

#### Year-end report January-December 2019

# PledPharma presents the fourth quarter and the year-end report 2019

#### **October-December**

- Quarterly net sales MSEK 17.1 (11.2)
- Quarterly results MSEK -23.0 (-22.1)
- Cash and cash equivalents MSEK 255.1 (229.9)
- Cash flow for the quarter MSEK -29.1 (-20.6)
- Result per share before and after dilution SEK -0.4 (-0.5)
- PledPharma's shares commenced trading on the Nasdaq Stockholm main market

#### **PledOx**®

- Global phase III study POLAR-A fully recruited
- PledPharma and Solasia entered a second license agreement for the development and commercialization of PledOx<sup>®</sup> in Asia, targeting neuropathy caused by taxanes and any other chemotherapy
- PledPharma's Asian partner Solasia entered an agreement with Japanese Maruho for commercialization of PledOx<sup>®</sup> in Japan

#### Aladote®

• Regulatory meetings held with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for advice and discussion on the Aladote development program and path to a possible market approval

#### January-December in brief

- PledPharma received MJPY 600, ca. MSEK 49, in milestone payment due to the inclusion of the first Asian patient into the global Phase III program for PledOx<sup>®</sup>
- Aladote<sup>®</sup> has been granted Orphan Drug Designation by FDA
- PledPharma initiated an indication expansion program for PledOx<sup>®</sup> in CIPN associated with taxanes
- PledPharma completed a directed new share Issue of 4,866,665 shares, raising proceeds of SEK 91 million
- The results of the proof of principle study with Aladote were published in the Lancet's journal EBioMedicine
- PledPharma and Solasia entered a second license agreement
- Trading in PledPharma's shares commenced on the Nasdaq Stockholm main market
- Global phase III study POLAR-A fully recruited

## Significant events after the reporting period

• FDA issued a clinical hold in the US of the phase III POLAR-M study

	2019	2018	2019	2018
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net revenues, KSEK	17,052	11,152	82,562	28,321
Result after tax, KSEK	-23,006	-22,138	-61,422	-85,003
Cash flow, KSEK	-29,083	-20,583	24,079	-80,567
Cash, KSEK	255,101	229,876	255,101	229,876
Equity ratio %	91%	91%	91%	91%
Result per share, SEK	-0.4	-0.5	-1.2	-1.7
Result per share after dilution, SEK	-0.4	-0.5	-1.2	-1.7
Average number of employees	9	8	9	8



#### PledPharma in brief – therapies for disabling and life-threatening diseases

PledPharma is an innovative, unique and integrated pharmaceutical drug development company, focusing on improving treatments for diseases with substantial unmet medical need.

The company's most advanced project **PledOx**<sup>®</sup> is a first in class drug candidate and is being developed to prevent nerve damage associated with chemotherapy. A phase III program is ongoing.

The drug candidate **Aladote**<sup>®</sup> is a first in class drug candidate and is being 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 next study is being finalised. Aladote<sup>®</sup> has been granted Orphan Drug Designation in the US. Ambition to initiate one pivotal study phase II/III study with Aladote for marketing authorization application in both US and EU.

PledPharma (STO: PLED) is listed on the Nasdaq Stockholm main market. For more information, see <u>http://www.pledpharma.com/</u>

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

2019 was in many respects an intense and interesting year, both for the company and our clinical projects PledOx<sup>®</sup> and Aladote<sup>®</sup>. The global Phase III study POLAR-A with PledOx, for the prevention of nerve damage associated with chemotherapy (CIPN), was fully recruited and top line results are expected Q1-2021.

#### POLAR program

In January 2020, we experienced a setback when the FDA issued a clinical hold in the US of the POLAR-M study. The decision by the FDA is due to their review of a few numbers of observed adverse events. Therefore, recruitment and dosing of patients is halted in the US. Based on the detailed evaluation of the independent Drug Safety Monitoring Board (DSMB), as well as available clinical and pre-clinical data, our position is that the overall safety profile for PledOx supports the continuation of the POLAR program.

