating margins, probability of success and date of



launch. Market practice discount rate of 10% has been applied. Fair value changes are due to changes in exchange rates and discount period. The company estimates market approval to 2023/2024.

KSEK	9/30/2021	9/30/2020
Opening balance, January 1st	58,216	-
Fair value changes	3,687	-
Closing balance	61,903	-

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. The PledOx project has been parked and will only be presented were relevant comparison numbers are necessary.

2021 Jul-Sep						2020 Jul-Sep				
KSEK	PledOx	Aladote	Emcitate	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	-	-	6,210	-	6,210	Revenues	2,572	-	-	2,572
Costs of goods sold	-	-	-1,921	-	-1,921	Costs of goods sold	-	-	-	-
Project costs	-1,523	-2,700	-9,522	-	-13,745	Project costs	-11,401	-7,891	-	-19,292
Other	-	-	-	-10,135	-10,135	Other	-16	-	-7,585	-7,601
Operating results	-1,523	-2,700	-5,233	-10,135	-19,591	Operating results	-8,846	-7,891	-7,585	-24,322
Net financial items					-2,939	Net financial items				-404
Pretax profit				·	-22,530	Pretax profit			=	-24,726

2021 Jan-Sep						2020 Jan-Sep				
KSEK	PledOx	Aladote	Emcitate	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	22,591	-	12,441	-	35,032	Revenues	35,772	-	-	35,772
Costs of goods sold	-	-	-5,358	-	-5,358	Costs of goods sold	-	-	-	-
Project costs	-32,081	-16,016	-22,069	-	-70,166	Project costs	-105,680	-11,738	-	-117,418
Other	-	-	-	-32,569	-32,569	Other	-37	-	-23,317	-23,354
Operating results	-9,490	-16,016	-14,986	-32,569	-73,061	Operating results	-69,944	-11,738	-23,317	-104,999
Net financial items					-3,110	Net financial items				1,289
Pretax profit				-	-76,171	Pretax profit			•	-103,710



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	-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 Country	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Japan	-	2,572	22,591	35,772	38,935
France	976	-	2,374	-	-
Spain	1,190	-	2,894	-	-
Sweden	140	-	1,040	-	87
Other countries	3,904	-	6,133	-	1,640
Total	6,210	2,572	35,032	35,772	40,662

#### Turnover by type of revenue

KSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Re-invoicing of					
costs to Solasia	-	2,572	22,591	35,772	38,935
Sales of goods	6,210	-	12,441	-	1,727
Total	6,210	2,572	35,032	35,772	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			
	12/31/2020	Cash flow	Acquisition of business	New lease agreements	9/30/2021
Lease liablilities	4,666	-992	-	845	4,519
Other liabilities	15,000	-5,625	-	-	9,375
Closing balance	19,666	-6,617	-	-	13,049

		No affect on cash flow			
	12/31/2019	Cash flow	Acquisition of business	Transition to IFRS 16	9/30/2020
Lease liablilities	-	-160	-	243	82
Closing balance	-	-160	-	243	82

		No affect on cash flow			
	12/31/2019	Cash flow	Acquisition of business	New lease agreements	12/31/2020
Lease liablilities	117	-215	-	4,764	4,666
Otherliabilities	0	0	15,000	-	15,000
Closing balance	117	-215	15,000	4,764	19,666



#### Note 6 - Related party transactions

Peder Wahlberg is consulting the company and has invoiced the company KSEK 982, 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-Sep	Jan-Sep	Jan-Dec
Α	Equity, KSEK	554,410	141,433	629,627
В	Balance sheet total, KSEK	777,377	164,000	893,967
A/B	Equity ratio %	71%	86%	70%
Α	Net result, KSEK	-76,171	-103,710	-179,120
В	Equity, KSEK	554,410	141,433	629,627
A/B	Return on equity, %	neg.	neg.	neg.
Α	Cash flow from operating activities, KSEK	-104,131	-95,616	-134,639
В	Average number of shares under the period, before	165,069	53,533	67,391
A/B	Cash flow from operating activities per shares, SEK	-0.6	-1.8	-2.0
Α	Equity, KSEK	554,410	141,433	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	3.4	2.6	9.3
Α	Equity, KSEK	554,410	141,433	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	3.4	2.6	9.3



#### Other information

#### **Next report**

Year-end report for the period January 1- December 31, 2021, February 17, 2022. Interim report January 1- March 31, April 26, 2022. Annual General Meeting May 10, 2022. Half-year report January 1- June 30, August 19, 2022. Interim report January 1- September 30, 2021, November 8, 2022.

This report, and further information is available on the website, www.egetis.com This report has been reviewed by the company's auditor. This is a translation of the Swedish interim report.

#### For further information, please contact:

Nicklas Westerholm, CEO Yilmaz Mahshid, CFO

E-mail: nicklas.westerholm@egetis.com E-mail: <u>yilmaz.mahshid@egetis.com</u>.

This information is such information as Egetis Therapeutics AB (publ.) is obliged to disclose in accordance with EU market abuse regulation and the Securities Markets Act. The information was submitted, through the above contact persons, for publication on November 4, 2021, at 8.00 am (CET).

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

www.egetis.com

#### **Analysts who follow Egetis Therapeutics**

ABGSC, Adam Karlsson Carnegie, Ulrik Trattner Pareto Securities, Dan Akschuti Redeye, Kevin Sule Rx Securities, Dr. Joseph Hedden



## Certification

This interim report for the January-September 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, November 4, 2021.	
Thomas Lönngren	Elisabeth Svanberg
Chairman of the board	Board member
Gunilla Osswald	Mats Blom
Board member	Board member
Peder Walberg	Nicklas Westerholm
Board member	CEO



Review report

Egetis Therapeutics AB (publ), org no 556706-6724

#### Introduction

We have reviewed the interim report for Egetis Therapeutics AB (publ) for the period January 1, 2021 – September 30, 2021. The Board of Directors and the Chief Executive Officer are responsible for the preparation and presentation of this interim report on in accordance with International Accounting Standard (IAS) 34, Interim Financial Reporting, and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim financial information based on our review.

#### Scope of Review

We conducted our review in accordance with International Standard on Review Engagements, ISRE 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (ISA) and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that would make us become aware of all significant matters that might be identified in an audit. Therefore, the conclusion based on a review does not give the same level of assurance as a conclusion based on an audit.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act for the Group, and in accordance with the Swedish Annual Account Acts for the Parent Company.

Sollentuna, November 4, 2021 BDO Mälardalen AB

Karin Siwertz **Authorized Public Accountant**