

## Half-Year report January-June 2019 STRENGTHENED FINANCIAL POSITION BENEFITS OUR DEVELOPMENT PROGRAMS

## April-June

- Quarterly net sales MSEK 4.4 (9.7)
- Quarterly results MSEK -29.4 (-28.2)
- Cash and cash equivalents MSEK 319.5 (267.1)
- Cash flow from operating activities MSEK 61.5 (-27.3)
- Result per share SEK -0.6 (-0.6)
- PledPharma completed a directed new share Issue of 4,866,665 shares, raising proceeds of SEK 91 million at a subscription price of SEK 18.7 per share, corresponding to zero percent discount to May 21 closing price

#### PledOx®

- Patient recruitment to the global phase III studies POLAR-A and POLAR-M is continuing. The ambition is to deliver top-line results before year-end 2020
- PledPharma presented the global Phase III program of PledOx<sup>®</sup> at the international cancer conference American Society of Clinical Oncology (ASCO)
- Pre-clinical studies to expand PledOx<sup>®</sup> indication to Chemotherapy Induced Peripheral Neuropathies (CIPN) associated with taxanes have been initiated

#### Aladote®

 PledPharma's drug candidate Aladote<sup>®</sup> and its proof of principle study (POP study) results were recognized as one of the highlights at one of the world's largest liver conferences, European Association of the Study of the Liver International Liver Congress (EASL ILC)

### Significant events after the reporting period

- Regulatory interactions with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the development program are planned for the fourth quarter 2019
- The Aladote study results was <sup>®</sup> published in Lancet EBioMedicine

	2019	2018	2019	2018	2018
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net revenues, SEKk	4,437	9,668	59,339	10,399	28,212
Result after tax, SEKk	-29,412	-28,211	-6,523	-44,022	-85,003
Cash flow, SEKk	61,512	-27,289	89,673	-42,478	-79,655
Cash, SEKk	319,549	267,053	319,549	267,053	229,876
Equity ratio %	92%	92%	92%	92%	91%
Result per share, SEK	-0.6	-0.6	-0.1	-0.9	-1.7
Result per share after dilution, SEK	-0.6	-0.6	-0.1	-0.9	-1.7
Average number of employees	10	8	10	7	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  $PledOx^{\otimes}$  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**<sup>®</sup> is a first in class drug candidate and is being developed to reduce the risk of acute liver injury associated with acetaminophen 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.

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



## Comments from the CEO COMPLETED RIGHTS ISSUE BENEFITS OUR DEVELOPMENT PROGRAMS

In the second quarter of 2019, a number of important milestones were passed, both for the company and our two clinical projects.

The Phase III program for PledOx<sup>®</sup> is well underway

The recruitment of our global Phase III POLAR studies of PledOx is proceeding, and it is our objective to deliver top line results before year end 2020 and after marketing authorization approval introduce the first drug to prevent CIPN caused by chemotherapy. The recruitment of patients in Europe, Asia and the US is well underway. In total 101 clinical sites in Belgium, France, Italy, England, Germany, Spain, Czech Republic, Hong Kong, Taiwan, Korea, US and Japan actively participates in the POLAR program. Earlier in the year, our Asian partner Solasia Pharma announced that the first patient had been included in Japan. As a result, we received our first milestone payment of MSEK 49 from Solasia.

# Strengthened financial position benefits our development programs

The company's financial position was strengthened with ca MSEK 91, gross, during the quarter. We have a clear strategic plan how to use the proceeds from the issue. Firstly, we will accommodate the clinical development of our drug candidate Aladote given the positive results from the first clinical study and the newly granted orphan drug designation (ODD) in the US. Secondly, the preclinical indication expansion program of PledOx® in Chemotherapy Induced Peripheral Neuropathy (CIPN) caused by taxanes is proceeding. Thirdly, activities required for a market authorization application of PledOx in oxaliplatin-induced CIPN.

Indication expansion for PledOx<sup>®</sup> ongoing with taxanes

To create further value with PledOx, we have initiated an indication expansion program in CIPN caused by taxanes with a high medical need similar to that of CIPN triggered by oxaliplatin. Taxanes have a significant use in clinical practice for example in the treatment of breast and ovarian cancer. Our ambition is to create an additional opportunity to offer cancer patients a treatment that prevents CIPN side effects and improves the quality of life. These preclinical studies are underway, and we will update you about this exciting opportunity in future announcements.

