

## Interim Report January 1-September 30, 2020

### January - September

- Net sales for the period amounted to MSEK 35.8 (65.5)
- Loss for the period MSEK -103.7 (-38.4)
- Cash and cash equivalents MSEK 159.4 (286.7)
- Cash flow for the period MSEK -95.6 (52,9)
- Loss per share before/after dilution SEK -1.9 (-0.8)

### Significant events during the period January-September

#### Aladote®

- PledPharma has planned for one pivotal phase II/III study which is expected to be sufficient for a marketing authorization application in both US and EU

#### PledOx®

- In March PledPharma decided to prematurely stop the POLAR phase III program. The decision was taken after a recommendation from the independent Drug Safety Monitoring Board (DSMB) and followed the clinical holds issued by FDA and ANSM earlier this year.
- PledPharma has finalized the data collection from the Phase III POLAR program during the Q3 2020 with the aim of communicating the primary results during the fourth quarter 2020. The totality of data generated will enable a thorough efficacy and safety evaluation and an assessment of the benefit/risk of PledOx. This evaluation will determine if further activities to find a path forward for PledOx to treat nerve damage associated with chemotherapy is motivated.
- Positive pre-clinical results with PledOx were presented at the Peripheral Nerve Society's annual meeting and were published in the scientific journal Antioxidants.

### July - September

- Quarterly net sales MSEK 2.6 (6.2)
- Quarterly result MSEK till -24.7 (-31.9)
- Cash and cash equivalents MSEK 159.4 (286.7)
- Cash flow for the period MSEK -24,6 (35.9)
- Loss per share before/after dilution SEK -0.5 (-0.6)

### Significant events after the reporting period

- PledPharma acquired all outstanding shares in Rare Thyroid Therapeutics International AB (RTT) on November 3, 2020. The purchase price for the shares in RTT consists of a cash component of 60 MSEK, funded from own cash-in-hand, and a share purchase price consisting of 63,773,345 new shares in PledPharma. These new shares were issued at a price of 5.25 SEK per share, amounting to a total of 334 810 061,25 SEK. In addition, the sellers of RTT are entitled to earnout payments based on the future net sales of Emcitate® as well as an earnout payable in connection with a potential sale of a so-called US Rare Pediatric Disease Priority Review Voucher. The acquisition is disclosed in note 7.
- The Extra General Meeting (EGM) on October 28, 2020 approved issuing no more than 38,238,085 shares with pre-emption rights for existing shareholders and, in the case of oversubscription, resolved to issue an additional maximum of 9,523,809 shares as an overallotment option.
- The design of the pivotal Phase IIb/III study for Aladote has been completed following interactions with the FDA, EMA and MHRA. The first patient is planned to be randomized in the study in H1 2021, pending approval of clinical trial applications and no unexpected disruption due to COVID 19.
- Peder Walberg was elected as a board member at the EGM on October 28, 2020.
- Notice of EGM issued for December 11, 2020 to resolve for a company name change to Egetis Therapeutics

	2020 Jul-Sep	2019 Jul-Sep	2020 Jan-Sep	2019 Jan-Sep	2019 Jan-Dec
Net revenues, KSEK	2,572	6,182	35,772	65,520	82,562
Result after tax, KSEK	-24,726	-31,893	-103,710	-38,416	-61,422
Cash flow, KSEK	-24,599	-35,903	-95,776	52,851	24,079
Cash, KSEK	159,424	286,748	159,424	286,748	255,101
Equity ratio %	86%	92%	86%	92%	91%
Result per share, SEK	-0.5	-0.6	-1.9	-0.8	-1.2
Result per share after dilution, SEK	-0.5	-0.6	-1.9	-0.8	-1.2
Average number of employees	8	9	9	9	9

## About PledPharma

PledPharma is an innovative, unique and integrated pharmaceutical drug development company, focusing on improving treatments for diseases with substantial unmet medical need. 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 holds Orphan Drug Designation in the US. The Phase III POLAR program for the drug candidate **PledOx** was prematurely stopped in Q2 2020. Results from POLAR program will determine if further development of PledOx is warranted via strategic partnerships and is expected to be announced in Q4 2020. PledPharma (STO: PLED) is listed on the Nasdaq Stockholm main market since October 31, 2019. For more information, see <http://www.pledpharma.com/>

## About Rare Thyroid Therapeutics

RTT is a privately held clinical stage research and development company, based in Stockholm, Sweden, specialized in therapies for rare thyroid hormone signaling disorders, a disease area which is currently underserved and where there is a significant unmet medical need. MCT8 deficiency is a rare congenital disorder of thyroid hormone trafficking with detrimental natural history and no therapy is currently available. Approximately 1 of 70,000 males are affected. A successful phase IIb trial of the drug candidate **Emcitate**, for addressing MCT8 deficiency, has been completed, and a pivotal (IIb/III) early intervention trial in very young subjects is planned to start H2 2020. Interim results are estimated to be available in 2022 and are expected to pave the way for regulatory approvals and commercial launch. Emcitate holds Orphan Drug Designation in both EU and the US. For more information, see <http://rarethyroid.com/>.

## Comments from the CEO

### **PledPharma's acquisition of Rare Thyroid Therapeutics creates a new focused orphan drug development company**

In Q3, we continued to work intensely with our clinical portfolio while also refining PledPharma's future strategy, which ultimately led up to one of the most fundamental events in the history of the company with the acquisition of Rare Thyroid Therapeutics (RTT), a privately held company focused on rare thyroid hormone signalling disorders. The acquisition creates a new specialized late-stage orphan drug development company with core expertise in clinical development, registration and commercialization.