POLAR-M, is progressing in EU and Asia, conducted in 420 patients with more progressed disease and is taking a little longer time. POLAR-M is expected to be fully recruited in Q2 2020.

We will continue to work with the FDA to provide the necessary information to lift the clinical hold. All other regulatory authorities involved in the POLAR program have been informed about the US clinical hold. We continue to have dialogue with the involved authorities. DSMB held an ordinary meeting in the second week of Feb and recommend that the POLAR program continue without modification.

#### Expanded Asian collaboration

In 2019, we also continued to move forward with our fruitful collaboration with our Japanese partner Solasia Pharma. In October, we signed a second license agreement for the development and commercialization of PledOx in Asia, targeting neuropathy caused by taxanes and any other chemotherapy. The agreement includes an upfront payment,

as well as development and regulatory milestones to PledPharma of up to approximately SEK 165 million, as well as sales milestones and royalties. This is on top of the first agreement from November 2017, which included development and sales milestone payments of up to approximately SEK 700 million. To date, PledPharma has received in total approximately SEK 65 million from Solasia in upfront and milestone payments, and in addition, Solasia is paying for the recruitment of patients to the POLAR program in Asia

The new agreement follows our initiated indication expansion program in CIPN caused by taxanes, where preclinical studies are already ongoing to guide further development into a clinical stage. There is a large unmet medical need preventing CIPN caused by taxanes, similar to CIPN triggered by oxaliplatin, where we see an additional substantial potential for PledOx. This is a key step in broadening our pipeline of development projects. We are very pleased with this important license agreement which deepens our collaboration with Solasia.

In December, Solasia also signed an exclusive license agreement with the Japanese pharmaceutical company Maruho for commercialization of PledOx for the treatment of CIPN in Japan. Under the agreement, Maruho will commercialize PledOx exclusively in Japan after Solasia and PledPharma complete development of the product in Japan. This agreement is a further strong validation of the potential for PledOx to address chemotherapy induced nerve damage.

#### **Progress with Aladote**

The other important asset of our portfolio is Aladote In 2019 we continued to further advance this drug candidate, in development for reducing liver damage due to paracetamol overdose. In March, we received an Orphan Drug Designation (ODD) by the FDA for Aladote. The ODD status



can benefit patients by potentially resulting in shorter development time.

Aladote has continuously caught the interest of the scientific community. In April, it was highlighted for a presentation at the global scientific conference EASL ILC, also known as The International Liver Congress, which is one of the largest scientific conferences in the field of liver diseases globally. In July, the results of our proof-of-principle study with Aladote were published in the Lancet's EBioMedicine. This journal sets very high standards for publishing and selects only the most important research results based on its quality and scientific impact. We see both these events as yet further confirmation that Aladote generates great interest potentially to meet the unmet medical need for the treatment of paracetamol poisoning beyond current standard of care.

Following interactions with both the FDA and EMA, early in January this year, we announced a development path forward with one pivotal Phase II/III study with Aladote for marketing authorization application in both the US and EU.

#### Listing on the main market

In parallel with our work advancing our clinical projects, we were involved in lots of other activities that ultimately benefit

the company, the shareholders and other stakeholders, including arranging a well-attended Capital Markets Day in Stockholm, completing a successful rights issue of SEK 91 million in May, and on October 31, making the important transition to the Nasdaq Stockholm's main list. Listing on Nasdaq Stockholm's main list is a natural step in the company's development that confirms the maturity of our business and increases awareness of the company. With a listing on a regulated market, PledPharma also becomes more accessible and attractive to both Swedish and international institutional investors.

Looking ahead, full focus will of course be on the development of our prioritized drug candidates PledOx and Aladote. The safety of patients in our clinical studies is our most important responsibility. We continue to work with the FDA on the issue around the clinical hold of POLAR-M in the US and the continued development with Aladote. I look forward to updating you on our continued progress.

