



PledPharma AB (publ)
Interim report first quarter 2015
21 April 2015

The phase IIb study confirms PledOx[®] potential to improve the lives for a large number of cancer patients

Significant events during January- March

- Top-line results from phase IIb study - PledOx[®] reduces nerve damage in conjunction with chemotherapy by 43 percent
- Net result for the period amounted to SEK -12 151 (-6 775)k
- Cash and cash equivalents at the end of the period amounted to SEK 86 070 (41 388)k
- Cash flow from operating activities amounted to SEK -13 972 (-7 914)k for the quarter
- Result per share amounted to SEK -0.4 (-0.3) for the period.

Significant events after the end of the period

- Annual General Meeting was held on April 14, 2015 where the General Meeting resolved in accordance with the submitted proposals. As members of the Board, Håkan Åström, Andreas Bunge, Martin Nicklasson, Sten Nilsson and Eva Redhe Ridderstad were elected.



CEO comment

We are now an important step closer to our ultimate goal of improving the lives of a large number of cancer patients.

At the end of the quarter, we finally had confirmation that PledOx[®] has the potential to reduce the serious nerve damage caused by chemotherapy, in patients treated for colorectal cancer. This nerve damage (chemotherapy induced peripheral neuropathy, CIPN) is, as we have previously described the most troublesome side-effect of chemotherapy. Chemotherapy can cure cancer, but a large proportion of patients suffer from nerve damage. Such nerve damage can cause debilitating problems that in many cases become chronic and irreversible. This may involve extreme sensitivity to cold, serious disturbances in fine motor skills or severe pain, particularly in the hands and feet, and there is currently no effective treatment available.

This is also the main reason that clinicians are forced to reduce the chemotherapy dose, temporarily cease or completely discontinue the treatment. So apart from these injuries, the patients also risk losing out on the needed chemotherapy. In addition to the suffering and problems, CIPN patients also incur significantly larger healthcare costs. Calculations have been made in the United States showing that the CIPN resulted in additional healthcare costs of over USD 17 000 per patient during the first year only. This was in addition to the workloss burden and cost for the cancer treatment in general.

This means that the positive outcomes (top-line) we presented on March 29 forms the so far most important milestone in PledPharma's history. The Phase IIb study PLIANT showed that our drug candidate PledOx[®] can prevent nerve damage arising from chemotherapy, without negatively affecting the anti-cancer effect of chemotherapy. This is something that no one else so far has succeeded with.

Patients were pretreated with PledOx[®] or placebo in the randomized, double-blind, placebo-controlled study, in order to reduce the risk of side effects associated with chemotherapy treatment of advanced colorectal cancer. The study showed a clinically relevant decrease of 43 percent compared to placebo in the incidence of neuropathy. In addition, it was found that the anti-cancer effect of the chemo was not negatively affected by PledOx[®]-pretreatment.

Bengt Glimelius, professor emeritus of oncology at Uppsala University and principal investigator of the study, commented the PLIANT top-line results; *"This is to my knowledge the first study in which a treatment has shown to reduce this type of side effects in a clinically meaningful way, without any seemingly negative impact on the anti-cancer effects of the chemotherapy."*

The study results will form the basis for the continued development plans, which according to plan will be discussed at an end of Phase II meeting with the FDA (US Food and Drug Administration). We now look forward to, based on the promising results of the study, intensify discussions with potential partners and continue preparations for the next step in the clinical development of PledOx[®].



PledPharma

In addition to our progress with the PLIANT study, we have continued the work with the drug candidate Aladote™. This project is also based on the PLED platform, but is focused on reducing or preventing acute liver failure as a result of an overdose of acetaminophen, one of the most common drug poisonings. After having secured the development of the project through a rights issue at the end of 2014, the goal is now implementing a phase II study in preparation for future licensing.

PledPharma stands stronger than ever before. We have further strengthened our project portfolio and with the clinical data for PledOx® we have reduced the risk and increased the opportunities in future discussions with potential partners and regulatory authorities. In addition, we have a stable financial base for the further development of the equally important Aladote™.