The new company, which will be called Egetis Therapeutics, will initially have two orphan drug assets in late stage development: Emcitate and Aladote. These products have a clear path to launch in EU and US in approximately three years. Egetis intends to set up a niche marketing organization to address the attractive orphan drug market.

At the same time, we announced a fully underwritten rights issue of approximately SEK 200 million (plus an over-allotment option of approximately SEK 50 million) which will finance the development of Emcitate and Aladote up to market approval.

Emcitate is developed for the treatment of MCT8 deficiency, which is 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. A successful Phase IIb trial has been completed. A pivotal Phase IIb/III early intervention trial in very young patients is planned to start in Q4 2020. Interim results are planned to be available in 2022 to pave the way for regulatory approvals and commercial launch. Emcitate has Orphan Drug Designation (ODD) in both EU and the US. We believe that Emcitate holds potential to become the first approved therapy for the treatment of MCT8 deficiency.

The acquisition of RTT is an important step towards building a company with a strategic focus on the attractive orphan drug patient segment. The RTT team, with long experience within orphan drugs, will complement PledPharma's late stage development focused organisation, building a sustainable orphan drug company dedicated to development and commercialisation of therapies for rare diseases. We look forward to building a new Swedish development company with the capacity to bring our own projects to market. The goal is to offer medicines to patients with serious and rare diseases lacking adequate medical treatments and create value for patients and shareholders.

### **Aladote registrational study**

Aladote represents PledPharma's internal orphan drug candidate. In October, we announced that the study design for the pivotal Phase IIb/III study with Aladote has been completed after interactions during Q2-Q3 2020 with the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Medicines & Healthcare products Regulatory Agency (MHRA) in the UK.

Following successful clinical trial applications and subsequent study conduct, marketing authorization applications in the US, EU and UK are planned for 2023.

Aladote has ODD status in the US and an application is pending also in the EU (post-Brexit). A proof of principle study has been successfully completed, establishing safety and tolerability, suggesting that Aladote may reduce liver injury after paracetamol overdose.

The Phase IIb/III study is targeting patients with increased risk of liver injury, arriving late, more than 8 hours after a paracetamol overdose, to hospital. In these patients, the current standard of care, N-acetylcystein (NAC), is no longer effective. The study consists of two parts, with an interim analysis carried out by an independent Drug Safety Monitoring Board (DSMB). The total planned number of patients are 225, and first patient is planned to be randomized in the study in H1 2021, pending approval of clinical trial applications and no unexpected disruption due to Covid-19.

We are very pleased to have completed the interactions with FDA, EMA and MHRA and look forward to initiating the study. We are committed to the continued development of Aladote and believe it 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.

### **PledOx POLAR program**

The phase III POLAR program for the drug candidate PledOx was prematurely stopped in Q2 2020. Results are expected to be announced in Q4 2020 and will enable a thorough evaluation of the safety and efficacy, providing an assessment of the benefit/risk of PledOx in patients with chemotherapy induced peripheral neuropathy (CIPN). This evaluation will determine if further development of PledOx via strategic partnership/s are motivated.



### **Robust cash position**

In order to continue the development of our clinical portfolio, we have a robust cash position of approximately 159 million SEK in cash reported on September 30, 2020, together with the planned underwritten rights issue of approximately SEK 200 million.

Our focus on our clinical development programs and participating subjects remain firm while we build the future of the new company, Egetis Therapeutics. 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.

I look forward to relaying news to you around our planned studies for Aladote and Emcitate, as well as the upcoming results from the POLAR program.

Nicklas Westerholm, CEO  
PledPharma AB (publ), Stockholm

## Project updates

# Aladote

### Events during the quarter

Regulatory interactions with the FDA, EMA and the MHRA on specific study details for the Aladote pivotal Phase IIb/III study.

### Significant events after the reporting period

The design of the pivotal Phase IIb/III study for Aladote was completed following interactions with FDA, EMA and MHRA.

### About Aladote

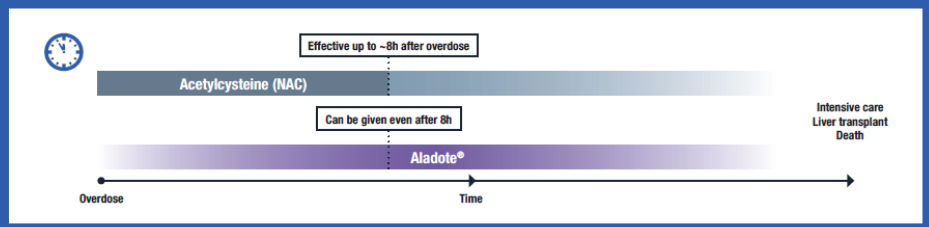
Aladote is a “first-in-class” drug candidate with the potential to reduce the risk of liver damage associated with paracetamol/acetaminophen poisoning. Aladote has shown good efficacy in relevant preclinical models, even in the time-window when N-acetylcysteine (NAC) treatment no longer is effective. A proof of principle study in patients with paracetamol poisoning has been successfully completed. The study results established the safety and tolerability of the combination of Aladote and NAC. Further, the results indicate that Aladote may reduce liver injury in this patient population. Aladote has been granted Orphan Drug Designation in the US and is expected to be eligible for an ODD in the EU after Brexit, for which an application is being developed.

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 – intentional or unintentional. Paracetamol overdose is also one of the most common methods in intentional suicide attempts. When excessive amounts of paracetamol are broken down in the liver, a

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 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 no longer effective. The study consists of two parts with an interim analysis carried out by an independent Drug Safety Monitoring Board (DSMB). The total planned number of patients are 225, who will be enrolled in the US, UK and in at least one EU country. The first patient is planned to be randomized in the study in H1 2021, pending approval of clinical trial applications and no unexpected disruption due to COVID 19. Application for market approval for sales in the US, EU and UK is planned for 2023 after completion of the study.