Nicklas Westerholm, CEO PledPharma AB, Stockholm



## Project updates

## **Pledox**<sup>®</sup>

#### Events during the quarter

POLAR-A was fully recruited in December. Top-line results are expected in Q1-2021. As previously communicated. POLAR-M is expected to be fully recruited by Q2 2020 with top line results approximately a year later. In total over 100 clinical sites in Belgium, France, Italy, England, Germany, Spain, Czech Republic, Hungary, Hong Kong, Taiwan, Korea, US and Japan have actively participated in the POLAR program.

PledPharma and Solasia entered a second license agreement for PledOx in Japan, China, Hong Kong, Macau, South Korea and Taiwan covering CIPN by any chemotherapy. The agreement includes development and regulatory milestones to PledPharma of up to approximately MSEK 165 (MUSD 17)\*, as well as sales milestones and royalties. In total the Solasia deal now covers milestones of up to approximately MSEK 880 (MUSD 100)\*.

Subsequently, Solasia entered an exclusive license agreement with Maruho for commercialization of PledOx in

Japan.

A scientific advisory board meeting was held in December to further discuss clinical development of PledOx in subjects who receive taxanes as part of their cancer therapy..

#### Significant events after the reporting period

FDA issued a clinical hold in the US of the phase III POLAR program on the 23<sup>rd</sup> of January for the lead candidate PledOx. The implication is that recruitment and dosing of patients in the POLAR-M study is halted in the US. We will continue to work with the FDA to provide the necessary information to lift the clinical hold.

The independent Drug Safety and Monitoring Board (DSMB) held an ordinary meeting in the second week of Feb and continued to recommend that the POLAR program continue without modification.

 $^{\ast}$  Contract based on JPY, the amount given in USD and SEK is subject to exchange rates.

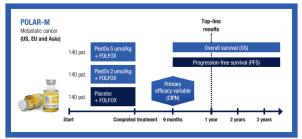
#### About PledOx®

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. PledOx showed 38% effect (odds ratio=0.62; p=0.16) on investigator reported sensory nerve damage, the primary endpoint, compared with the placebo group. This was not statistically significant, but a difference of this magnitude is considered clinically relevant. After completion of chemotherapy, PledOx showed 77% effect (odds ratio=0.23; exploratory analysis: p=0.014) on patientreported moderate and severe neuropathy compared to the placebo group. This is considered valuable for the success

of the POLAR studies, where patient-reported symptoms after completion of treatment will be the primary efficacy parameter. No apparent negative effect on the efficacy of the cancer treatment was observed. The ongoing global phase III program for PledOx consists of two double blinded randomized placebo-controlled trials, POLAR-M and POLAR-A. POLAR-M includes 420 patients undergoing chemotherapy treatment for metastatic colorectal cancer and is being conducted in Asia, Europe and the US. The study compares PledOx at doses of 2 µmol/kg and 5 µmol/kg with placebo. POLAR-A includes 280 patients undergoing adjuvant chemotherapy treatment for colorectal cancer and is being conducted in Asia and Europe. The study compares PledOx at a dose of 5 µmol/kg with placebo. POLAR-A was fully recruited in December 2019. Top-line results are expected approximately one year later. Recruitment for POLAR-M is ongoing in Europe and Asia.







## Aladote®

#### Events during the quarter

PledPharma held meetings with the FDA and EMA for advice and discussion on the Aladote development program.

Significant events after the reporting period

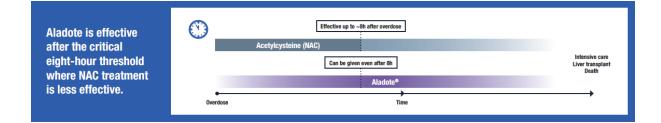
Following regulatory interactions with the FDA and the EMA, the company has finalized the development program for Aladote. The development program consists of one pivotal phase II/III study which is expected to be sufficient for a marketing authorization application in both US and EU. Continued interactions are ongoing with the regulatory agencies to finalize specific study details.