Jacques Näsström
CEO, PledPharma AB (publ)



PledPharma

PledPharma in brief

PledPharma develops new drugs that protect the body against oxidative stress – a condition that can be caused by chemotherapy treatment and acetaminophen (paracetamol) poisoning. The company's most advanced project PledOx[®] reduces nerve damage associated with chemotherapy. The drug candidate Aladote[™] 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's drug candidates are based on the further development of a compound that, for completely different purposes, already has been used by more than 200 000 patients. This may limit the development risk and simplify the approval process. Pledpharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bankaktiebolag is the company's Certified Adviser. For more information, see www.pledpharma.se

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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 out-licensing of the PledOx project with attractive commercial revenues and to develop Aladote 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 licensed out, 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 in-licensed patents covering therapeutic use of PLED therapeutics. In addition, 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, China, Hong Kong, Russia, Australia and Japan with patent protection until 2028. The second was approved in 2013 in South Africa as the first country with patent protection until 2030.

PledPharma has trademark protection for PledOx[®] and has recently applied for trademark protection for Aladote[™].

Our projects

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

PledOx[®] (colorectal cancer)

PledOx[®] (calmangafodipir) is tested in an international phase IIb study in patients with colorectal cancer treated with the chemotherapy combination FOLFOX. The study goes according to plan and the first top-line results were presented at the end of the first quarter of 2015.



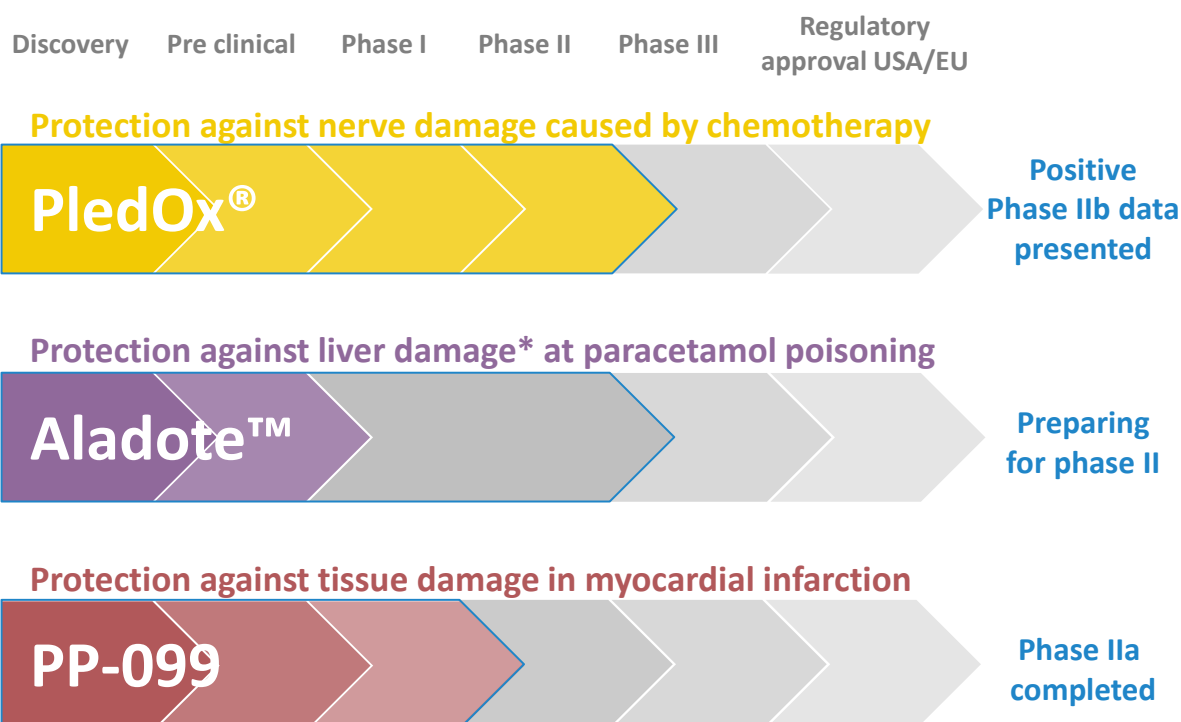
Aladote™ (hepatic/ALF)

Aladote™ is a new formulation based on calmagafodipir 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 planned.

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



* Acute liver failure means that the liver suddenly becomes so badly damaged that it can not function as it should. This is a very serious condition with a risk of death if treatment is not given



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Financial summary First quarter 2015

Revenue

Revenue amounted to SEK 49 (90)k during the quarter and consisted of rental revenues and foreign exchange gains. Interest income amounted to SEK 70 (95)k for the same period.

Expenses

Operating expenses amounted to SEK 12 270 (6 960)k for the quarter.

Of these, planned project costs mainly related to the ongoing clinical study in PP95 project amounted to SEK 7 506 (1 744)k.

For the same period, employee costs amounted to SEK 2 685 (1 246)k and other expenses to 2 078 (3 969)k.