**Aladote is effective after the critical eight-hour threshold where NAC treatment is less effective.**



## Pledox

### Events during the quarter

PledPharma have finalised the data collection from the Phase III POLAR program during the Q3 2020 with the aim to communicate the primary result during the fourth quarter 2020. The totality of data generated will enable a thorough efficacy and safety evaluation and an assessment of the benefit/risk of PledOx as a prevention of CIPN. This evaluation will determine if further activities to find a path forward for PledOx to treat nerve damage associated with chemotherapy are motivated.

Positive pre-clinical results with PledOx were presented at Peripheral Nerve Society's annual meeting and published in the peer-reviewed journal Antioxidants. The pre-clinical oxaliplatin study confirms a protective effect of PledOx (calmangafodipir) against oxaliplatin-induced small fiber neuropathy

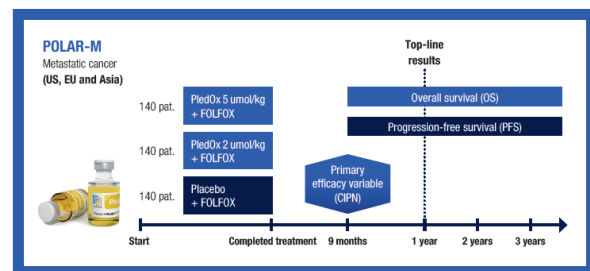
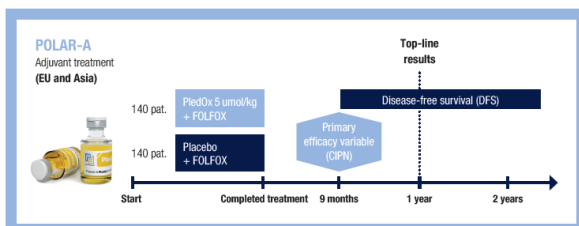
### Significant events after the reporting period

There are no events to report.

### About PledOx

PledOx is a "first in class" drug candidate developed 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 results from a completed Phase IIb trial (PLIANT), where patients with metastatic colorectal cancer were treated with the chemotherapy combination FOLFOX and PledOx, indicate that the patients who received PledOx had a lower risk than the placebo group to suffer from nerve damage during the chemotherapy. No apparent negative effect on the efficacy of the cancer treatment was observed. The global phase III program for PledOx consists of two double blinded randomized placebo-controlled trials, POLAR-M and POLAR-A. POLAR-M was designed to include 420 patients undergoing chemotherapy treatment for metastatic colorectal cancer and was conducted in Asia, Europe and

the US. The study aimed to compare PledOx at doses of 2  $\mu\text{mol/kg}$  and 5  $\mu\text{mol/kg}$  with placebo. POLAR-A was designed to include 280 patients undergoing adjuvant chemotherapy treatment for colorectal cancer and is being conducted in Asia and Europe. The study aimed to compare PledOx at a dose of 5  $\mu\text{mol/kg}$  with placebo. In Q1 2019 US Food and Drug 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 program was prematurely stopped, and the data cut-off for data collection took place in Q3 2020. The totality of data will enable a thorough efficacy and safety evaluation and an assessment of the benefit/risk of PledOx as a treatment of CIPN.



## Financial Information

### Interim report, January – September 2020

#### Revenue, and results

##### Revenues

Revenues amounted to KSEK 2,572 (6,182) during the quarter and KSEK 35,772 (65,520) for the period. Revenues during the quarter and period was due to forwarding of expenses related to the Asian part of the POLAR program. The decrease in revenues in the corresponding period 2019 is primarily due to a milestone payment from Solasia Pharma K.K of JPY 600M (c. SEK 49M).

##### Expenses

Operating expenses amounted to KSEK 26,893 (41,473) during the quarter and KSEK 140,771 (114,877) during the period. The project expenses amounted to KSEK 19,292 (33,633) during the quarter and KSEK 117,418 (85,974) during the period.

The increase is due to activities related to the global POLAR program with PledOx. Project costs related to PledPharma amounted to KSEK 16,712 (26,806) during the quarter and KSEK 81,620 (67,037) during the period.

Employee costs amounted to KSEK 4,608 (4,569) for the quarter and KSEK 15,963 (15,818) for the period.

Other external costs amounted to KSEK 2,884 (3,218) for the quarter and KSEK 6,590 (10,175) for the period. The decrease in the quarter and period is a net of expenses due to acquisition of RTT during 2020 and expenses that was attributed to the change of trading platform for the company's shares during 2019. Depreciation amounted to KSEK 53 (54) for the quarter and KSEK 159 (156) for the period. The depreciation is due to right-of-use assets according to IFRS 16.

##### Results

Operating results amounted to KSEK -24,322 (-35,292) for the quarter and KSEK -104,999 (-49,357) for the period. Net financial items amounted to KSEK -404 (3,399) for the quarter and KSEK 1,289 (10,942) for the period. Results are related to unrealized revaluation of company's FX-accounts at the end of the quarter. Results after financial items amounted to KSEK -24,726 (-31,893) for the quarter and KSEK -103,710 (-38,416) for the period. Result per share before and after dilution amounted to SEK -0.5 (-0.6) for the quarter and SEK -1.9 (-0.8) for the period.

#### Financial position

##### Cash

Cash as of September 30, 2020 amounted to KSEK 159,424 (286,748).

