

**Interim report January-September 2019** 

# Recruitment in POLAR-A confirms availability of top-line results before year end 2020

## July-September

- Quarterly net sales MSEK 6.2 (6.7)
- Quarterly results MSEK -31.9 (-18.8)
- Cash and cash equivalents MSEK 286.7 (250.3)
- Cash flow for the guarter MSEK -35.9 (-16.1)
- Result per share before and after dilution SEK -0.6 (-0.4)

## PledOx®

- Patient recruitment to the global phase III studies POLAR-A and POLAR-M is well underway. Recruitment in POLAR-A is expected to be completed before year end 2019, with top line results before year end 2020, as previously communicated. POLAR-M is expected to be fully recruited by Q2 2020
- The independent Data and Safety Monitoring Board (DSMB) held its first meeting and recommended that the POLAR program could continue without modification

#### **Aladote®**

- PledPharma has been granted a meeting with the FDA for the fourth quarter for advice and discussion on the next Aladote study and path to a possible market approval. A meeting with the European Medicines Agency, EMA, will take place during the same period
- The results of the proof of principle study with Aladote were published in the Lancet's journal EBioMedicine, one of the most prominent biomedical research journals

## January-September 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®
- Aladote® has been granted Orphan Drug Designation by FDA
- PledPharma initiated an indication expansion program for PledOx in CIPN associated with taxanes
- PledPharma completed a directed new share Issue of 4,866,665 shares, raising proceeds of SEK 91 million

## Significant events after the reporting period

- PledPharma and Solasia entered a second license agreement for the development and commercialisation of PledOx® in Asia, targeting neuropathy caused by taxanes and any other chemotherapy
- Nasdaq Stockholm's Listing Committee has approved the admission of the company's shares for trading on the main market of Nasdag Stockholm, subject to customary conditions

	2019 Jul-Sep	2018 Jul-Sep	2019 Jan-Sep	2018 Jan-Sep	2018 Jan-Dec
Net revenues, KSEK	6,182	6.715	65,520	17.114	28,212
Net revenues, NSEN	0,102	0,713	05,520	17,114	20,212
Result after tax, KSEK	-31,893	-18,844	-38,416	-62,866	-85,003
Cash flow, KSEK	-35,903	-16,080	52,851	-60,424	-81,355
Cash, KSEK	286,748	250,267	286,748	250,267	229,876
Equity ratio %	92%	95%	92%	95%	91%
Result per share, SEK	-0.6	-0.4	-0.8	-1.3	-1.7
Result per share after dilution, SEK	-0.6	-0.4	-0.8	-1.3	-1.7
Average number of employees	9	8	9	8	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® is a first in class drug candidate and is being developed to prevent nerve damage associated with chemotherapy. A global phase III program is ongoing.

The drug candidate Aladote® 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® has been granted Orphan Drug Designation in the US.

PledPharma (STO:PLED) is listed on Nasdaq First North Growth Market. Erik Penser Bank acts Certified Adviser (www.penser.se). For further information, please see www.pledpharma.se

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

# Recruitment in POLAR-A is expected to be completed before year end 2019

In and just after the third quarter of 2019, we passed a number of significant milestones, both for the company and our clinical projects PledOx® and Aladote®.

## POLAR-A part of PledOx Global Phase III program expects to be fully recruited before year end 2019

We are on target to complete the recruitment of the 280 patients in the POLAR-A study. This is an important milestone for us, which paves the way to top-line results by the end of 2020 as previously communicated. The second study, POLAR-M (420 patients), conducted in patients with more progressed disease is taking a little longer time. POLAR-M is expected to be fully recruited in Q2 2020, and it is anticipated that we will have top line results approximately a year later.

#### Second license agreement with Solasia Pharma

After the period, in October, we signed a second license agreement with Solasia, covering chemotherapy induced peripheral neuropathy (CIPN) 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 MSEK 165, as well as sales milestones and royalties.

The new agreement follows our initiated indication expansion program in CIPN caused by taxanes, where preclinical studies are already ongoing to guide further development in 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 deepen our collaboration with our partner Solasia.

## Continued significant scientific interest for our clinical projects

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 this as yet another confirmation that Aladote results generate great interest potentially to meet the unmet medical need for the treatment of paracetamol poisoning beyond current standard of care.

#### Listing on the main market

In parallel with our groundbreaking work with our clinical projects, we are very pleased with the completion of the process to be listed on Nasdaq Stockholm's main list. On October 16, we announced that Nasdaq Stockholm's Listing Committee has approved that the company's shares are admitted to trading subject to customary conditions. The October 31 is set as the first day of trading. 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.

