



# PledPharma AB (publ)

## Interim report first quarter 2016

April 29, 2016

### **The projects are progressing according to plan**

#### **Quarter summary**

- Net result for the quarter amounted to SEK -6 846 (-12 163) k
- Cash equivalents at the end of the quarter amounted to SEK 43 684 (86 318) k
- Cash flow from operating activities amounted to SEK -6 676 (-13 985) k
- Result per share amounted to SEK -0.2 (-0.4)

#### **Significant events during the quarter**

- No significant events to report for the period

#### **Significant events after the end of the period**

- During the AGM the CEO reported that active discussions are being held with a number of potential partners in the ongoing process of finding one or more appropriate commercial partners for the continued development of PledOx<sup>®</sup>.
- The Annual General Meeting was held on April 14, 2016 where the General Meeting resolved in accordance with the submitted proposals. As members of the Board, Håkan Åström (Chairman), Andreas Bunge, Martin Nicklasson, Sten Nilsson and Eva Redhe were elected.

## CEO comment

During the first quarter, our work has mainly focused on next step in the PledOx project and we now have active discussions with a number of pharmaceutical companies.

The PledOx project, where we reported positive top-line results from the Phase II study PLIANT in the spring of 2015, focuses on the development of a drug to reduce the incidence of nerve damage associated with chemotherapy treatment of colorectal cancer.

The National Cancer Institute has published advice, for affected patients how they can handle this type of very severe side-effects of chemotherapy. For example, to ask for help when they will do so simple everyday tasks such as buttoning buttons, use a computer or a pen. PledOx aims to solve these and other significant problems for a large number of individuals. It is therefore positive that the results we have obtained so far, shows a significant reduction of this type of side effects. I look forward to additional follow-up data, the so-called progression-free survival i.e., survival without tumor growth, which we expect to report in the second quarter.

During the quarter, we have also been working on our second project Aladote and preparations for the start of a clinical trial. The drug candidate Aladote is being developed with the aim to prevent acute liver damage associated with acetaminophen overdose. The study is expected to start in late 2016.

With robust clinical data, an approved composition of matter patent, valuable information from this autumn's constructive meeting with the FDA, a strong team and a significant commercial potential, we have a good basis for the remaining development, partnership and commercialization of PledOx.

**Jacques Näsström**

CEO, PledPharma AB (publ)



## PledPharma in brief

PledPharma develops new drugs that protect the body against oxidative stress – a potentially disabling and sometimes life-threatening condition that can be caused by chemotherapy treatment and acetaminophen (paracetamol) poisoning. The company's most advanced project PledOx<sup>®</sup> reduces nerve damage associated with chemotherapy and positive results from the Phase IIb study PLIANT were presented during the spring of 2015. The drug candidate Aladote<sup>®</sup> is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. The project PP-099 seeks to limit the damage that occurs to the heart muscle during myocardial infarction.

PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the company's Certified Adviser (tel +46 8 463 80 00). For more information, see [www.pledpharma.se](http://www.pledpharma.se)

### Vision

PledPharma will be a leading pharmaceutical company, which develops unique therapies with breakthrough therapy potential for life-threatening diseases.

### Business idea, goals and strategy

PledPharma develops therapeutics to improve the treatment of life-threatening diseases based on the company's patented and clinically proven technology, PLED. The primary goal is a successful transaction of the PledOx<sup>®</sup> project with attractive commercial revenues and to develop Aladote<sup>®</sup> to commercialization together with a partner. PledPharma conducts a partner-based development model focusing on taking project through phase IIb, whereafter the costly Phase III clinical trials and global marketing are sold, whereby the financial exposure is reduced. The typical compensation is anticipated to be received in the form of signing fees, milestone payments and royalties.

### Patents and trademarks

PledPharma has four applications for a large number of countries aiming to get an exclusive market protection and broad commercial rights for the manufacture and use of PLED therapeutics. The first is so far approved in the US, EU, China, Hong Kong, Russia, Australia and Japan with patent protection until 2028. The second is approved in Australia, Japan, Canada, Mexico, Russia and South Africa with patent protection until 2030. For the third and most important, the compound patent for calmagafodipir, for the active ingredient of the drug candidates PledOx<sup>®</sup> and Aladote<sup>®</sup> is approved in the US with patent protection until December 2032. The fourth application has entered the national phase and is expected to provide patent protection until October 2033. In addition, PledPharma has four in-licensed patents covering therapeutic use of PLED therapeutics.

PledPharma has trademark protection for PledOx<sup>®</sup> since 2010 and since 2015 for Aladote<sup>®</sup>.

