



PledPharma AB (publ) Interim Report First Quarter 2013

First patient treated in the PledOx™ phase I Ib study, PLIANT

Significant events after the end of the period

- **PledPharma proposes a rights issue of shares that can provide the company with up to 18.6 million SEK. The proposal will be tabled at an EGM to be held in conjunction with the AGM on April 18. The share issue is done to expand the PLIANT study with more study centers worldwide to ensure the recruitment rate and to achieve greater flexibility and time to perform the best possible out-licensing deal of PledPharma's drug candidate PledOx**
- **All patients included in the ongoing small clinical phase IIa study MANAMI, examining another PLED-compound's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with percutaneous coronary intervention (PCI)**

Significant events during January – March

- **First patient treated at Uppsala University Hospital (UAS) in the PledOx™ phase I Ib study PLIANT**
- **Green light received from the DSMB (Drug Safety Monitoring Board), an independent panel of experts) to continue patient recruitment for the phase I Ib study PLIANT**
- **FDA approved the IND application for the clinical trial PLIANT in the US**
- **Addition of the Oncology clinics at Linköping University Hospital and the University of Texas Health Science Center, San Antonio, USA, to the first part of the PLIANT study**
- **The Swedish Medicinal Products Agency (MPA) approved expanding the patient base in the PLIANT study**
- **Patent application regarding the use of PLED compounds in cancer treatment approved and issued in the US**
- Net result amounted to SEK -8 032k (-9 277k)
- Cash and cash equivalents on March 31 amounted to SEK 48 264k (81 646k)
- Cash flow from operating activities amounted to SEK -10 544k (-8 852k)
- Result per share amounted to SEK -0.4 (-0.5)

CEO comments

"The first patient is now treated at Uppsala University Hospital (UAS) and we expect to be able to include the remaining 8-11 patients in the initial dose-escalation part of the study until



mid-2013. Thereafter patients will be included at all clinics in the subsequent randomized part of the study.

We have also decided to perform a rights issue of shares as a consequence of the delay in the recruitment of patients in the first part of the PLIANT study. We have taken measures to widen the patient base, additional centers in the first part of the study have been added, and the communication with patients as well as investigators has been improved. In addition we are offering resources to facilitate additional test in addition to standard of care to improve patient acceptance. The additional financial resources will be used to expand the PLIANT study with more study centers worldwide to ensure the recruitment rate in the randomized part of the study. With these measures, we believe that we can get "top line" results from the study by mid-2014. The share issue is done to achieve greater flexibility and time to implement the best possible out-licensing deal for PledPharma's PledOx™, says Jacques Näsström, CEO of PledPharma.

COMPANY PROFILE

PledPharma is a Swedish specialty pharma company that develops PledOx™ in order to prevent serious side effects during chemotherapy treatment of cancer. These side effects are often so severe that the treatment cannot be completed as planned. The global market for supportive cancer care is about SEK 70 billion. PledOx is a drug candidate in the patented substance class PLED, which protects the body's normal cells against oxidative stress. PledOx is a lowMEM (Low Molecular Enzyme Mimetic) that mimics the body's own enzyme manganese superoxide dismutase (MnSOD), which is our main protection against oxidative stress. Oxidative stress is caused by overproduction of harmful oxygen/nitrogen molecules, e.g. as a result of chemotherapy treatment.

PledPharma is also evaluating the possibility of using PLED substances during the treatment of other life-threatening diseases.

ABOUT THE PLIANT-STUDY

The PLIANT study is divided in two parts with an initial dose-escalation part, in order to determine the correct dose level, and a randomized part, with the goal to establish PledOx's effect. The dose-escalation phase comprises of 9-12 patients from three selected medical centers in Sweden and one in the US – the Oncology Clinic at Uppsala University Hospital, Karolinska University Hospital, Department of Oncology, Linköping University Hospital and the Cancer Therapy & Research Center at The University of Texas Health Science Center in San Antonio, USA. In the next phase, the randomized part, aiming at 126 patients from approximately 30 centers in Europe and the United States, the patients will be divided into three equal groups to receive either placebo or PledOx in two different doses. For further details please see www.clinicaltrials.gov

MISSION

PledPharma develops drugs to improve the treatment of life-threatening diseases related to oxidative stress based on the company's patented and clinically proven technology, PLED.

BUSINESS MODEL

We focus on developing clinical projects through Phase IIb and then out-license the continued development and commercialization for traditional consideration including signing fees, milestone payments and royalty payments.



VISION

We will be a leading specialty pharma company, which develops drugs that protect healthy cells from oxidative stress during treatment of life-threatening diseases.

BUSINESS GOALS

The goal is that out-licensing discussions of the PledOx[™] project will be initiated in 2013.

STRATEGY

PledPharma conducts a partner-based development model aiming to maximize project performance, while financial exposure is reduced. Operations are conducted with a small focused internal organization which has extensive industry experience ensuring that the company has the expertise needed to very cost-effectively drive value growth in clinical programs in collaboration with our external partners.