##### Cash flow

Cash flow from operating activities amounted to KSEK -24,546 (-35,849) for the quarter and KSEK -95,616 (-33,922) for the period. Cash flow amounted to KSEK -24,599 (-35,903) for the quarter and KSEK -95,776 (52,851) for the period. Cash flow from operating activities is driven by costs from the clinical studies and by the milestone payment received in 2019. Cash flow from financing activities amounted to -53 (-54) for the quarter and -160 (86,774) for the period. The positive cash flow during the corresponding period 2019 derives from a share issue of KSEK 91,258.

##### Equity and equity ratio

As of September 30, 2020, equity amounted to KSEK 141,433 (267,882). Shareholders' equity per share amounted to SEK 2.6 (5.0), at the end of the period. The company's equity ratio was 86 (92) %.

##### Debts and receivables

Long-term liabilities amounted to KSEK 86 (117) and are due to IFRS 2 and IFRS16. Current liabilities amounted to KSEK 22,481 (23,277). Accounts receivables amounted to KSEK 471 (1,853). Right-of-use assets amounted to KSEK 81 (176) and are due to IFRS16.

##### Investments, tangible and intangible assets

During the quarter and period, investments in tangible and intangible fixed assets corresponded to KSEK 0 (0).

##### Share

The number of shares as of September 30, 2020 were 53,533,321. PledPharma's shares are listed on Nasdaq Stockholm's main market since October 31, 2019.

#### Stock option plan and warrant programs

##### 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. See note 1, IFRS 2, share based payments for terms and accounting policy.

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. 3,000,000 warrants was allotted to the employees in April 2020.

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

#### **Warrant program 2017/2020 and 2018/2021**

2,306,000 warrants have been acquired by employees and board members. 1,526,500 of the warrants have been subscribed in the warrant program 2017/2020 and 779,500 in the warrant program 2018/2021. The CEO holds 500,000 warrants in the warrant program 2017/2020 and 193,703 of the warrants in the warrant program 2018/2021.

Full utilization of granted options and warrants would increase the shares with 6,248,600 to a total of 59,781,921.

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.

### **Employees**

Number of employees as of September 30, 2020 were 7 (9) persons, 3 women and 4 men.

### **Parent company**

The parent company's revenues for the quarter amounted to KSEK 2,572 (6,182) and KSEK 35,772 (65,520) for the period. The expenses for the quarter amounted to KSEK 26,093 (41,474) and KSEK 139,972 (114,886) for the period.

The parent company's result amounted to KSEK -23,925 (-31,893) for the quarter and KSEK -102,906 (-38,420) for the period. Changes in the parent company's statements corresponds to the consolidated changes.



## Consolidated statement of comprehensive income

KSEK	2020 Jul-Sep	2019 Jul-Sep	2020 Jan-Sep	2019 Jan-Sep	2019 Jan-Dec
<b>Revenue</b>					
Sales	2,572	6,171	35,772	65,509	82,562
Other operating income	-	11	-	11	-
	<b>2,572</b>	<b>6,182</b>	<b>35,772</b>	<b>65,520</b>	<b>82,562</b>
<b>Operating expenses</b>					
Project costs	-19,292	-33,633	-117,418	-85,974	-112,240
Other external costs	-2,884	-3,218	-6,590	-10,175	-13,334
Employee costs	-4,608	-4,569	-15,963	-15,818	-23,386
Depreciation and impairment	-53	-54	-159	-156	-210
Other operating expenses	-56	-	-643	-2,755	-74
<b>Operating results</b>	<b>-24,322</b>	<b>-35,292</b>	<b>-104,999</b>	<b>-49,357</b>	<b>-66,681</b>
<b>Financial items</b>					
Depreciation of investment in subsidiaries					
Interest income and similar items	44	3,400	1,298	10,947	5,266
Interest expense and similar items	-448	-1	-9	-6	-7
Sum financial items	-404	3,399	1,289	10,942	5,259
<b>Results after financial net</b>	<b>-24,726</b>	<b>-31,893</b>	<b>-103,710</b>	<b>-38,416</b>	<b>-61,422</b>
Group contribution received	-	-	-	-	-
Tax	-	-	-	-	-
<b>Results after tax</b>	<b>-24,726</b>	<b>-31,893</b>	<b>-103,710</b>	<b>-38,416</b>	<b>-61,422</b>
<b>Statement of comprehensive income</b>					
Other comprehensive income	-	-	-	-	-
<b>Comprehensive income for the period</b>	<b>-24,726</b>	<b>-31,893</b>	<b>-103,710</b>	<b>-38,416</b>	<b>-61,422</b>
Net earnings and comprehensive income is entirely attributable to parent company shareholders					
<b>Share Data</b>					
Number of shares at the end of period	53,533,321	53,533,321	53,533,321	53,533,321	53,533,321
Average number of shares during period	53,533,321	53,533,321	53,533,321	50,974,743	51,626,655
Result per share before dilution (SEK)	-0.5	-0.6	-1.9	-0.8	-1.2
Result per share after dilution (SEK)	-0.5	-0.6	-1.9	-0.8	-1.2
Equity per share (SEK)	2.6	5.0	2.6	5.0	4.6
Equity per share after dilution (SEK)	2.6	5.0	2.6	5.0	4.6