## Our projects

PledPharma develops therapeutics based on PLED therapeutics and currently has three projects in or about to enter the clinical phase.



### PledOx<sup>®</sup> (colorectal cancer)

PledOx<sup>®</sup> developed to provide patients with colorectal cancer protection against the nerve damage that often occurs in conjunction with chemotherapy drugs. The side-effects of chemotherapy treatment often lead to a reduction of the planned chemotherapy dose or in



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worst case, treatment discontinuation. Unfortunately, it is common that the chemo will result in permanent nerve damage. Patients may, for example, bring inconvenience and discomfort in the hands and feet, difficulty with balance and problems with sensation during the rest of their lives.

This is the first time in a controlled clinical trial that one has succeeded in preventing chemotherapy caused nerve damage in a clinically significant manner without the effect of cancer treatment negatively affected. The results from the Phase IIb study PLIANT, where patients with colorectal cancer (colorectal cancer) treated with the chemotherapy combination FOLFOX and PledOx<sup>®</sup> (calmangafodipir), shows that the patients who received PledOx<sup>®</sup> had a lower risk than the placebo group to suffer from nerve damage.

### Aladote<sup>®</sup>

#### Aladote<sup>®</sup> (hepatic/ALF)

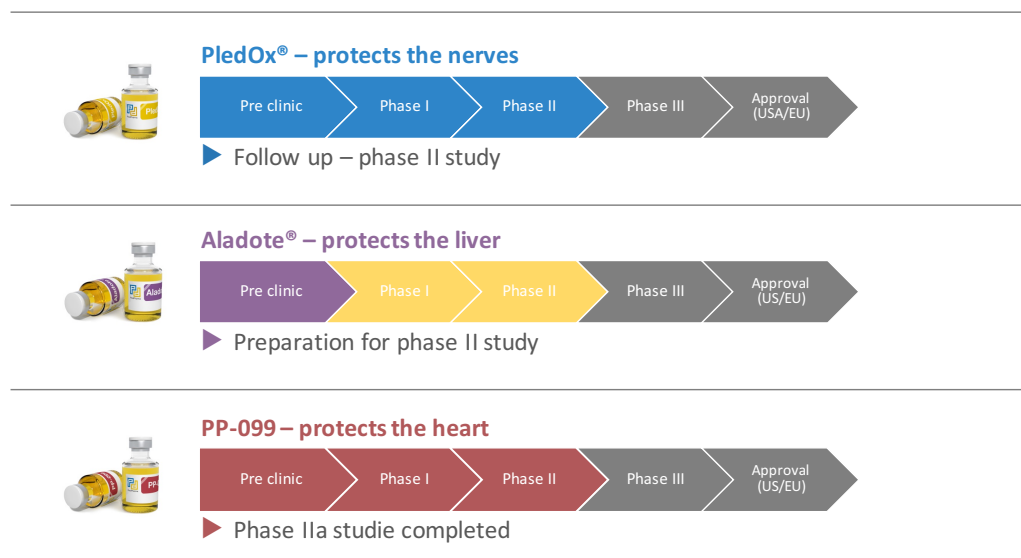
Aladote<sup>®</sup> is a new formulation based on calmangafodipir evaluated and tested pre-clinically with promising results. A clinical trial for the prevention of acute liver failure (ALF) in patients with acetaminophen induced poisoning is under preparation.

### PP-099

#### Project PP-099 (myocardial infarction)

The PLED substance mangafodipir has been tested in a smaller national phase IIa study in heart attack patients undergoing angioplasty. The study indicated that PLED therapeutics can reduce reperfusion damage after acute myocardial infarction. No additional studies will be carried out without a partner.

### Status in PledPharma’s ongoing projects





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## Financial summary - Group First quarter 2016

### Financial performance

#### Revenue Jan-March 2016

Revenue amounted to SEK 48 (49) k during the quarter and consisted of rental revenues and foreign exchange gains. Interest income amounted to SEK 37 (70) k for the period.

#### Expenses Jan –March 2016

Operating expenses amounted to SEK 6 931 (12 283) k for the quarter. Of these, planned project costs amounted to SEK 1 914 (7 506) k. The planned project cost mainly consisted of patent costs, development cost for the PP 100 project and cost for the follow up of the clinical study with PledOx. Employee costs amounted to SEK 1 590 (2 685) k for the quarter. Other operating costs amounted to SEK 3 413 (2 051) k for the quarter and the increase in costs is largely related to licensing patents and consultants. Depreciation amounted to SEK 0 (1) k.