MARKET

The market for the treatment of loss of white blood cells in cancer was more than \$ 5 billion in 2010 according to Datamonitor. PledOx has the potential to dramatically reduce the side effects in the treatment of colorectal cancer with oxaliplatin, the base of FOLFOX used in colorectal cancer treatment which in 2010 was given in 3.3 million doses globally according to IMS. IMS has in a focus group study in the United States estimated a price of 2,000 USD per dose. Since our aim is that PledOx is to be used at each dose of oxaliplatin a very large market potential is assumed even with a limited market penetration. Furthermore, PledOx has the possibility not only to be used in case of loss of white blood cells, but can also reduce nerve damage and has the potential to be used in other chemotherapies as well as radiation. This may implicate that PledOx can contribute to growth in the market segment where currently there is no treatment.

OXADITIVE STRESS AND PLED SUBSTANCES

Oxidative stress is caused by the overproduction of harmful oxygen/nitrogen molecules. PledOx is a drug candidate in the patented substance class PLED, which protects the body's normal cells against oxidative stress. As the PLED substances reduce the oxidative stress there is a potential to use the substance at various diseases. The world market only in supportive cancer treatment is over 10 billion USD.

Progress has been made on the company's patent position. A compositional matter patent application regarding PledOx has been made to strengthen and extend PledPharmas patent protection and in February 2013, a patent was approved for the US market regarding the use of PLED substances in cancer treatment with patent protection until 2028.

OTHER

In the ongoing small clinical Phase IIa study MANAMI, examining another PLED-compound's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with coronary angioplasty, all twenty patients now are included. After proper analysis of data, results are expected during 2013.

PledPharma (STO:PLED) is listed on NASDAQ OMX First North. For more information, please visit: www.pledpharma.se

Financial summary

First quarter 2013

Income

Revenue during the quarter amounted to SEK 89k (89k) and consisted of foreign exchange gains. Interest income for the quarter amounted to SEK 140k (158k).

Costs

Operating expenses in the first quarter amounted to SEK 8 260k (9 524k). Of this, project costs amounted to 4 197k (5 138k) and employee costs to 1 551k (1 643k). Depreciation amounted to 1k (1k).

Results and financial position

Operating result for the quarter, amounted to SEK -8 171k (-9 435k). Result after financial items amounted to SEK -8 032k (-9 277) and the result after tax was SEK -8 032k (-9 277k).

The cash flow during the quarter amounted to SEK -10 544k (-8 902k).

Cash flow from operating activities amounted to SEK -10 544k (-8 852k).

Cash at the end of the period amounted to 48 264k (81 646k).

Shareholders' equity amounted to SEK 45 910k (78 255k) and the company's equity ratio was 91 percent (95). Shareholders' equity per share amounted to SEK 2.3 (3.9). No long-term debts were outstanding

(-). Current liabilities at March 31, 2013 amounted to SEK 4 536k (4 102k).

Employees

Average number of employees during the period was 6 (6) persons.

Options Program

131 000 call options, in the in 2012 decided options scheme, were subscribed by employees in the company as of March 31, 2013.

Significant risks and uncertainties

Risks are described in the prospectus issued in connection with a right share issue which took place in June 2011 as well as in the Annual Report for 2012. No changes in the company's risk assessment have taken place during the period.

Share

Number of shares at March 31, 2013 were 20 247 775. After full dilution, the number of shares were 20 647 775. PledPharma shares were listed on NASDAQ OMX First North on 7 April 2011.

Seasonal variations

PledPharma activity is not subject to seasonal variations.

Income statement

SEKk	2013 Jan-March	2012 Jan-March	2012 Jan-Dec
Revenue			
Activated work for own account	-	-	-
Capitalized costs	-	-	-
Other operating income	89	89	672
	89	89	672
Operating expenses			
Project costs	-4 197	-5 138	-18 601
Employee benefit costs	-1 551	-1 643	-8 127
Other operating costs	-2 512	-2 742	-9 249
Depreciation and impairment, fixed assets	-1	-1	-4
Operating result	-8 171	-9 435	-35 310
Net financial items			
Interest income	140	158	1 454
Interest expense and similar items	0	-	-1
Result after financial net	-8 032	-9 277	-33 857
Result before tax	-8 032	-9 277	-33 857
Tax	-	-	-
Result after tax	-8 032	-9 277	-33 857
Share Data			
Number of shares at the end of period	20 247 775	20 247 775	20 247 775
Result per share before and after dilution (SEK)	-0,4	-0,5	-1,7
Equity per share (SEK)	2,3	3,9	2,7
Equity per share after dilution (SEK)	2,2	3,9	2,6