## Consolidated statement of financial position

KSEK	9/30/2020	9/30/2019	12/31/2019
<b>ASSETS</b>			
<b>Non-current assets</b>			
Rights of use assets	-	176	123
<b>Total non-current assets</b>	<b>81</b>	<b>176</b>	<b>123</b>
<b>Current assets</b>			
Accounts receivables	471	1,853	5,200
Other receivables	803	601	1,704
Prepaid expenses and accrued income	3,221	1,899	7,945
	<b>4,494</b>	<b>4,352</b>	<b>14,849</b>
Cash and bank balance	159,424	286,748	255,101
<b>Total current assets</b>	<b>163,918</b>	<b>291,100</b>	<b>269,950</b>
<b>Total assets</b>	<b>164,000</b>	<b>291,276</b>	<b>270,073</b>

KSEK	9/30/2020	9/30/2019	12/31/2019
<b>Equity</b>			
Share capital	2,818	2,818	2,818
Other capital contributions	705,551	705,278	705,278
Accumulated loss including net loss	-566,936	-440,213	-463,220
<b>Total equity</b>	<b>141,433</b>	<b>267,882</b>	<b>244,876</b>
<b>Total Long-term liabilities</b>	<b>86</b>	<b>117</b>	<b>117</b>
<b>Current liabilities</b>			
Accounts payable	3,904	2,909	11,207
Other liabilities	856	1,481	1,328
Accrued expenses and deferred income	17,721	18,887	12,546
<b>Total current liabilities</b>	<b>22,481</b>	<b>23,277</b>	<b>25,081</b>
<b>Total equity and liabilities</b>	<b>164,000</b>	<b>291,276</b>	<b>270,073</b>

## Consolidated statement of cash flows

KSEK	2020 Jul-Sep	2019 Jul-Sep	2020 Jan-Sep	2019 Jan-Sep	2019 Jan-Dec
<b>OPERATING ACTIVITIES</b>					
Result after financial net	-24,726	-31,893	-103,710	-38,416	-61,422
Adjustments for non-cash items*	715	-3,049	421	-3,865	-937
<b>Cash flow from operating activities before changes in working capital</b>	<b>-24,012</b>	<b>-34,942</b>	<b>-103,289</b>	<b>-42,281</b>	<b>-62,358</b>
Changes in short term receivables	4,105	239	10,355	10,546	49
Changes in accounts payable	-6,185	-11,567	-7,302	-12,265	-3,967
Changes in other liabilities	1,545	10,421	4,620	10,077	3,636
<b>Cash flow from operating activities</b>	<b>-24,546</b>	<b>-35,849</b>	<b>-95,616</b>	<b>-33,922</b>	<b>-62,641</b>
<b>INVESTING ACTIVITIES</b>					
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>FINANCING ACTIVITIES</b>					
New share/Warrants issue	-	-	-	91,258	91,258
Cost new share issue	-	-	-	-4,323	-4,323
Repayment of lease liability	-53	-54	-160	-162	-216
<b>Cash flow from financing activities</b>	<b>-53</b>	<b>-54</b>	<b>-160</b>	<b>86,774</b>	<b>86,720</b>
<b>Cash flow for the period</b>	<b>-24,599</b>	<b>-35,903</b>	<b>-95,776</b>	<b>52,851</b>	<b>24,079</b>
Balance at beginning of period	184,470	319,549	255,101	229,876	229,876
Change in cash	-24,599	-35,903	-95,776	52,851	24,079
Exchange rate difference in cash	-446	3,102	99	4,021	1,146
<b>CASH BALANCE AT THE END OF THE PERIOD</b>	<b>159,424</b>	<b>286,748</b>	<b>159,424</b>	<b>286,748</b>	<b>255,101</b>

\*predominantly due to unrealized exchange rate differences of company bank deposits in foreign currency

## Consolidated statement of changes in equity

KSEK	Share capital	Other capital contributions	Accumulated loss incl. net result for the period	Total equity
<b>Opening balance 20200101</b>	<b>2,818</b>	<b>705,278</b>	<b>-463,227</b>	<b>244,876</b>
Incentive program/New share issue	-	273	-	273
Comprehensive income for period	-	-	-103,709	-103,709
<b>Closing balance 20200930</b>	<b>2,818</b>	<b>705,551</b>	<b>-566,936</b>	<b>141,433</b>
<b>Opening balance 20190101</b>	<b>2,561</b>	<b>618,598</b>	<b>-401,798</b>	<b>219,362</b>
Incentive program/New share issue	256	91,002	-	91,258
Cost new share issue	-	-4,323	-	-4,323
Comprehensive income for period	-	-	-38,416	-38,416
<b>Closing balance 20190930</b>	<b>2,818</b>	<b>705,278</b>	<b>-440,213</b>	<b>267,882</b>
<b>Opening balance 20190101</b>	<b>2,561</b>	<b>618,598</b>	<b>-401,798</b>	<b>219,362</b>
New share issue	256	91,002	-	91,258
Cost new share issue	-	-4,323	-	-4,323
Comprehensive income for period	-	-	-61,422	-61,422
<b>Closing balance 20191231</b>	<b>2,818</b>	<b>705,278</b>	<b>-463,220</b>	<b>244,876</b>

## Consolidated key ratios

The key ratios below are useful to those who read the financial statements and a complement to other performance targets in evaluating strategic investment implementation and the Group's ability to achieve financial goals and commitments.