# Significant scientific interest validates the possibilities for our clinical projects

In April, the results from the proof-of-principle study (phase Ib/IIa) of Aladote were presented at the annual EASL International Liver Congress, in Vienna, Austria, which is one of the largest global scientific conferences in the field of hepatology. The study results were recognized as one of the highlights at the conference, which of course is very gratifying for us. After the period, in July, the results of our proof-of-principle with Aladote were published in the Lancet's EBioMedicine. This publication 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.

The global phase III program POLAR with PledOx was presented at a poster session during the annual ASCO conference in Chicago in June. The presentation of the study of PledOx at the most prominent oncology conference is a validation of the interest in its potential.

#### Listing on the main market

The process to list our share on Nasdaq Stockholm's main market is progressing, and we aim to have it completed in the fourth quarter. Our desire with this move is to create further interest from a broader investor base, which will also reflect the maturity of our business.

#### **Eventful period ahead**

The most important milestone is of course the completion of the recruitment to the POLAR studies.

During the fourth quarter of 2019, we are having regulatory interactions with the US FDA and the EMA, in relation to the development program of Aladote to optimize the path to a possible market approval. These are important steps towards meeting the medical need of those suffering from paracetamol poisoning and is one of many project activities that we will achieve in the near future.

With the events and activities mentioned above, combined with a globally robust IP portfolio for PledOx and Aladote and our strong organization, I am looking forward to an eventful and exciting period ahead of us.

Nicklas Westerholm, CEO PledPharma AB, Stockholm



## Project updates

## Pledox®

#### Events during the quarter

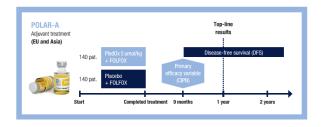
Patient recruitment to the global phase III studies, POLAR-A and POLAR-M, is ongoing on all three continents. In total 101 clinical sites in Belgium, France, Italy, England, Germany, Spain, Czech Republic, Hong Kong, Taiwan, Korea, US and Japan actively participates in the POLAR program. To contribute to good recruitment with high quality PledPharma has been establishing relations with the majority of the investigators and clinical study personnel through visits. Top-line results are still expected in the fourth quarter of 2020. The first Preclinical studies to support the indication expansion program for PledOx in CIPN associated with taxanes were initiated in the quarter, an area with similar unmet medical need as CIPN associated with oxaliplatin.

In June, the POLAR program was presented at the global cancer conference American Society of Clinical Oncology in Chicago.

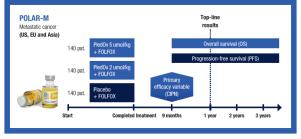
Significant events after the reporting period There are no events to report.

#### 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. 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 forthcoming 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 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

The positive results from the Phase Ib/IIa proof-of-principle study of Aladote was presented orally at the global conference EASL ILC 2019, also known as The International Liver Congress. The conference is one of the largest scientific conferences in the field of hepatology (liver diseases) globally. The results were recognized as one of the highlights of the conference.

#### Significant events after the reporting period

A meeting with the FDA for advice and discussion regarding theAladote development program and the regulatory path to approval has been confirmed to the fourth quarter. Advice from the EMA is expected in the same time 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.

#### About Aladote®

Aladote is a "first-in-class" drug candidate with the potential to prevent the development of acute liver failure 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 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. 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.

Aladote is effective after the critical	•	Effective up to -8h after overdose Acetylcysteine (NAC)	
eight-hour threshold where NAC treatment		Can be given even after 8h	Intensive care Liver transplant Death
is less effective.		Aladote®	<b>_</b>
	Overdose	Time	,



## **Financial Information**

Half-Year report, January - June 2019

### Revenue, and results

#### Revenues

Revenues amounted to KSEK 4,437 (9,668) during the quarter and KSEK 59,339 (10,399) for the first six months. Revenues during the quarter were primarily due to forward expenses for PledOx and during the first six months to the milestone payment of JPYM 600 (ca SEKM 49) from our Asian partner for the inclusion of the first Asian patient into the global phase III program for PledOx.

#### Expenses

Operating expenses amounted to KSEK 38,271 (40,088) for the quarter and KSEK 73,404 (59,274) for the first six months. Of these, project costs amounted to KSEK 26,101 (30,730) for the quarter and KSEK 52,340 (41,616) for the first six months. The increase for the first six months is attributable to the POLAR program.