#### **About Aladote®**

Aladote is a "first-in-class" drug candidate with the potential to reduce the risk of acute liver injury caused by paracetamol overdose. Aladote has shown good efficacy in relevant preclinical models, even in the time-window when N-acetylcysteine (NAC) treatment is no longer 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. This is based on the measurement of the predefined exploratory biomarkers, Keratin-18 (K18) and microRNA-122 (miR-122) in patients treated with Aladote and NAC compared to NAC alone. Following regulatory interactions with the FDA and the EMA, the company has finalized the development program for Aladote. The

development program consists of one pivotal phase II/III study which is expected to be sufficient for a marketing authorization application in both US and EU. Aladote has been granted Orphan Drug Designation in the US.

Paracetamol 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 method in intentional suicide attempts. When excessive amounts of paracetamol are broken down in the liver, the harmful metabolite NAPQI is formed, which can cause acute liver failure. 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.





## **Financial Information**

Year-end report, January - December 2019

#### Revenue, and results

#### Revenues

Revenues amounted to KSEK 17,052 (11,152) during the quarter and KSEK 82,562 (28,321) for the period. Revenues during the quarter were due to forward expenses for the PledOx POLAR program to Solasia and signing fee related to the expanded license agreement of MSEK 7.9 and MSEK 9.2, respectively. During the period milestone payment of MJPY 700 (ca MSEK 58) was received from our Asian partner for inclusion of the first Asian patient into the global phase III program for PledOx and the signing of the expanded license agreement regarding PledOx.

#### **Expenses**

Operating expenses amounted to KSEK 37,462 (33,027) for the quarter and KSEK 149,243 (115,215) for the period. Of these, project costs amounted to KSEK 26,266 (24,248) for the quarter and KSEK 112,240 (83,855) for the period. The increase for the period is attributable to the advancement of the POLAR program.

Employee costs amounted to KSEK 7,569 (6,188) for the quarter and KSEK 23,386 (20,034) for the period. The increase is due to the recruitment of new employees during 2019. Also, remuneration for the Board of Directors which is paid as salary according to new regulations are included. The increase in employee costs are mostly mitigated by the reduction of contracted consultants.

Other external costs amounted to KSEK 3,159 (2,591) for the quarter and KSEK 13,334 (11,325) for the period. The increase is attributed to the announced listing of company's shares on the main market of Nasdaq Stockholm. Depreciation amounted to KSEK 54 (0) for the quarter and KSEK 210 (0) for the period and is due to the implementation of IFRS 16 at the beginning of 2019. Other operating items amounted to KSEK -415 (54) for the quarter and KSEK -74 (110) for the period and is attributed to revaluation of accounts due to currency fluctuations. Historical values related to exchange rate differences from cash at hand and operational activities have been recategorized to better fit in respective category.

#### Results

Operating results amounted to KSEK -20,409 (-21,876) for the quarter and KSEK -66,681 (-86,894) for the period. Net financial items amounted to KSEK -2,597 (-262) for the quarter and KSEK 5,259 (1,891) for the period. Results are related to revaluation of company's FX-accounts at the end of the quarter. Results after financial items amounted to KSEK -23,006 (-22,138) for the quarter and KSEK -61,422 (-85,003) for the period. No income tax was reported for the periods. Result per share before and after dilution amounted to SEK -0.4 (-0.5) for the quarter and SEK -1.2 (-1,7) for the period.

#### **Financial position**

#### Cash

Cash at December 31, 2019 amounted to KSEK 255,101 (229,876).

#### Cash flow

Cash flow from operating activities amounted to KSEK -29,029 (-20,583) for the quarter and KSEK -62,641 (-81,222) for the period. Cash flow amounted to KSEK -29,083 (-20,583) for the quarter and KSEK 24,079 (-80,567) for the period. The positive cash flow for the period is due to the milestone payment from our Asian partner during the first quarter, the signing fee during the fourth quarter and the directed rights issue of ca MSEK 91 that was conducted during the second quarter.