KSEK	2020 Jul-Sep	2019 Jul-Sep	2020 Jan-Sep	2019 Jan-Sep	2019 Jan-Dec
Equity	141,433	267,882	141,433	267,882	244,876
Equity ratio %	86%	92%	86%	92%	91%
Return on equity %	neg.	neg.	neg.	neg.	neg.
Number of shares at the end of the period	53,533,321	53,533,321	53,533,321	53,533,321	53,533,321
Number of shares at the end of the period after dilution	53,533,321	53,533,321	53,533,321	53,533,321	53,533,321
Average number of shares under the period	53,533,321	53,533,321	53,533,321	50,974,743	51,626,655
Average number of shares under the period after dilution	53,533,321	53,533,321	53,533,321	50,974,743	51,626,655

### Share Data

Result per share	-0.5	-0.6	-1.9	-0.8	-1.2
Result per share after dilution	-0.5	-0.6	-1.9	-0.8	-1.2
Cash flow from operating activities	-0.5	-0.7	-1.8	-0.7	-1.2
Equity per share	2.6	5.0	2.6	5.0	4.6
Equity per share after dilution	2.6	5.0	2.6	5.0	4.6
Dividend	-	-	-	-	-
Average number of employees	8	9	9	9	9

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

## Key ratios definitions

### Ratios that have been calculated according to IFRS

**Earnings per share** Net income divided by average number of shares before dilution

**Number of shares at end of period** The number of outstanding shares before dilution at the end of the period

**Number of shares after dilution** The number of issued shares after dilution effect of potential shares at end of period

**Average number of shares during the period** Average number of outstanding shares before dilution for the period

**Average number of shares during the period after dilution** Average number of issued shares after dilution effect of potential shares

### Ratios that have not been calculated in accordance with IFRS

**Equity ratio, %** The company defines the ratio as follows; 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, %** The company defines the ratio as follows; 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** The company defines the ratio as follows; 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** The company defines the ratio as follows; 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

		2020	2019	2020	2019	2019
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
A	Equity, KSEK	141,433	267,882	141,433	267,882	244,876
B	Balance sheet total, KSEK	164,000	291,276	164,000	291,276	270,073
<b>A/B</b>	<b>Equity ratio %</b>	<b>86%</b>	<b>92%</b>	<b>86%</b>	<b>92%</b>	<b>91%</b>
A	Net result, KSEK	-24,726	-31,893	-103,710	-38,416	-61,422
B	Equity, KSEK	141,433	267,882	141,433	267,882	244,876
<b>A/B</b>	<b>Equity per share, %</b>	<b>neg.</b>	<b>neg.</b>	<b>neg.</b>	<b>neg.</b>	<b>neg.</b>
A	Cash flow from operating activities, SEK	-24,546	-35,849	-95,616	-33,922	-62,641
B	Average number of shares under the period, before dilution	53,533	53,533	53,533	50,975	51,627
<b>A/B</b>	<b>Cash flow from operating activities per shares, SEK</b>	<b>-0.5</b>	<b>-0.7</b>	<b>-1.8</b>	<b>-0.7</b>	<b>-1.2</b>
A	Equity, KSEK	141,433	267,882	141,433	267,882	244,876
B	Number of shares at the end of the period before dilution, thousand	53,533	53,533	53,533	53,533	53,533
<b>A/B</b>	<b>Equity per share before dilution, %</b>	<b>2.6</b>	<b>5.0</b>	<b>2.6</b>	<b>5.0</b>	<b>4.6</b>
A	Equity, KSEK	141,433	267,882	141,433	267,882	244,876
B	Number of shares at the end of the period after dilution thousand	53,533	53,533	53,533	53,533	53,533
<b>A/B</b>	<b>Equity per share after dilution, %</b>	<b>2.6</b>	<b>5.0</b>	<b>2.6</b>	<b>5.0</b>	<b>4.6</b>

## Parent company - income statement

KSEK	2020 Jul-Sep	2019 Jul-Sep	2020 Jan-Sep	2019 Jan-Sep	2019 Jan-Dec
<b>Revenue</b>					
Sales	2,572	6,171	35,772	65,509	82,562
Other operating income	-	11	-	11	-
	<b>2,572</b>	<b>6,182</b>	<b>35,772</b>	<b>65,520</b>	<b>82,562</b>
<b>Operating expenses</b>					
Project costs	-19,292	-33,633	-117,418	-85,974	-112,240
Other external costs	-2,137	-3,273	-5,949	-10,339	-13,553
Employee costs	-4,608	-4,569	-15,963	-15,818	-23,386
Other operating expenses	-56	-	-643	-2,755	-74
<b>Operating results</b>	<b>-23,522</b>	<b>-35,293</b>	<b>-104,199</b>	<b>-49,365</b>	<b>-66,690</b>
<b>Financial items</b>					
Interest income and similar items	44	3,400	1,298	10,947	5,266
Interest expense and similar items	-448	0	-6	-2	-2
Sum financial items	-404	3,400	1,293	10,945	5,264
<b>Results after financial net</b>	<b>-23,925</b>	<b>-31,893</b>	<b>-102,906</b>	<b>-38,420</b>	<b>-61,427</b>
Tax	-	-	-	-	-
<b>Results after tax</b>	<b>-23,925</b>	<b>-31,893</b>	<b>-102,906</b>	<b>-38,420</b>	<b>-61,427</b>

## Parent company - balance sheet

KSEK	9/30/2020	9/30/2019	12/31/2019
<b>ASSETS</b>			
<b>Non-current assets</b>			
Financial non-current assets	50	50	50
<b>Total non-current assets</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Current assets</b>			
Accounts receivables	471	1,853	5,200
Other receivables	802	601	1,704
Prepaid expenses and accrued income	4,022	1,899	7,945
	5,295	4,352	14,849
Cash and bank balance	159,125	286,447	254,800
<b>Total current assets</b>	<b>164,420</b>	<b>290,799</b>	<b>269,649</b>
<b>Total assets</b>	<b>164,470</b>	<b>290,849</b>	<b>269,699</b>