Depreciation amounted to SEK 1 (1)k for the quarter.

Results and financial position

Operating result amounted to SEK -12 221 (-6 870)k for the quarter and the result after financial items amounted to SEK -12 151 (-6 775)k. No income tax was recorded for the period (-).

Cash flow from operating activities amounted to SEK -13 972 (-7 914)k for the quarter and was identical to the cash flow for the period.

Cash per 31 March 2015 amounted to SEK 86 070 (41 388)k and shareholders' equity amounted to SEK 78 507 (40 178)k. The company's equity ratio was 89 (94) %. No long-term debts were outstanding (-), current

liabilities amounted to SEK 9 945 (2 434)k and shareholders' equity per share amounted to SEK 2.8 (1.8).

Employees

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

Options Program

As of March 31, 2015, 131 000 warrants, in the in 2012 decided options scheme, had been subscribed by employees in the company. After the end of the reporting period, 42,000 new shares, after exercise of these warrants, were subscribed for, while the remaining warrants expired unexercised.

Significant risks and uncertainties

Risks are described in the Annual Report for 2014. No changes in the company's risk assessment have taken place during the period.

Share

Number of shares at March 31, 2015 were 28 346 883. After full dilution, the number of shares is 28 746 883. After the subscription of shares in the Options Program, as described above, after the end of the reporting period, the number of shares amounted to 28 388 883. PledPharma's shares were listed on NASDAQ Stockholm First North on 7 April 2011.

Seasonal variations

PledPharma's activity is not subject to seasonal variations.

Income statement

SEKk	2015 Jan-Mar	2014 Jan-Mar	2014 Jan-Dec
Revenue			
Other operating income	49	90	233
	49	90	233
Operating expenses			
Project costs	-7 506	-1 744	-29 459
Employee benefit costs	-2 685	-1 246	-6 271
Other operating costs	-2 078	-3 969	-13 067
Depreciation and impairment, fixed assets	-1	-1	-2
Operating result	-12 221	-6 870	-48 566
Net financial items			
Depreciation of investment in subsidiaries	-	-	-19
Interest income	70	95	312
Interest expense and similar items	-	-	-147
Result after financial net	-12 151	-6 775	-48 420
Result before tax	-12 151	-6 775	-48 420
Tax	-	-	-
Result after tax	-12 151	-6 775	-48 420
Share Data			
Number of shares at the end of period	28 346 883	21 935 089	28 346 883
Average number of shares during period	28 346 883	21 935 089	22 649 770
Result per share before and after dilution (SEK)	-0,4	-0,3	-1,7
Result per average share (SEK)	-0,4	-0,3	-2,1
Equity per share (SEK)	2,8	1,8	2,7
Equity per share after dilution (SEK)	2,7	1,8	2,6



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Balance sheet

SEKk	2015-03-31	2014-03-31	2014-12-31
ASSETS			
Fixed assets			
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	2	4	3
<i>Financial assets</i>			
Shares and participations in group companies	50	50	50
Total fixed assets	52	54	53
Current assets			
<i>Current receivables</i>			
Receivables group companies	216	234	216
Other receivables	1 620	443	2 727
Prepaid expenses and accrued income	493	491	430
	2 329	1 169	3 373
<i>Cash and bank balances</i>			
	86 070	41 388	100 043
Total current assets	88 400	42 557	103 415
Total assets	88 452	42 612	103 468
 EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	1 492	1 154	1 492
<i>Non-restricted equity</i>			
Share premium reserve	89 166	45 798	137 586
Result for the period	-12 151	-6 775	-48 420
	77 015	39 024	89 166
Total equity	78 507	40 178	90 658
 <i>Accounts payable</i>			
	5 102	189	9 967
<i>Current tax liabilities</i>			
	-	27	-
<i>Other liabilities</i>			
	389	-	292
<i>Accrued expenses and deferred income</i>			
	4 454	2 218	2 551
Total short term liabilities	9 945	2 434	12 810
Total equity and liabilities	88 452	42 612	103 468