#### Eventful period ahead

We have a very interesting and exciting period ahead of us, and an important milestone is of course the completion of the recruitment to the POLAR studies. During the fourth quarter of 2019, we are also having regulatory interactions with the FDA and the EMA, in relation to the development program of Aladote to optimize the path to a possible market approval. Preclinical taxanes studies are progressing as planned, and we are looking forward to the results from them early next year. In parallel, we are also planning a



Scientific advisory board meeting in December to further discuss clinical development of PledOx in taxanes. These are important steps and I look forward to updating you on our continued progress.

Nicklas Westerholm, CEO PledPharma AB, Stockholm



## **Project updates**

## Pledox®

#### **Events during the quarter**

Patient recruitment to the global phase III studies, POLAR-A and POLAR-M, is progressing on all three continents. In total over 100 clinical sites in Belgium, France, Italy, England, Germany, Spain, Czech Republic, Hong Kong, Taiwan, Korea, US and Japan actively participate in the POLAR program. Recruitment in POLAR-A is expected to be completed before year end 2019, with top line results before year end 2020, as previously communicated. POLAR-M is expected to be fully recruited by Q2 2020 and PledPharma anticipate top line results approximately a year

The independent Data Safety and Monitoring Board

(DSMB) held its first meeting and recommended that the POLAR program could continue without modification

#### Significant events after the reporting period

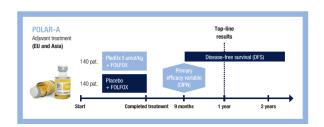
PledPharma and Solasia have entered a second license agreement for PledPharma's lead candidate PledOx® in Japan, China, Hong Kong, Macau, South Korea and Taiwan, covering chemotherapy induced peripheral neuropathy (CIPN) by any chemotherapy in any cancer type. The agreement includes development and regulatory milestones to PledPharma of up to approximately MSEK 165 (MUSD 17)\*, as well as sales milestones and royalties..

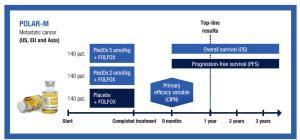
\* Contract based on JPY, the amount given in USD and SEK is subject to exchange

#### 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.







## **Aladote®**

#### **Events during the quarter**

PledPharma has been granted a meeting with the FDA in the fourth guarter for advice and discussion on the Aladote development program. A meeting with the European Medicines Agency, EMA, will take place during the same period.

The Lancet's EBioMedicine, one the most well-known biomedical scientific journals, has published the positive results from the proof-of-principle study of Aladote.

#### Significant events after the reporting period

There are no events to report.

## About Aladote®

Aladote is a "first-in-class" drug candidate with the potential to reduce the risk of acute liver injury 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. Proposals for the design of the next study have been finalised together with our

external advisory board and will serve the basis for upcoming regulatory interactions. 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.

Effective up to ~8h after overdose **Aladote is effective** after the critical eight-hour threshold where NAC treatment is less effective.



## **Financial Information**

## Interim report, January - September 2019

#### Revenue, and results

#### Revenues

Revenues amounted to KSEK 6,182 (6,715) during the quarter and KSEK 65,520 (17,114) for the first nine months. Revenues during the quarter were primarily due to forward expenses for the PledOx POLAR program to Solasia and during the first nine months to the milestone payment of MJPY 600 (ca MSEK 49) from our Asian partner for inclusion of the first Asian patient into the global phase III program for PledOx.

#### **Expenses**

Operating expenses amounted to KSEK 41,473 (27,317) for the quarter and KSEK 114,877 (86,591) for the first nine months. Of these, project costs amounted to KSEK 33,633 (17,991) for the quarter and KSEK 85,974 (59,607) for the first nine months. The increase for the first nine months is attributable to the advancement of the POLAR program.

Employee costs amounted to KSEK 4,569 (4,355) for the quarter and KSEK 15,818 (13,846) for the first nine months. 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 3,218 (2,460) for the quarter and KSEK 10,175 (8,734) for the first nine months. 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 156 (0) for the first nine months and is due to the implementation of IFRS 16 at the beginning of 2019. Other operating items amounted to KSEK 0 (-2,510) for the quarter and KSEK -2,755 (-4,404) for the first nine months and is attributed to revaluation of accounts due to currency fluctuations.