#### Equity and equity ratio

At December 31, 2019 equity amounted to KSEK 244,876 (219,362). Shareholders' equity per share amounted to SEK 4.6 (4.5), at the end of the period. The company's equity ratio was 91 (91) %.

#### **Debts and receivables**

Long-term liabilities amounted to KSEK 117 (0). Current liabilities amounted to KSEK 25,081 (22,675). Accounts receivables amounted to KSEK 5,200 (9,444). Non-current assets amounted to KSEK 123 (0). New items on the balance sheet are due to the implementation of IFRS 16.

#### Investments, tangible and intangible assets

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

#### Share

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

#### Warrant program

The 2018 Annual General Meeting resolved on a warrants program for employees of PledPharma of 779,500 warrants, each warrant entitles the holder to subscribe for one (1) new share in the company at a subscription price of SEK 26 per share. As of March 31, 2019, 395,000 warrants were subscribed for by employees, of which the CFO and the



CMO subscribed for the maximum allowed allocation of 100,000 each. 1,526,500 warrants had been subscribed for by employees and board members of PledPharma from the previous warrants program, of which the CEO holds 500,000 warrants.

At full utilization of all warrants, the company's shares will be increased by 2,306,000 to 55,839,321.

#### Employees

Number of employees as of December 31, 2019 were 9 (8) persons, 3 women and 6 men.

#### **Parent company**

The parent company's revenues for the quarter amounted to KSEK 17,052 (11,152) and KSEK 82,562 (28,321) for the period. Expenses for the quarter amounted to KSEK 37,463 (33,026) and KSEK 149,252 (115,214) for the period.

The parent company's result amounted to KSEK -23,006 (-22,137) for the quarter and KSEK -61,427 (-85,003) for the period. Changes in the parent company's statements corresponds to the consolidated changes.



## Consolidated statement of comprehensive income

KSEK	2019	2018	2019	2018
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Revenue				
Sales	17,052	11,098	82,562	28,211
Other operating income	-	54	-	110
	17,052	11,152	82,562	28,321
Operating expenses				
Project costs	-26,266	-24,248	-112,240	-83,855
Other external costs	-3,159	-2,591	-13,334	-11,325
Employee costs	-7,569	-6,188	-23,386	-20,034
Depreciation and impairment	-54	-	-210	-
Other operating expenses	-415	-	-74	-
Operating results	-20,409	-21,876	-66,681	-86,894
Financial items				
Interest income and similar items	46	48	5,266	1,891
Interest expense and similar items	-2,643	-310	-7	-1
Results after financial net	-23,006	-22,138	-61,422	-85,003
Тах	-	-	-	-
Results after tax	-23,006	-22,138	-61,422	-85,003
Statement of comprehensive income				
Other comprehensive income	-	-	-	-
Comprehensive income for the period	-23,006	-22,138	-61,422	-85,003
Net earnings and comprehensive				
income is entirely attributable to parent				
company shareholders				
Share Data				
Number of shares at the end of period	53,533,321	48,666,656	53,533,321	48,666,656
Average number of shares during period		48,666,656		
Result per share before dilution (SEK)	-0.4	-0.5	-1.2	
Result per share after dilution (SEK)	-0.4		-1.2	
Equity per share (SEK)	4.6	4.5	4.7	
Equity per share after dilution (SEK)	4.6	4.5	4.7	-
	1.0			1.0



### Consolidated statement of financial position

KSEK	12/31/2019	12/31/2018
ASSETS		
Non-current assets		
Tangible non-current assets	123	-
Total non-current assets	123	-
Current assets		
Accounts receivables	F 200	0.444
	5,200	9,444
Other receivables	1,704	624
Prepaid expenses and accrued income	7,945	2,093
	14,849	12,161
Cash and bank balance	255,101	229,876
Total current assets	269,950	242,037
Total assets	270,073	242,037