#### Results Jan - March 2016

Operating result amounted to SEK -6 883 (-12 234) k for the quarter. Result after financial items amounted to SEK -6 846 (-12 163) k. No income tax was recorded for the quarter (-) Result per average share amounted to SEK -0.2 (-0.4).

### Financial position

#### Cash

Cash at 31 March 2016 amounted to SEK 43 684 (86 318) k.

#### Cash flow Jan – March 2016

Cash flow from operating activities amounted to SEK -6 676 (-13 985) k for the quarter. Cash flow amounted to SEK -6 676 (-13 985) k for the quarter.

#### Equity and equity ratio

Shareholders' equity amounted to SEK 41 187 (78 494) k. The company's equity ratio was 92 (89) %.

#### Debts

No long-term debts were outstanding (-), current liabilities amounted to SEK 3 481 (9 945) k and shareholders' equity per share amounted to SEK 1.5 (2.8), at the end of the period.

#### Investments, tangible and intangible assets

During the period, investments in tangible fixed assets corresponding to 0 (0) SEK.

#### Employees

Average number of employees during the period was four (four) persons.

#### Share

The number of shares at March 31 2016 were 28 388 883. PledPharma's shares were listed on NASDAQ Stockholm First North on 7 April 2011.

### Parent Company

#### Expenses Jan - March 2016

The parent company's expenses for the period amounted to SEK 6 931 (12 270) k.

#### Results Jan - March 2016

The parent company's result after financial items amounted to SEK -6 846 (-12 151) k for the period.

## Consolidated statement of comprehensive income

SEKk	2016 Jan-March	2015 Jan-March	2015 Jan-Dec
<b>Revenue</b>			
Other operating income	48	49	378
	<b>48</b>	<b>49</b>	<b>378</b>
<b>Operating expenses</b>			
Project costs	-1 914	-7 506	-26 093
Other external costs	-3 413	-2 051	-11 274
Employee benefit costs	-1 590	-2 685	-6 909
Depreciation and impairment, fixed assets	0	-1	-2
Other operating expenses	-14	-40	-128
<b>Operating result</b>	<b>-6 883</b>	<b>-12 234</b>	<b>-44 028</b>
<b>Net financial items</b>			
Interest income	37	70	203
Interest expense and similar items	-	-	(10)
<b>Result after financial net</b>	<b>-6 846</b>	<b>-12 163</b>	<b>-43 836</b>
<b>Result before tax</b>	<b>-6 846</b>	<b>-12 163</b>	<b>-43 836</b>
Tax	-	-	-
<b>Result after tax</b>	<b>-6 846</b>	<b>-12 163</b>	<b>-43 836</b>
<b>Statement of comprehensive income</b>			
Other comprehensive income	-	-	-
<b>Comprehensive income for the period</b>	<b>-6 846</b>	<b>-12 163</b>	<b>-43 836</b>

Net earnings and comprehensive income is entirely attributable to parent company shareholders

### Share Data

Number of shares at the end of period	28 388 883	28 346 883	28 388 883
Average number of shares during period	28 388 883	28 346 883	28 373 133
Result per share before dilution (SEK)	-0,2	-0,4	-1,5
Result per share after dilution (SEK)	-0,2	-0,4	-1,5
Equity per share (SEK)	1,5	2,8	1,7
Equity per share after dilution (SEK)	1,5	2,7	1,7

## Consolidated statement of financial position

SEKk	2016-03-31	2015-03-31	2015-12-31
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	0	2	0
<b>Total fixed assets</b>	<b>0</b>	<b>2</b>	<b>0</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Other receivables	399	1 626	788
Prepaid expenses and accrued income	585	493	1 213
	984	2 119	2 001
Cash and bank balances	43 684	86 318	50 360
<b>Total current assets</b>	<b>44 668</b>	<b>88 437</b>	<b>52 361</b>
<b>Total assets</b>	<b>44 668</b>	<b>88 439</b>	<b>52 361</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	1 494	1 492	1 494
Other capital contributions	46 538	89 166	90 374
Accumulated loss including net loss	-6 846	-12 163	-43 836
<b>Total equity</b>	<b>41 187</b>	<b>78 494</b>	<b>48 032</b>
<b>Short term liabilities</b>			
Accounts payable	1 102	5 102	1 766
Other liabilities	213	389	177
Accrued expenses and deferred income	2 166	4 454	2 386
<b>Total short term liabilities</b>	<b>3 481</b>	<b>9 945</b>	<b>4 329</b>
<b>Total equity and liabilities</b>	<b>44 668</b>	<b>88 439</b>	<b>52 361</b>