#### **Results**

Operating result amounted to KSEK -35,292 (-20,601) for the quarter and KSEK -49,357 (-69,477) for the first nine months. Financial and related items amounted to KSEK 3,399 (1,757) for the guarter and KSEK 10,942 (6,610) for the first nine months. Results are related to revaluation of company's FX-accounts at the end of the guarter. Results after financial items amounted to KSEK -31,893 (-18,844) for the guarter and KSEK -38,416 (-62,866) for the first nine months. No income tax was reported for the periods. Result per share before and after dilution amounted to SEK -0.6

(-0.4) for the guarter and SEK -0.8 (-1.3) for the first nine months.

## **Financial position**

#### Cash

Cash at September 30, 2019 amounted to KSEK 286,748 (250, 267).

#### Cash flow

Cash flow from operating activities amounted to KSEK -35,849 (-16,735) for the quarter and KSEK -33,922 (-61,079) for the first nine months. Cash flow amounted to KSEK -35,903 (-16,080) for the quarter and KSEK 52,851 (-60,424) for the first nine months. The positive cash flow for the first nine months is due to the milestone payment from our Asian partner during the first quarter and the directed rights issue of ca MSEK 91 that was conducted during the second quarter.

#### Equity and equity ratio

At September 30, 2019 equity amounted to KSEK 267,882 (241,499). Shareholders' equity per share amounted to SEK 5.0 (5.0), at the end of the period. The company's equity ratio was 92 (95) %.

## **Debts and receivables**

Long-term liabilities amounted to KSEK 117 (0). Current liabilities amounted to KSEK 23,277 (12,742). Accounts receivables amounted to KSEK 1,853 (374). Non-current assets amounted to KSEK 176 (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 September 30, 2019 were 53,533,321. PledPharma's shares are listed on Nasdaq First North since April 7, 2011.

#### 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 September 30, 2019 were 9 (8) persons, 3 women and 6 men.

## **Parent company**

The parent company's revenues for the quarter amounted to KSEK 6,182 (6,715) and KSEK 65,520 (17,114) for the first nine months. Expenses for the quarter amounted to KSEK 41,474 (27,317) and KSEK 114,886 (86,590) for the first nine months.

The parent company's result amounted to KSEK -31,893 (-18,844) for the quarter and KSEK -38,420 (-62,865) for the first nine months. Changes in the parent company's statements corresponds to the consolidated changes.



# Consolidated statement of comprehensive income

KSEK	2019	2018	2019	2018	2018
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
_					
Revenue					
Sales	6,171	6,715	65,509	17,113	28,211
Other operating income	11		11	2	2
	6,182	6,715	65,520	17,114	28,212
Operating expenses					
Project costs	-33,633	-17,991	-85,974	-59,607	-83,855
Other external costs	-3,218	-2,460	-10,175	-8,734	-11,325
Employee costs	-4,569	-4,355	-15,818	-13,846	-20,034
Depreciation and impairment	-54	-	-156	-	-
Other operating revenues/expenses	-	-2,510	-2,755	-4,404	-5,511
Operating results	-35,292	-20,601	-49,357	-69,477	-92,514
Financial items					
Interest income and similar items	3,400	1,757	10,947	6,611	7,511
Interest expense and similar items	-1	-	-6	0	-1
Results after financial net	-31,893	-18,844	-38,416	-62,866	-85,003
Tax	-	-	-	-	
Results after tax	-31,893	-18,844	-38,416	-62,866	-85,003
Statement of comprehensive income					
Other comprehensive income	-	-	-	-	_
Comprehensive income for the period	-31,893	-18,844	-38,416	-62,866	-85,003
				-	
Net earnings and comprehensive income is					
entirely attributable to parent company					
Share Data					
Number of shares at the end of period	53,533,321	48,666,656	53,533,321	48,666,656	48,666,656
Average number of shares during period	53,533,321	48,666,656	50,974,743	48,666,656	48,666,656
Result per share before dilution (SEK)	-0.6	-0.4	-0.8	-1.3	-1.7
Result per share after dilution (SEK)	-0.6	-0.4	-0.8	-1.3	-1.7
Equity per share (SEK)	5.0	5.0	5.0	5.0	4.5
Equity per share after dilution (SEK)	5.0	5.0	5.0	5.0	4.5
Equity por origin and and anatori (OLIV)	0.0	5.0	5.0	5.0	7.0



# Consolidated statement of financial position

KSEK	9/30/2019	9/30/2018	12/31/2018
ASSETS			
Non-current assets			
Tangible non-current assets	176	-	-
Total non-current assets	176	-	-
Current assets			
Accounts receivables	1,853	374	9,444
Other receivables	601	733	624
Prepaid expenses and accrued income	1,899	2,866	2,093
	4,352	3,974	12,161
Cash and bank balance	286,748	250,267	229,876
Total current assets	291,100	254,241	242,037
Total assets	291,276	254,241	242,037