KSEK	12/31/2019	12/31/2018
Equity		
Share capital	2,818	2,561
Other capital contributions	705,278	618,598
Accumulated loss including net loss	-463,220	-401,798
Total equity	244,876	219,362
Long-term liabilities	117	-
Current liabilities		
Accounts payable	11,207	15,174
Other liabilities	1,328	1,205
Accrued expenses and deferred income	12,546	6,296
Total current liabilities	25,081	22,675
Total equity and liabilities	270,073	242,037



#### Consolidated statement of cash flows

KSEK	2019	2018	2019	2018
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
OPERATING ACTIVITIES				
Result after financial net	-23,006	-22,138	-61,422	-85,003
Adjustments for non-cash items*	2,618	-191	-937	-912
Cash flow from operating activities before	-20,388	-22,329	-62,358	-85,916
changes in working capital				
Changes in short term receivables	-10,497	-8,137	49	-6,273
Changes in accounts payable	8,298	8,360	-3,967	9,202
Changes in other liabilities	-6,441	1,523	3,636	1,765
Cash flow from operating activities	-29,029	-20,583	-62,641	-81,222
INVESTING ACTIVITIES		_		
Cash flow from investing activities	-	-	-	-
FINANCING ACTIVITIES				
New share/Warrants issue			01 259	655
Cost new share issue	-	-	91,258	655
	- -54	-	-4,323	-
Repayment of lease liability	-54 -54		-216	- 655
Cash flow from financing activities	-34	-	86,720	655
Cash flow for the period	-29,083	-20,583	24,079	-80,567
Cash now for the period	-25,005	-20,303	24,075	-00,507
Balance at beginning of period	286,748	250,267	229,876	309,531
Change in cash	-29,083	-20,583	24,079	-80,567
Exchange rate difference in cash	-2,564	191	1,146	912
CASH BALANCE AT THE END OF THE PERIOD	255,101	229,876	255,101	229,876
	,	-,	,	- ,

\*predominantly revaluation of bank accounts 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
Opening balance 20190101	2,561	618,598	-401,798	219,362
Transactions with shareholders	-	-	-	-
New share issue	256	91,002	-	91,258
Cost new share issue	-	-4,323	-	-4,323
Comprehensive income for period	-	-	-61,422	-61,422
Closing balance 20191231	2,818	705,278	-463,220	244,876
Opening balance 20180101	2,561	617,944	-316,794	303,711
Transactions with shareholders	-	-	-	-
Incentive program	-	655	-	655
Comprehensive income for period	-	-	-85,003	-85,003
Closing balance 20181231	2,561	618,598	-401,798	219,362

#### **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	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Equity	244,876			
Equity ratio %	91%	91%	91%	91%
Return on equity %	neg.	neg.	neg.	neg.
Number of shares at the end of the period	53,533,321	48,666,656	53,533,321	48,666,656
Number of shares at the end of the period after dilution	53,533,321	48,666,656	53,533,321	48,666,656
Average number of shares under the period	53,533,321	48,666,656	51,626,655	48,666,656
Average number of shares under the period after dilution	53,533,321	48,666,656	51,626,655	48,666,656
Share Data				
Result per share	-0.4	-0.5	-1.2	-1.7
Result per share after dilution	-0.4	-0.5	-1.2	-1.7
Cash flow from operating activities	-0.5	-0.4	-1.2	-1.7
Equity per share	4.6	4.5	4.7	4.5
Equity per share after dilution	4.6	4.5	4.7	4.5
Dividend	-	-	-	-
Average number of employees *Effect from dilution is not considered when result is r	9 negative.	8	9	8



#### **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 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. 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



#### Parent company - income statement

KSEK	2019 Oct Doc	2018 Oct Doc	2019	2018
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Revenue				
	17.050			
Sales	17,052	11,098	82,562	28,211
Other operating income	-	54	-	110
	17,052	11,152	82,562	28,321
Operating expenses				
Project costs	-26,266	-24,248	-112,240	-83,855
Other external costs	-3,214	-2,590	-13,553	-11,324
Employee costs	-7,569	-6,188	-23,386	-20,034
Other operating expenses	-415	-	-74	-
Operating results	-20,410	-21,875	-66,690	-86,893
Financial items				
Interest income and similar items	46	48	5,266	1,890
Interest expense and similar items	-2,642	-310	-2	-1
Results after financial net	-23,006	-22,137	-61,427	-85,003
Group contribution received	-	654	-	654
Тах	-	-	-	-
Results after tax	-23,006	-21,483	-61,427	-84,350