## Consolidated statement of cash flows

SEKk	2016 Jan-March	2015 Jan-March	2015 Jan-Dec
<b>OPERATING ACTIVITIES</b>			
Result after financial net	-6 846	-12 163	-43 836
Adjustments for non-cash items	0	1	2
Tax paid	-	-	-
<b>Cash flow from operating activities before changes in working capital</b>	<b>-6 845</b>	<b>-12 163</b>	<b>-43 833</b>
Changes in short term liabilities	1 017	1 043	1 161
Changes in account payables	-664	-4 865	-8 201
Changes in operating liabilities	-183	2 000	-281
<b>Cash flow from operating activities</b>	<b>-6 676</b>	<b>-13 985</b>	<b>-51 154</b>
<b>INVESTING ACTIVITIES</b>			
<b>Cash flow from investing activities</b>	-	-	-
<b>FINANCING ACTIVITIES</b>			
New share issue	-	-	1 210
Cost new share issue	-	-	-
<b>Cash flow from financing activities</b>	-	-	1 210
<b>Cash flow for the period</b>			
Balance at beginning of period	50 360	100 304	100 304
Change in cash	-6 676	-13 985	-49 944
<b>CASH BALANCE AT THE END OF THE PERIOD</b>	<b>43 684</b>	<b>86 318</b>	<b>50 360</b>



## Consolidates statement of changes in equity

kSEK	Share capital	Other capital contributions	Accumulated loss incl. net result for the period	Totalt equity
<b>Opening balance 20150101</b>	<b>1 492</b>	<b>137 586</b>	<b>(48 420)</b>	<b>90 658</b>
Loss allocation according AGM resolution	-	(48 420)	48 420	-
Comprehensive income for period	-	-	(12 163)	(12 163)
<b>Closing balance 20150331</b>	<b>1 492</b>	<b>89 166</b>	<b>(12 163)</b>	<b>78 494</b>
<b>Opening balance 20160101</b>	<b>1 494</b>	<b>90 374</b>	<b>(43 836)</b>	<b>48 032</b>
Loss allocation according AGM resolution	-	(43 836)	43 836	-
Comprehensive income for period	-	-	(6 846)	(6 846)
<b>Closing balance 20160331</b>	<b>1 494</b>	<b>46 538</b>	<b>(6 846)</b>	<b>41 187</b>
<b>Opening balance 20150101</b>	<b>1 492</b>	<b>137 586</b>	<b>(48 420)</b>	<b>90 658</b>
Loss allocation according AGM resolution	-	(48 420)	48 420	-
New share issue	2	1 208	-	1 210
Comprehensive income for period	-	-	(43 836)	(43 836)
<b>Closing balance 20151231</b>	<b>1 494</b>	<b>90 374</b>	<b>(43 836)</b>	<b>48 032</b>

## Consolidated key ratios

KSEK	2016 Jan-March	2015 Jan-March	2015 Jan-Dec
Operating result (EBIT)	-6 883	-12 234	-44 028
Operating margin %	neg.	neg.	neg.
Result for the period	-6 846	-12 163	-43 836
Cash flow from operating activities	-6 676	-13 985	-51 154
Total assets	44 668	88 439	52 361
Equity	41 187	78 494	48 032
Equity ratio %	92%	89%	92%
Return on equity %	neg.	neg.	neg.
Number of shares at the end of the period	28 388 883	28 346 883	28 388 883
Number of shares at the end of the period after dilution	28 388 883	28 746 883	28 388 883
Average number of shares under the period	28 388 883	28 346 883	28 373 133
Average number of shares under the period after dilution	28 388 883	28 746 883	28 373 133
<b>Share Data</b>			
Result per share	-0,2	-0,4	-1,5
Result per average share	-0,2	-0,4	-1,5
Cash flow from operating activities	-0,2	-0,5	-1,8
Equity per share	1,5	2,8	1,7
Equity per share after dilution	1,5	2,7	1,7
Dividend	-	-	-
Number of employees	4	4	4