KSEK	9/30/2020	9/30/2019	12/31/2019
<b>Equity</b>			
Share capital	2,818	2,818	2,818
<i>Non-restricted equity</i>			
Value of employee services	273	-	-
Share premium reserve	705,277	705,277	705,277
Retained earnings	-542,457	-408,577	-402,049
Net profit for the year	-23,925	-31,893	-61,427
<b>Total equity</b>	<b>141,986</b>	<b>267,625</b>	<b>244,619</b>
<b>Total Long-term liabilities</b>	<b>86</b>	<b>-</b>	<b>-</b>
<b>Current liabilities</b>			
Accounts payable	3,904	2,909	11,207
Other liabilities	773	1,428	1,328
Accrued expenses and deferred income	17,721	18,887	12,546
<b>Total current liabilities</b>	<b>22,399</b>	<b>23,224</b>	<b>25,081</b>
<b>Total equity and liabilities</b>	<b>164,470</b>	<b>290,849</b>	<b>269,699</b>



## Notes

### Note 1 - Accounting principles

PledPharma 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 PledPharmas consolidated financial statements for the year ended December 31, 2019. 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 2019. No new accounting principles or policies is being implemented by the Group during 2020. All the numbers in this interim report are, if nothing else is stated, stated in thousands.

As of May 1, 2020, the group applies IFRS 2 regarding stock option plan 2020/2024.

As of April 1, 2019, the group has categorized and identified two independent segments of development for calmangafodipir, PledOx and Aladote. These two segments are independent R&D projects for which the CEO allocates company's resources.

### Parent company

The parent company PledPharma 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.

### IFRS 2 share based payments

The 2020 Annual General Meeting has approved an employee stock option plan of 3,000,000 stock options in PledPharma. Each option provides the right to subscribe for one (1) new share in the company at SEK 12.2 per share. The stock options may be exercised between May 2023 up until May 2024. The stock options have been allotted free of charge during April 2020 and the vesting time is from allotment date until May 2023. The stock options are not valid if the employee terminate their employment during the vesting time. The stock options were calculated according to the Black-Scholes option price formula.

Social security costs attributable to equity-related instruments to employees as remuneration to purchase services shall be expensed over the period the services will be performed. The expenses are measured by using the same valuation model that was used when the options were issued. The provision recognized must be revalued at each reporting period on the basis of a calculation of the social security costs that may be paid when the instruments are subscribed. PledPharma has secured costs related to the stock option plan by subscription of 942,600 warrants to PledPharma's subsidiary. The total amount of warrants that the Parent Company has issued to PledPharma I AB amounts to 3,942,600. PledPharma I AB has allotted 3,000,000 of the warrants to the employees in PledPharma.

### 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 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 PledPharma's 2019 Annual Report. There are no major changes in the Group's risk exposure in 2020 compared with previous year.

### COVID-19 uncertainties

The impact of the coronavirus outbreak for PledPharma and its operations has so far been limited. PledPharma is closely monitoring developments and is evaluating the extent to which this may affect operations in the short and long term. Risks and uncertainties the company currently have identified are potential impact on the POLAR program and the initiation of the next studies for Aladote and Emcitate.

### 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 5. For events after the period, see page 1. Note 3 – Financial assets and liabilities.

### Note 3 – Financial assets and liabilities

KSEK	Hold to collect	Financial debts	Total
	Amortised cost	Amortised cost	
<b>Group September 30, 2020</b>			
Accounts receivable	471	-	471
Cash	159,424	-	159,424
<b>Total financial assets</b>	<b>159,895</b>	<b>-</b>	<b>159,895</b>
Accounts payable	-	3,904	3,904
Other liabilities	-	82	82
<b>Total financial liabilities</b>	<b>-</b>	<b>3,987</b>	<b>3,987</b>
<b>Group September 30, 2019</b>			
Accounts receivable	1,853	-	1,853
Cash	286,748	-	286,748
<b>Total financial assets</b>	<b>288,600</b>	<b>-</b>	<b>288,600</b>
Accounts payable	-	2,909	2,909
Other liabilities	-	170	170
<b>Total financial liabilities</b>	<b>-</b>	<b>3,079</b>	<b>3,079</b>

### Note 4 – Related party transactions

There are no transactions to be reported with related parties.

### Note 5 – Segments

As of June 1, 2019, the group has categorized and identified two independent areas of development for calmagafodipir. The chief operating decision maker in the company allocates company resources between these two projects. 2019 PledOx revenues reported are attributed to milestone payments and forward expenses for the Asian part of the POLAR studies. 2020 PledOx revenues reported are attributed to forward expenses for the Asian part of the POLAR studies. Table below depicts revenues and costs attributed to PledOx and Aladote.

2020					2019				
Jul-Sep					Jul-Sep				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	2,572	-	-	<b>2,572</b>	Revenues	6,159	-	22	<b>6,182</b>
Project costs	-11,401	-7,891	-	<b>-19,292</b>	Project costs	-32,922	-711	-	<b>-33,633</b>
Other	-16	-	-7,585	<b>-7,601</b>	Other	-65	-	-7,775	<b>-7,840</b>
Operating results	<b>-8,846</b>	<b>-7,891</b>	<b>-7,585</b>	<b>-24,322</b>	Operating results	<b>-26,828</b>	<b>-711</b>	<b>-7,752</b>	<b>-35,292</b>
Net financial items				<b>-404</b>	Net financial items				<b>3,399</b>
Pretax profit				<b>-24,726</b>	Pretax profit				<b>-31,893</b>