#### Parent company - balance sheet

KSEK	12/31/2019	12/31/2018
ASSETS		
Non-current assets		
Financial non-current assets	50	50
Total non-current assets	50	50
Current assets		
Receivables from group companies	-	2,686
Accounts receivables	5,200	9,444
Other receivables	1,704	624
Prepaid expenses and accrued income	7,945	2,093
	14,849	14,848
Cash and bank balance	254,800	227,139
Total current assets	269,649	241,987
Total assets	269,699	242,037
KSEK	12/31/2019	12/31/2018
Equity		
<b>Equity</b> Restricted Equity		
	2,818	2,561
Restricted Equity	2,818	2,561
Restricted Equity Share capital	2,818 705,026	2,561 618,598
Restricted Equity Share capital Non-restricted equity	·	·
Restricted Equity Share capital Non-restricted equity Share premium reserve	705,026	618,598
Restricted Equity Share capital Non-restricted equity Share premium reserve Retained earnings	705,026 -401,798	618,598 -317,448
Restricted Equity Share capital Non-restricted equity Share premium reserve Retained earnings Net profit for the year	705,026 -401,798 -61,427	618,598 -317,448 -84,350
Restricted Equity Share capital Non-restricted equity Share premium reserve Retained earnings Net profit for the year Total equity	705,026 -401,798 -61,427	618,598 -317,448 -84,350
Restricted Equity Share capital Non-restricted equity Share premium reserve Retained earnings Net profit for the year Total equity Long-term liabilities	705,026 -401,798 -61,427	618,598 -317,448 -84,350
Restricted Equity Share capital Non-restricted equity Share premium reserve Retained earnings Net profit for the year Total equity Long-term liabilities Current liabilities	705,026 -401,798 -61,427 <b>244,619</b>	618,598 -317,448 -84,350 <b>219,362</b>
Restricted Equity   Share capital   Non-restricted equity   Share premium reserve   Retained earnings   Net profit for the year   Total equity   Long-term liabilities   Accounts payable	705,026 -401,798 -61,427 <b>244,619</b> - 11,207	618,598 -317,448 -84,350 <b>219,362</b> - 15,174
Restricted Equity   Share capital   Non-restricted equity   Share premium reserve   Retained earnings   Net profit for the year   Total equity   Long-term liabilities   Accounts payable   Other liabilities	705,026 -401,798 -61,427 <b>244,619</b> - 11,207 1,328	618,598 -317,448 -84,350 <b>219,362</b> - 15,174 1,205



#### 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. Applied accounting principles and calculation methods are the same as in the latest annual report for 2018. Except that the company, as of January 1, 2019, has shifted to account according to IFRS 16. All the numbers in this interim report are, if nothing else is stated, stated in thousands.

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. All leases are reported operationally in the Parent Company.

#### New standards, amendments and interpretations applied by the Group as of January 1, 2019

IFRS 16 has entered into force on January 1, 2019. IFRS 16 replaces IAS 17 Lease Agreement, with new accounting requirements for lessee. All leases, except short-term and low value leasing contracts, shall be reported as an asset with right of use and as a corresponding liability in the leaseholder's balance sheet. The standard is expected to provisionally mean that most of the leases reported in these financial statements as operating leases will, as of January 1, 2019 be reported according to IFRS 16. Hence, costs consist of interest expense and depreciation and are reported accordingly. PledPharma applies the simplified transition model in the group's consolidated numbers. Leasing contracts of low value will henceforth be accounted as operating leases and reported in the income statement. Group's leasing portfolio consists of five agreements which includes operating leases of office, office equipment and cars. At the entry into 2019 one of the group's rental agreements had a duration of less than 12 months and two contracts related to office equipment were regarded to be of low value. These agreements fall into the exception of short term leasing contracts and minor leasing contracts.