## Parent company - Income statement

SEKk	2016 Jan-March	2015 Jan-March	2015 Jan-Dec
<b>Revenue</b>			
Other operating income	48	49	378
	<b>48</b>	<b>49</b>	<b>378</b>
<b>Operating expenses</b>			
Project costs	-1 914	-7 506	-26 093
Other external costs	-3 413	-2 038	-11 258
Employee benefit costs	-1 590	-2 685	-6 909
Depreciation and impairment, fixed assets	0	-1	-2
Other operating expenses	-14	-40	-128
<b>Operating result</b>	<b>-6 883</b>	<b>-12 221</b>	<b>-44 012</b>
<b>Net financial items</b>			
Depreciation of investment in subsidiaries	-	-	-16
Interest income	37	70	203
Interest expense and similar items	-	-	-10
<b>Result after financial net</b>	<b>-6 846</b>	<b>-12 151</b>	<b>-43 836</b>
<b>Result before tax</b>	<b>-6 846</b>	<b>-12 151</b>	<b>-43 836</b>
Tax	-	-	-
<b>Result after tax</b>	<b>-6 846</b>	<b>-12 151</b>	<b>-43 836</b>

## Parent company - Balance sheet

SEKk	2016-03-31	2015-03-31	2015-12-31
<b>ASSETS</b>			
<b>Fixed assets</b>			
Property, plant and equipment			
Equipment, tools, fixtures and fittings		2	0
<i>Financial assets</i>			
Shares and participations in group companies	50	50	50
<b>Total fixed assets</b>	<b>50</b>	<b>52</b>	<b>50</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Receivables group companies			
Other receivables	399	1 620	787
Prepaid expenses and accrued income	585	493	1 213
	984	2 329	2 001
<i>Cash and bank balances</i>	43 684	86 070	50 360
<b>Total current assets</b>	<b>44 668</b>	<b>88 400</b>	<b>52 361</b>
<b>Total assets</b>	<b>44 718</b>	<b>88 452</b>	<b>52 411</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	1 494	1 492	1 494
<i>Non-restricted equity</i>			
Share premium reserve	46 538	89 166	90 374
Result for the period	-6 846	-12 151	-43 836
<b>Total equity</b>	<b>41 187</b>	<b>78 507</b>	<b>48 032</b>
<b>Short term liabilities</b>			
Debt to group company	50	-	51
Accounts payable	1 102	5 102	1 766
Other liabilities	213	389	176
Accrued expenses and deferred income	2 166	4 454	2 386
<b>Total short term liabilities</b>	<b>3 531</b>	<b>9 945</b>	<b>4 379</b>
<b>Total equity and liabilities</b>	<b>44 718</b>	<b>88 452</b>	<b>52 411</b>

**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. The parent company's interim report is prepared in accordance with the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and the Swedish Annual Accounts Act. Applied accounting principles and calculation methods are the same as in the latest annual report for 2015.

**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 the first page.

**NOTE 3 – Financial assets and debts**

**Group 31 Mars 2016**

The fair value and carrying value are shown in the table below:

	<b>Account and loan receivables</b>	<b>Financial debts</b>	<b>Total carrying amount</b>	<b>Fair value</b>
Accounts receivable	-	-	-	-
Accrued but not invoiced income	-	-	-	-
Cash	43 684	-	43 684	43 684
<b>Total assets</b>	<b>43 684</b>	-	<b>43 684</b>	<b>43 684</b>
Accounts payable	-	1 102	1 102	1 102
Other liabilities	-	-	-	-
<b>Total debts</b>	-	<b>1 102</b>	<b>1 102</b>	<b>1 102</b>

**Group 31 December 2015**

The fair value and carrying value are shown in the table below:

	<b>Account and loan receivables</b>	<b>Financial debts</b>	<b>Total carrying amount</b>	<b>Fair value</b>
Accounts receivable	-	-	-	-
Accrued but not invoiced income	-	-	-	-
Cash	50 360	-	50 360	50 360
<b>Total assets</b>	<b>50 360</b>	-	<b>50 360</b>	<b>50 360</b>
Accounts payable	-	1 766	1 766	1 766
Other liabilities	-	-	-	-
<b>Total debts</b>	-	<b>1 766</b>	<b>1 766</b>	<b>1 766</b>

**NOTE 4- Related parties transactions**

No transactions with related parties have occurred during the period.



## Other information

### Next reports

Interim report April – June, 25 August 2016

Interim report July-Sept, 20 October 2016

PledPharma is required to publish the information in this report under Swedish Securities Market Act. The information was submitted for publication on 29 February, 2016.

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

This report has not been audited.

### For further information contact:

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### Certified Advisor

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

### Analysts who follow PledPharma

Erik Penser Bank, through Erik Penser Access

Pareto, Finlay Heppenstall, Peter Östling

Redeye, Klas Palin.

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### **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, April 29, 2016

Håkan Åström  
*Chairman of the board*

Andreas Bunge  
*Board member*

Martin Nicklasson  
*Board member*

Sten Nilsson  
*Board member*

Eva Redhe  
*Board member*