Employee costs amounted to KSEK 5,711 (4,778) for the quarter and KSEK 11,249 (9,491) for the first six 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 4,233 (3,257) for the quarter and KSEK 6,957 (6,274) for the first six months. The increase is attributed to the ongoing change of trading platform for the company's shares. Depreciation amounted to KSEK 54 (0) for the quarter and KSEK 102 (0) for the first six months and is due to the implementation of IFRS 16 at the beginning of 2019. Other operating costs amounted to KSEK 2,172 (1,324) for the quarter and KSEK 2,755 (1,893) for the first six months and is due to currency fluctuations.

#### Results

Operating result amounted to KSEK -33,834 (-30,421) for the quarter and KSEK -14,065 (-48,875) for the first six months. Financial and related items amounted to KSEK 4,425 (2,210) for the quarter and KSEK 7,547 (4,854) for the first six months. Results are related to revaluation of company's FX-accounts at the end of the quarter. Results after financial items amounted to KSEK -29,412 (-28,211) for the quarter and KSEK -6,523 (-44,022) for the first six months. No income tax was reported for the periods. Result per share before and after dilution amounted to SEK -0.6 (-0.6) for the quarter and SEK -0.1 (-0.9) for the first six months.

## **Financial position**

#### Cash

Cash at June 30, 2019 amounted to KSEK 319,549 (267,053).

#### **Cash flow**

Cash flow from operating activities amounted to KSEK -25,170 (-27,289) for the quarter and KSEK 2,846 (-42,478) for the first six months. Cash flow amounted to KSEK 61,512 (-27,289) for the quarter and KSEK 89,673 (-42,478) for the first six months. The positive cash flow for the first six 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 quarter.

#### Equity and equity ratio

At June 30, 2019 equity amounted to KSEK 300,192 (259,689). Shareholders' equity per share amounted to SEK 5.9 (5.3), at the end of the period. The company's equity ratio was 93 (92) %.

#### **Debts and receivables**

Long-term liabilities amounted to KSEK 117 (0). Current liabilities amounted to KSEK 24,478 (21,432). Accounts receivables amounted to KSEK 2,000 (9 696). Non-current assets amounted to KSEK 230 (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 June 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 June 30, 2019 were 10 (8) persons, 3 women and 7 men.

### Parent company

The parent company's revenues for the quarter amounted to KSEK 4,437 (9,668) and KSEK 59,339 (10,399) for the first six months. Expenses for the quarter amounted to KSEK 38,272 (40,088) and KSEK 73,411 (59,273) for the first six months.

The parent company's result amounted to KSEK -29,412 (-28,211) for the quarter and KSEK -6,527 (-44,021) for the first six months. Changes in the parent company's statements corresponds to the consolidated changes.

## Consolidated statement of comprehensive income

KSEK	2019	2018	2019	2018	2018
	Apr-Jun	Apr-Jun	Jan-Jun		Jan-Dec
Revenue					
Sales	4,437	9,668	59,339	10,397	28,211
Other operating income	-	-	-	2	2
	4,437	9,668	59,339	10,399	28,212
Operating expenses					
Project costs	-26,101	-30,730	-52,340	-41,616	-83,855
Other external costs	-4,233	-3,257	-6,957	-6,274	-11,325
Employee costs	-5,711	-4,778	-11,249	-9,491	-20,034
Depreciation and impairment	-54	-	-102	-	-
Other operating expenses	-2,172	-1,324	-2,755	-1,893	-5,511
Operating results	-33,834	-30,421	-14,065	-48,875	-92,514
Financial items					
Interest income and similar items	4,425	2,210	7,547	4,854	7,511
Interest expense and similar items	-3	0	-4	0	-1
Results after financial net	-29,412	-28,211	-6,523	-44,022	-85,003
Result before tax					
Тах	-	-	-	-	-
Results after tax	-29,412	-28,211	-6,523	-44,022	-85,003
Statement of comprehensive income					
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	-29,412	-28,211	-6,523	-44,022	-85,003
Net earnings and comprehensive					
income is entirely attributable to parent					
Share Data					
Number of shares at the end of period				48,666,656	
Average number of shares during period				48,666,656	
Result per share before dilution (SEK)	-0.6		-0.1	-0.9	-1.7
Result per share after dilution (SEK)	-0.6		-0.1		-1.7
Equity per share (SEK)	5.9		5.9		4.5
Equity per share after dilution (SEK)	5.9	5.3	5.9	5.3	4.5