KSEK	9/30/2019	9/30/2018	12/31/2018
Familia			
Equity			
Share capital	2,818	2,561	2,561
Other capital contributions	705,278	618,598	618,598
Accumulated loss including net loss	-440,213	-379,661	-401,798
Total equity	267,882	241,499	219,362
Long-term liabilities	117	-	-
Current liabilities			
Accounts payable	2,909	6,814	15,174
Other liabilities	1,481	1,089	1,205
Accrued expenses and deferred income	18,887	4,840	6,296
Total current liabilities	23,277	12,742	22,675
Total equity and liabilities	291,276	254,241	242,037



# **Consolidated statement of cash flows**

KSEK	2019	2018	2019	2018	2018
ODED ATINIO AOTI (ITIE)	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
OPERATING ACTIVITIES	04.000	10011	00.440	00.000	0= 000
Result after financial net	-31,893	-18,844	-38,416	-62,866	-85,003
Adjustments for non-cash items*	-3,049	705	-3,865	-1,161	-1,700
Cash flow from operating activities before changes	-34,942	-18,139	-42,281	-64,027	-86,703
in working capital					
Changes in short term receivables	239	10,095	10,546	1,864	-6,273
Changes in accounts payable	-11.567	-8.839	-12.265	842	9.202
. ,	10,421	-0,039	10,077	243	1,765
Changes in other liabilities					
Cash flow from operating activities	-35,849	-16,735	-33,922	-61,079	-82,009
INVESTING ACTIVITIES					
Cash flow from investing activities	-		_	-	
ouen non mon mounty uoun noo					
FINANCING ACTIVITIES					
New share/Warrants issue	-	655	91,258	655	655
Cost new share issue	-	-	-4,323	-	-
Repayment of lease liability	-54	-	-162	-	-
Cash flow from financing activities	-54	655	86,774	655	655
Cash flow for the period	-35,903	-16,080	52,851	-60,424	-81,355
oash now for the period	-55,505	-10,000	32,031	-00,424	-01,555
Balance at beginning of period	319,549	267,053	229,876	309,531	309,531
Change in cash	-35,903	-16,080	52,851	-60,424	-81,355
Exchange rate difference in cash	3,102	-705	4,021	1,161	1,700
CASH BALANCE AT THE END OF THE PERIOD	286,748	250,267	286,748	250,267	229,876

<sup>\*</sup>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	Total equity
			the period	
Opening balance 20180101	2,561	617,944	-316,794	303,711
Transactions with shareholders	-	-	-	-
Incentive program	-	655	-	655
Comprehensive income for period	-	-	-62,866	-62,866
Closing balance 20180930	2,561	618,598	-379,661	241,499
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	-	-	-38,416	-38,416
Closing balance 20190930	2,818	705,278	-440,213	267,882
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	2018	2019	2018	2018
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Equity	267,882	241,499	267,882	241,499	219,362
Equity ratio %	92%	95%	92%	95%	91%
Return on equity %	neg.	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	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	48,666,656
Average number of shares under the period	53,533,321	48,666,656	50,974,743	48,666,656	48,666,656
Average number of shares under the period after dilution	53,533,321	48,666,656	50,974,743	48,666,656	48,666,656
Share Data					
Result per share	-0.6	-0.4	-0.8	-1.3	-1.7
Result per share after dilution	-0.6	-0.4	-0.8	-1.3	-1.7
Cash flow from operating activities	-0.7	-0.3	-0.7	-1.3	-1.7
Equity per share	5.0	5.0	5.0	5.0	4.5
Equity per share after dilution	5.0	5.0	5.0	5.0	4.5
Dividend	-	-	-	-	-
Average number of employees	9	8	9	8	8
*Effect from dilution is not considered when result is negative	æ.				