SEKk	
Leasing agreements according to Note 20, annual report	1,109
Deduction for short-term leases	-907
Discounted according to Group's borrowing interest rate of 2%	-7
Adjustments future lease payments	137
Presented liability, 2019-01-01	332

#### **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 2018 Annual Report. There are no major changes in the Group's risk exposure in 2019 compared with previous year.

#### 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 6. For events after the period, see page 1.



#### Note 3 – Financial assets and liabilities

KSEK	Hold to collect	Financial debts	Total
	Amortised	Amortised	
	cost	cost	
Group December 31, 2019			
Accounts receivable	5,200	-	5,200
Cash	255,101	-	255,101
Total financial assets	260,301	-	260,301
Long-term liabilities	-	117	117
Accounts payable	-	11,207	11,207
Other liabilities	-	1	1
Total financial liabilities	-	11,324	11,324
Group December 31, 2018			
Accounts receivable	9,444	-	9,444
Cash	229,876	-	229,876
Total financial assets	239,320	-	239,320
Accounts payable	-	15,174	15,174
Other liabilities	-	-	-
Total financial liabilities	-	15,174	15,174

#### Note 4 – Related party transactions

There are none transactions to be reported with related parties.

#### Note 5 – Segments

Operating results

Pretax profit

Net financial items

-23,684

-6,091

-36,906 -66,681

5,259

-61,422

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

2019					2018				
Oct-dec					Oct-dec				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	17,052	-	-	17,052	Revenues	11,098	-	54	11,152
Project costs	-23,435	-2,831	-	-26,266	Project costs	-21,058	-2,931	-259	-24,248
Other	-10	-	-11,186	-11,196	Other	-3	-	-8,776	-8,779
Operating results	-6,393	-2,831	-11,186	-20,409	Operating results	-9,964	-2,931	-8,982	-21,876
Net financial items				-2,597	Net financial items				-262
Pretax profit				-23,006	Pretax profit				-22,138
2019					2018				
Jan-Dec					Jan-Dec				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	82,539	-	22	82,562	Revenues	28,211	-	110	28,321
Project costs	-106,148	-6,091	-	-112,240	Project costs	-76,398	-7,044	-414	-83,855
Other	-75	-	-36,928	-37,003	Other	-3	-	-31,356	-31,359

Operating results

Net financial items

Pretax profit

-48,190 -7,044

-31,660 -86,894

1,891

-85,003



#### 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 0 and long-term liabilities of KSEK 117. Opening leasing liability for the year 2019 was SEK 0. Non cash flow items in the transition to IFRS 16 was KSEK 332. Amortization for the period was KSEK 210 and closing balance leasing liability was KSEK 123.



#### **Other information**

#### **Next reports**

Interim report Jan – Mar 2020, April 22, 2020 Half-year report Jan – Jun 2020, August 20, 2020 Interim report Jan – Sep 2020, November 4, 2020

This report, and further information is available on the website, www.pledpharma.se This report has not been reviewed by the company's auditor. This is a translation of the Swedish interim report.

#### **Annual General Meeting 2020**

Annual general meeting will be held April 23, 2020. Time: 16:00 CET, Venue: Erik Penser Bank, Apelbergsgatan 27, Stockholm. The annual report will be published during week 13, 2020.

PledPharma's board of directors do not recommend any dividend for the full-year 2019.

For further information, please contact:

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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 February 18, 2020 at 8.00 am (CET).

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#### Analysts who follow PledPharma

Pareto Securities, Dan Akschuti and Johan Unnérus Redeye, Klas Palin. Carnegie, Ulrik Trattner.



#### Certification

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

Stockholm, February 18, 2020

Håkan Åström Chairman of the board

Marie Ekström Trägårdh Board member

Sten Nilsson

Board member

Gunilla Osswald Board member

Elisabeth Svanberg Board member Nicklas Westerholm CEO