## Consolidated statement of financial position

KSEK	6/30/2019	6/30/2018	12/31/2018
ASSETS			
Non-current assets			
Tangible non-current assets	230	-	-
Total non-current assets	230	-	-
Current assets			
Accounts receivables	2,000	9,696	9,444
Other receivables	871	725	624
Prepaid expenses and accrued income	1,721	3,647	2,093
	4,591	14,068	12,161
Cash and bank balance	319,549	267,053	229,876
Total current assets	324,140	281,121	242,037
Total assets	324,370	281,121	242,037

KSEK	6/30/2019	6/30/2018	12/31/2018
Equity			
Share capital	2,818	2,561	2,561
Other capital contributions	705,027	617,944	617,945
Accumulated loss including net loss	-408,070	-360,817	-401,144
Total equity	299,775	259,689	219,362
Long-term liabilities	117	-	-
Current liabilities			
Accounts payable	14,476	15,652	15,174
Other liabilities	1,592	995	1,205
Accrued expenses and deferred income	8,410	4,785	6,296
Total current liabilities	24,478	21,432	22,675
Total equity and liabilities	324,370	281,121	242,037



### Consolidated statement of cash flows

KSEK	2019	2018	2019	2018	2018
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-29,412	-28,211	-6,523	-44,022	-85,003
Adjustments for non-cash items	54	-	102	-	-
Cash flow from operating activities before	-29,359	-28,211	-6,420	-44,022	-85,003
changes in working capital					
Changes in short term receivables	5,876	-8,362	10,307	-8,230	-6,273
Changes in accounts payable	-2,358	9,634	-698	9,680	9,202
Changes in other liabilities	672	-350	-343	94	1,765
Cash flow from operating activities	-25,170	-27,289	2,846	-42,478	-80,310
INVESTING ACTIVITIES					
Cash flow from investing activities	-	-	-	-	-
FINANCING ACTIVITIES					
New share/Warrants issue	91,058	-	91,258	-	655
Cost new share issue	-4,323	-	-4,323	-	-
Repayment of lease liability	-54	-	-108	-	-
Cash flow from financing activities	86,682	-	86,827	-	655
5	,		,		
Cash flow for the period					
Balance at beginning of period	258,036	294,342	229,876	309,531	309,531
Change in cash	61,512	-27,289	89,673	-42,478	-79,655
CASH BALANCE AT THE END OF THE PERIOD	319,549	267,053	319,549	267,053	229,876



## Consolidated statement of changes in equity

KSEK	Share capital	Other capital	Accumulated loss	Total equity
KOEK	Unare capitar	contributions	incl. net result for	Total equity
		Continuations		
Opening balance 20180101	2,561	617,944	<u>the period</u> -316,794	303,711
Comprehensive income for period	-	-	-44,022	-44,022
Closing balance 20180630	2,561	617,944	-360,817	259,689
Opening balance 20190101	2,561	618,598	-401,798	219,362
Transactions with shareholders	-	-	-	-
Incentive program	256	91,002	-	91,258
Cost new share issue	-	-4,323	-	-4,323
Comprehensive income for period	-	-	-6,523	-6,523
Closing balance 20190630	2,818	705,278	-408,320	299,775
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 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
Equity	299,775	259,689	299,775	259,689	219,362
Equity ratio %	92%	92%	92%	92%	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	50,689,876	48,666,656	49,667,026	48,666,656	48,666,656
Average number of shares under the period	50,689,876	48,666,656	49,667,026	48,666,656	48,666,656
after dilution					
Share Data					
Result per share	-0.6	-0.6	-0.1	-0.9	-1.7
Result per share after dilution	-0.6	-0.6	-0.1	-0.9	-1.7
Cash flow from operating activities	-0.5	-0.6	0.1	-0.9	-1.7
Equity per share	5.9	5.3	5.9	5.3	4.5
Equity per share after dilution	5.9	5.3	5.9	5.3	4.5
Dividend	-	-	-	-	-
Average number of employees	10	8	10	7	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	2018	2019	2018	2018
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Revenue					
Sales	4,437	9,668	59,339	10,397	28,211
Other operating income	-	-	-	2	2
	4,437	9,668	59,339	10,399	28,212
Operating expenses					
Project costs	-26,101	-30,730	-52,340	-41,616	-83,855
Other external costs	-4,288	-3,257	-7,066	-6,273	-11,324
Employee costs	-5,711	-4,778	-11,249	-9,491	-20,034
Other operating expenses	-2,172	-1,324	-2,755	-1,893	-5,511
Operating results	-33,835	-30,421	-14,072	-48,874	-92,513
Financial items					
Interest income and similar items	4,425	2,210	7,547	4,854	7,510
Interest expense and similar items	-2	0	-2	0	-1
Results after financial net	-29,412	-28,211	-6,527	-44,021	-85,003
Result before tax					
Tax	-	-	-	-	-
Results after tax	-29,412	-28,211	-6,527	-44,021	-84,350