2020					2019				
Jan-Sep					Jan-Sep				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	35,772	-	-	<b>35,772</b>	Revenues	65,498	-	22	<b>65,520</b>
Project costs	-105,680	-11,738	-	<b>-117,418</b>	Project costs	-82,713	-3,260	-	<b>-85,974</b>
Other	-37	-	-23,317	<b>-23,354</b>	Other	-65	-	-28,838	<b>-28,904</b>
Operating results	<b>-69,944</b>	<b>-11,738</b>	<b>-23,317</b>	<b>-104,999</b>	Operating results	<b>-17,281</b>	<b>-3,260</b>	<b>-28,816</b>	<b>-49,357</b>
Net financial items				<b>1,289</b>	Net financial items				<b>10,942</b>
Pretax profit				<b>-103,710</b>	Pretax profit				<b>-38,416</b>

2019				
Jan-Dec				
KSEK	PledOx	Aladote	Common	Sum
Revenues	82,539	-	22	<b>82,562</b>
Project costs	-106,148	-6,091	-	<b>-112,240</b>
Other	-75	-	-36,928	<b>-37,003</b>
Operating results	<b>-23,684</b>	<b>-6,091</b>	<b>-36,906</b>	<b>-66,681</b>
Net financial items				<b>5,259</b>
Pretax profit				<b>-61,422</b>

### Note 6 – Changes in financial liabilities in the financing activities

Group's financial liabilities in the financial items consists of current leasing liabilities of KSEK 82 (53) and long-term liabilities of 0 KSEK (117). Opening leasing liability for the year 2020 was KSEK 117. Amortization for the period was KSEK 53 (54) and closing balance leasing liability was KSEK 82 (170). All items are related to IFRS16.

### Note 7 – Acquisition of Rare Thyroid Therapeutics International AB (RTT)

PledPharma entered into an agreement to acquire all outstanding shares in RTT on October 5, 2020. The acquisition was completed on November 3, 2020.

RTT will be consolidated into PledPharma's financial reporting as of November 3, 2020.

The purpose of the acquisition is to create a new company with a strategic focus on late-stage orphan drug development and commercialization of orphan drugs.

The acquisition creates a new specialized late-stage orphan drug development company with core expertise in clinical development, registration and commercialization. The fixed purchase price for the shares in RTT paid at the closing consists of a cash purchase price of 60 MSEK, a share purchase price consisting of 63,773,345 new shares in PledPharma and a deferred purchase price of 10 MSEK (which relates to compensation for converted shareholder contributions) that shall be repaid within 24 months.

The remaining part of the acquisition value consists of a contingent consideration based earnout payments on future net sales of Emticate. The estimated amount calculated at present value amounts to 58,2 MSEK. as well an earn-out payable in connection with a potential sale of a so-called US Rare Paediatric Disease Priority Review Voucher from FDA. The voucher has not currently been assigned any value in the pro forma accounts as the FDA's program is expiring and a future opportunity requires an extension of the program by the US Congress.

KSEK	
<b>Purchase consideration</b>	
New shares issued	337,999
Cash	60,000
Contingent consideration	58,216
Deferred purchase price	10,000
<b>Total purchase consideration</b>	<b>466,215</b>

### Preliminary purchase price allocation

A preliminary purchase price allocation of RTT follows. This analysis is preliminary, mainly due to the measurement and allocation of the surplus value attributable to ongoing research and development projects and deferred tax liabilities are not definitive. Completion is expected coincident with reporting of the fourth quarter 2020.

KSEK	
<b>Fair value of acquired assets and assumed liabilities</b>	
Ongoing research and development projects	586,570
Deferred tax liabilities	-120,833
Cash	478
<b>Total acquired net assets</b>	<b>466,215</b>
<b>Deductible items</b>	
New shares issued	-337,999
Contingent consideration	-58,216
Deferred purchase price	-10,000
Cash	-478
<b>Net cash flow on acquisition of operation</b>	<b>59,522</b>



PledPharma

## Other information

### Next reports

Year-end report for the period January 1- December 31, 2020, February 17, 2021.

Interim report January 1.-March 31, April 22, 2021.

Annual General Meeting April 29,2021.

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

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

This report, and further information is available on the website, [www.pledpharma.se](http://www.pledpharma.se)

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

Phone: +46 (0)73-354 20 62

E-mail: [nicklas.westerholm@pledpharma.se](mailto:nicklas.westerholm@pledpharma.se)

Marie-Louise Alamaa, Interim CFO

Phone: +46 (0)70-861 88 42

E-mail: [marie-louise.alamaa@pledpharma.se](mailto:marie-louise.alamaa@pledpharma.se).

This information is such information as PledPharma 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 11, 2020 at 8.00 am (CET).

PledPharma AB (publ)

Grev Turegatan 11c, 114 46 Stockholm

Org.nr. 556706-6724

Phone: +46(0)8-679 72 10

[www.pledpharma.se](http://www.pledpharma.se)

### Analysts who follow PledPharma

Pareto Securities, Dan Axschuti

Redeye, Niklas Elmhammer

Carnegie, Ulrik Trattner



PledPharma

## Certification

This interim report regarding January to September 2020 provides a true and fair overview of the company's business activities, financial position, and results of operations, and describes significant risks and uncertainties to which the company is exposed.

Stockholm, November 11, 2020.

Håkan Åström

*Chairman of the board*

Elisabeth Svanberg

Board member

Sten Nilsson

Board member

Gunilla Osswald

Board member

Peder Walberg

*Styrelseledamot*

Nicklas Westerholm

CEO



## Review report

### Pledpharma AB (publ), org no 556706-6724

#### Introduction

We have reviewed the interim report for Pledpharma AB (publ) for the period 1 January 2020 – 30 September 2020. 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 11, 2020  
BDO Mälardalen AB

Jörgen Lövgren  
Authorized Public Accountant