## **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	2018	2019	2018	2018
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Revenue					
Sales	6,171	6,715	65,509	17,113	28,211
Other operating income	11	-	11	2	2
	6,182	6,715	65,520	17,114	28,212
Operating expenses					
Project costs	-33,633	-17,991	-85,974	-59,607	-83,855
Other external costs	-3,273	-2,460	-10,339	-8,733	-11,324
Employee costs	-4,569	-4,355	-15,818	-13,846	-20,034
Other operating revenues/expenses	-	-2,510	-2,755	-4,404	-5,511
Operating results	-35,293	-20,601	-49,365	-69,476	-92,513
Financial items					
Interest income and similar items	3,400	1,757	10,947	6,611	7,510
Interest expense and similar items	0	-	-2	0	-1
Results after financial net	-31,893	-18,844	-38,420	-62,865	-85,003
Тах	-	-	-	-	
Results after tax	-31,893	-18,844	-38,420	-62,865	-84,350



# Parent company - balance sheet

KSEK	9/30/2019	9/30/2018	12/31/2018
ASSETS			
Non-current assets			
Financial non-current assets	50	50	50
Total non-current assets	50	50	50
Current assets			
Receivables from group companies	-	2,083	2,686
Accounts receivables	1,853	374	9,444
Other receivables	601	733	624
Prepaid expenses and accrued income	1,899	2,866	2,093
	4,352	6,057	14,848
Cash and bank balance	286,447	247,531	227,139
Total current assets	290,799	253,587	241,987
Total assets	290,849	253,637	242,037
KSEK	9/30/2019	9/30/2018	12/31/2018
Equity			
Share capital	2,818	2,561	2,561
Non-restricted equity			
Share premium reserve	705,277	618,598	618,598
Retained earnings	-408,577	-317,449	-317,448
Net profit for the year	-31,893	-62,865	-84,350
Total equity	267,625	240,845	219,362
Long-term liabilities	-	-	-
Current liabilities			
Liabilities to group company	-	50	-
Accounts payable	2,909	6,814	15,174
Other liabilities	1,428	1,089	1,205
Accrued expenses and deferred income	18,887	4,840	6,296
Total current liabilities	23,224	12,792	22,675
Total equity and liabilities	290,849	253,637	242,037



#### **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 equipments was 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 5. 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 September 30, 2019			
Accounts receivable	1,853	-	1,853
Cash	286,748	-	286,748
Total financial assets	288,600	-	288,600
Long-term liabilities	-	117	117
Accounts payable	-	2,909	2,909
Other liabilities	-	54	54
Total financial liabilities	-	3,080	3,080
Group 30 September 2018			
Accounts receivable	374	-	374
Cash	250,267	-	250,267
Total financial assets	250,642	-	250,642
Accounts payable	-	6,814	6,814
Other liabilities		-	-
Total financial liabilities	-	6,814	6,814

## Note 4 – Related parties transactions

There are none 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 calmangafodipir. The chief operating decision maker in the company allocates company resources between these two projects. PledOx revenues reported are attributed to a milestone payment and forward expenses for the asian part of the POLAR studies. Table below depicts revenues and costs attributed to PledOx and Aladote.

2019					2018				
Jul-Sep					Jul-Sep				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	6,159	-	22	6,182	Revenues	6,715	-	-	6,715
Project costs	-32,922	-711	-	-33,633	Project costs	-14,866	-2,995	-130	-17,991
Other	-65	-	-7,775	-7,840	Other	-	-	-9,326	-9,326
Operating results	-26,828	-711	-7,752	-35,292	Operating results	-8,151	-2,995	-9,456	-20,601
Net financial items			_	3,399	Net financial items			_	1,757
Pretax profit				-31,893	Pretax profit				-18,844

2019					2018				
Jan-Sep					Jan-Sep				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	65,498	-	22	65,520	Revenues	17,113	-	2	17,114
Project costs	-82,713	-3,260	-	-85,974	Project costs	-55,339	-4,113	-154	-59,607
Other	-65	-	-28,838	-28,904	Other	-	-	-26,984	-26,984
Operating results	-17,281	-3,260	-28,816	-49,357	Operating results	-38,227	-4,113	-27,137	-69,477
Net financial items				10,942	Net financial items			-	6,610
Pretax profit				-38,416	Pretax profit				-62,866



## 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 53 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 first nine month period was KSEK 156 and closing balance leasing liability was KSEK 176.



## Other information

#### **Next reports**

Year-end report Jan – Dec 2019, February 18, 2020 Interim report Jan – Mar 2019, April 22, 2020

This report, and further information is available on the website, www.pledpharma.se This report has 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.

#### 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 October 23, 2019 at 8.00 am (CET).

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#### **Certified Adviser**

The company's Certified Advisor is Erik Penser Bank (phone +46 8 463 80 00).

#### Analysts who follow PledPharma

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, October 23, 2019

Håkan Åström Marie Ekström Trägårdh

Chairman of the board Board member

Sten Nilsson Gunilla Osswald

Board member Board member

Elisabeth Svanberg Nicklas Westerholm

Board member 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 2019 – 30 September 2019. 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 23 October 2019 BDO Mälardalen AB

Jörgen Lövgren Authorized Public Accountant