## Parent company - balance sheet

KSEK	6/30/2019	6/30/2018	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	2,000	9,696	9,444
Other receivables	870	725	624
Prepaid expenses and accrued income	1,721	3,647	2,093
	4,591	16,151	14,848
Cash and bank balance	319,248	264,971	227,139
Total current assets	323,839	281,122	241,987
Total assets	323,889	281,172	242,037
KSEK	6/30/2019	6/30/2018	12/31/2018
Equity			
Restricted Equity			
Share capital	2,818	2,561	2,561
Non-restricted equity			
Share premium reserve	705,027	617,943	617,944
Retained earnings	-378,914	-316,794	-316,794
Net profit for the year	-29,412	-44,021	-84,350
Total equity	299,518	259,689	219,362
Long-term liabilities			
Current liabilities			
Accounts payable	14,476	15,652	15,174
Other liabilities	1,485	995	1,205
Accrued expenses and deferred income	8,410	4,785	6,296
Total current liabilities	24,371	21,482	22,675
Total equity and liabilities	323,889	281,172	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.

#### **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 minor 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, the cost of these are broken down into interest expense and depreciation and reported accordingly. PledPharma applies the simplified transition model. Leasing contracts of minor value will henceforth be accounted as operating leases and reported in the income statement. Company'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 company's rental agreements had a duration of less than 12 months and two contracts related to office equipments was regarded to be of minor 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. PledPharma is, among others, exposed to the following risks:

- Pharmaceutical development
- Manufacturing
- Regulatory
- Intellectual property
- Need of working capital

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

#### The fair value and carrying value are shown in the table below: Group 30 June 2019 KSEK Hold to Financial Total collect debts Amortised Amortised cost cost Tangible non-current assets 230 230 -Accounts receivable 2,000 2,000 -Cash 319,549 319,549 **Total assets** 321,778 321,778 -Long-term liabilities 117 117 -Accounts payable 14,476 14,476 -Other liabilities 109 109 **Total liabilities** -14,702 14,702 Group 30 June 2018 Accounts receivable 9,696 9,696 -Cash 267,053 267,053 **Total assets** 276,748 -276,748 Accounts payable 15,652 15,652 -Other liabilities -**Total liabilities** 15,652 \_ 15,652

#### Note 4 – Related parties transactions

There are none transactions to be reported with related parties.

#### Note 5 – Segments

The company has identified two independent areas of development for calmangafodipir. The highest officer in the company allocates company resources between these two projects. Table below depicts revenues and costs attributed to PledOx and Aladote.

2019 Q2					2018 Q2				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	4,437	-	-	4,437	Revenues	9,668	-	-	9,668
Project costs	-25,096	-1,005	-	-26,101	Project costs	-29,993	-712	-25	-30,730
Other	-	-	-12,170	-12,170	Other	-	-	-9,359	-9,359
Operating results				-33,834	Operating results				-30,421
Net financial items				4,422	Net financial items				2,209
Pretax profit				-29,412	Pretax profit				-28,211

2019 H1					2018 H1				
KSEK	PledOx	Aladote	Common	Sum	KSEK	PledOx	Aladote	Common	Sum
Revenues	59,339	-	-	59,339	Revenues	10,397	-	2	10,399
Project costs	-49,791	-2,549	-	-52,340	Project costs	-40,761	-831	-25	-41,616
Other	-	-	-21,064	-21,064	Other	-	-	-17,658	-17,658
Operating results				-14,065	Operating results				-48,875
Net financial items				7,543	Net financial items				4,853
Pretax profit				-6,523	Pretax profit				-44,022



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

Company's financial liabilities in the financial items consists of current leasing liabilities of KSEK 108 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 107 and closing balance leasing liability was KSEK 225.



### **Other information**

Next reports Interim report Jan – Sep 2019, Oct 23, 2019 Year-end report Jan – Dec 2019, Feb 18, 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.

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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 Aug 21, 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, Aug 21, 2019

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