Balance sheet

SEKk	2013-03-31	2012-03-31	2012-12-31
ASSETS			
Fixed assets			
<i>Intangible assets</i>			
Capitalized expenditure for research and development	-	-	-
Concessions, patents, licences, trademarks	-	-	-
	-	-	-
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	7	11	7
<i>Financial assets</i>			
Shares and participations in group companies	50	50	50
Total fixed assets	57	61	57
Current assets			
<i>Current receivables</i>			
Receivables group companies	266	-	266
Other receivables	997	549	629
Prepaid expenses and accrued income	861	102	697
	2 125	650	1 592
<i>Cash and bank balances</i>			
	48 264	81 646	58 808
Total current assets	50 389	82 296	60 399
Total assets	50 445	82 357	60 457
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	1 066	1 066	1 066
<i>Non-restricted equity</i>			
Received group contributions	0	-	266
Share premium reserve	52 876	86 466	86 466
Result for the period	-8 032	-9 277	-33 857
	44 844	77 189	52 876
Total equity	45 910	78 255	53 941
Accounts payable	984	1 730	2 331
Current tax liabilities	143	154	-
Other liabilities	171	264	403
Accrued expenses and deferred income	3 238	1 954	3 782
Total short term liabilities	4 536	4 102	6 516
Total equity and liabilities	50 445	82 357	60 457

Cash flow statement

SEkk	2013 Jan-March	2012 Jan-March	2012 Jan-Dec
OPERATING ACTIVITIES			
Result after financial net	-8 032	-9 277	-33 857
Adjustments for non-cash items	1	1	4
Tax paid	31	-10	-32
Cash flow from operating activities before changes in working capital	-7 999	-9 286	-33 885
Changes in short term liabilities	-648	209	-678
Changes in account payables	-1 347	298	899
Changes in operating liabilities	-549	-73	1 708
Cash flow from operating activities	-10 544	-8 852	-31 956
INVESTING ACTIVITIES			
Investment in intangible assets	-	-	-
Received group contribution	-	-	266
Investment in financial assets	-	-50	-50
Purchase of property, plant and equipment	-	-	-
Cash flow from investing activities	-	-50	216
FINANCING ACTIVITIES			
New share issue	-	-	-
Share issue costs	-	-	-
Cash flow from financing activities	-	-	-
Cash flow for the period			
Balance at beginning of period	58 808	90 548	90 548
Change in cash	-10 544	-8 902	-31 740
CASH BALANCE AT THE END OF THE PERIOD	48 264	81 646	58 808

Change in Equity

SEKk	Share capital	Other	Share premium reserve	Net income	Total equity
Opening balance 2012-01-01	1 066	-	119 712	-33 246	87 532
Transfer of the 2010 year result	-	-	-33 246	33 246	-
Net result for the period	-	-	-	-9 277	-9 277
Closing balance 2012-03-31	1 066	-	86 466	-9 277	78 255
Opening balance 2013-01-01	1 066	266	86 466	-33 857	53 941
Transfer of 2012 year result	-	-266	-33 590	33 857	-
Net result for the period	-	-	-	-8 032	-8 032
Closing balance 2013-03-31	1 066	-	52 876	-8 032	45 910

Key ratios

KSEK	2013	2012	2012
	Jan-March	Jan-March	Jan-Dec
Operating result (EBIT)	-8 171	-9 435	-35 310
Operating margin %	neg.	neg.	neg.
Result for the period	-8 032	-9 277	-33 857
Cash flow from operating activities	-10 544	-8 852	-31 956
Total assets	50 445	82 357	60 457
Equity	45 910	78 255	53 941
Equity ratio %	91%	95%	89%
Return on equity %	neg.	neg.	neg.
Number of shares at the end of the period	20 247 775	20 247 775	20 247 775
Number of shares at the end of the period after dilution	20 647 775	20 247 775	20 647 775
Average number of shares under the period	20 247 775	20 247 775	20 247 775
Average number of shares under the period after dilution	20 647 775	20 247 775	20 547 775
Share Data			
Result per share	-0,4	-0,5	-1,7
Result per average share	-0,4	-0,5	-1,7
Cash flow from operating activities	-0,5	-0,4	-1,6
Equity per share	2,3	3,9	2,7
Equity per share after dilution	2,2	3,9	2,6
Dividend	-	-	-
Number of employees	6	6	6



Accounting principles

This report has been prepared in compliance with the Swedish Financial Accounting Standards Council's recommendation RR 20 on Interim Financial Reporting and the Annual accounts Act. The company's Annual Report for 2012 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 raised.

Amounts are expressed in KSEK (thousands Swedish kronor). Figures in parentheses refer to the corresponding period last year.

This report has not been reviewed 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.

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 prospectus issued in connection with the right share issue which took place in June 2011 as well as in the Annual Report for 2012.

Stockholm April 18, 2013

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Next reports

The interim report for the period January-June 2013 will be published on August 29, 2013.
The interim report for the period January-September 2013 will be published on October 25, 2013.

Certified Advisor

The company's Certified Advisor is Erik Penser Bankaktiebolag.

Analysts who follow PledPharma

Erik Penser Bankaktiebolag via Erik Penser Access.
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