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Cash flow statement

SEkk	2015 Jan-Mar	2014 Jan-Mar	2014 Jan-Dec
OPERATING ACTIVITIES			
Result after financial net	-12 151	-6 775	-48 420
Adjustments for non-cash items	1	1	21
Tax paid	-	59	-
Cash flow from operating activities before changes in working capital	-12 150	-6 715	-48 399
Changes in short term liabilities	1 043	217	-1 888
Changes in account payables	-4 865	-1 088	8 690
Changes in operating liabilities	2 000	-327	213
Cash flow from operating activities	-13 972	-7 914	-41 384
INVESTING ACTIVITIES			
Investment in intangible assets	-	-	-
Received group contribution	-	-	-
Investment in financial assets	-	-	-
Purchase of property, plant and equipment	-	-	-
Cash flow from investing activities	-	-	-
FINANCING ACTIVITIES			
New share issue	-	-	95 839
Cost new share issue	-	-	-3 714
Cash flow from financing activities	-	-	92 125
Cash flow for the period			
Balance at beginning of period	100 043	49 302	49 302
Change in cash	-13 972	-7 914	50 741
CASH BALANCE AT THE END OF THE PERIOD	86 070	41 388	100 043

Change in Equity

SEKk	Share capital	Other premium reserve	Net income	Total equity	
Opening balance 2014-01-01	1 154	-	71 347	-25 549	46 953
Loss allocation according AGM resolution	-	-	-25 549	25 549	-
New share issue	-	-	-	-6 775	-6 775
Closing balance 2014-03-31	1 154	-	45 798	-6 775	40 178
Opening balance 2014-01-01	1 492	-	137 586	-48 420	90 657
Loss allocation according AGM resolution	-	-	-48 420	48 420	-
New share issue	-	-	-	-12 151	-12 151
Closing balance 2015-03-31	1 492	-	89 165	-12 151	78 506

Key ratios

KSEK	2015	2014	2014	2013
	Jan-Mar	Jan-Mar	Jan-Dec	Jan-Dec
Operating result (EBIT)	-12 221	-6 870	-48 566	-26 084
Operating margin %	neg.	neg.	neg.	neg.
Result for the period	-12 151	-6 775	-48 420	-25 549
Cash flow from operating activities	-13 972	-7 914	-41 385	-28 066
Total assets	88 452	42 612	103 468	51 011
Equity	78 507	40 178	90 658	46 954
Equity ratio %	89%	94%	88%	92%
Return on equity %	neg.	neg.	neg.	neg.
Number of shares at the end of the period	28 346 883	21 935 089	28 346 883	21 935 089
Number of shares at the end of the period after	28 746 883	22 335 089	28 746 883	22 335 089
Average number of shares under the period	28 346 883	21 935 089	22 649 770	21 190 579
Average number of shares under the period aft	28 746 883	22 335 089	23 049 770	21 590 579
Share Data				
Result per share	-0,4	-0,3	-1,7	-1,2
Result per average share	-0,4	-0,3	-2,1	-1,2
Cash flow from operating activities	-0,5	-0,4	-1,5	-1,3
Equity per share	2,8	1,8	3,2	2,1
Equity per share after dilution	2,7	1,8	3,2	2,1
Dividend	-	-	-	-
Number of employees	4	4	4	5

Accounting principles

This report is prepared in accordance with the Annual Accounts Act and the Accounting Standards Board. In preparation of the interim reports the BFNAR 2007: 1 is used and additionally guidance from the Swedish Financial Accounting Standards Council's recommendation RR 20 for Interim Reports. No differences have been identified between the previous rules and K3 which have a bearing on the previous year's balance sheet and profit and thus on the opening balance of equity. The company's Annual Report for 2014 provides a more detailed description of the company's accounting policies. In the event of differences between the English translation and the Swedish original, the Swedish text shall prevail.

With the support of the Annual Accounts Act, Section 7, § 5, of minor significance for the business, a consolidated financial statements for the parent company and its subsidiaries will not be prepared. Amounts are expressed in KSEK (thousands Swedish kronor). Figures in parentheses refer to the corresponding period last year.

This report has not been subject to review by the company's auditors.

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.

Other

After the close of the reporting period, the Annual General Meeting was held on April 14, 2015 where the General Meeting resolved in accordance with the submitted proposals. As members of the Board, Håkan Åström, Andreas Bunge, Martin Nicklasson, Sten Nilsson and Eva Redhe Ridderstad were elected.

Forward looking statement

This report includes statements that are forward looking. Actual results may differ from those indicated. Detailed reviews of risks are described in the Annual Report for 2014.

Stockholm April 21, 2015
Jacques Näsström
CEO

Next reports

The interim report for the period January-June 2015 will be published on August 18, 2015.

The interim report for the period January-September 2015 will be published on October 20, 2015.

Certified Advisor

The company's Certified Advisor is Erik Penser Bankaktiebolag.

Analysts who follow PledPharma

Erik Penser Bankaktiebolag, through Erik Penser Access
Pareto, Yilmaz Mahshid
Redeye, Klas Palin.

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