PledPharma AB (publ)
Full Year Report 2012

First patient treated in the PledOx™ phase IIb study, PLIANT

Significant events after the end of the period

- **First patient treated at Uppsala University Hopsital (UAS) in the PledOx™ phase IIb study PLIANT**
- **Patent application regarding the use of PLED compounds in cancer treatment approved and issued in the US**
- **FDA approved the IND application for the clinical trial PLIANT in the US**
- **Addition of 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**

Significant events during 2012

- **Conducted four preclinical safety studies**
- **Manufactured Active Pharmaceutical Ingredient (API) with GMP standard**
- **Developed and manufactured finished product formulation of PledOx for clinical trials**
- **Negotiated contract with CRO to run the clinical trial PLIANT**
- **Appointed professor Bengt Glimelius, UAS, as coordinating principal investigator**
- **Received regulatory approval for the PLIANT study by the Swedish MPA as well as regional ethics committees**
- **Recruited approximately 30 clinical trial centres in EU and US for the 126 patients to be recruited in the randomized phase of the study**
- **Screened patients at UAS and Karolinska University Hospital (KS) for the initial dose-escalation phase of the PLIANT study**
- **Published three key papers on PLED compounds in Translational Oncology**
- **Filed PCT compositional matter patent application on PledOx (calmangafodipir)**

The period October – December

- Net result amounted to SEK -8 389k (-25 426k)
- Cash and cash equivalents on Dec 31 amounted to SEK 58 808k (90 548k)
- Cash flow from operating activities amounted to SEK -6 679k (-7 112k)
- Result per share amounted to SEK -0.4 (-1.3)

Full Year 2012

- Net result amounted to SEK -33 857k (-33 246k)
- Cash flow from operating activities amounted to SEK -31 690k (-14 396k)
- Result per share amounted to SEK -1.7 (-2.0)

CEO comments

"The first patient is now treated at Uppsala University Hospital (UAS), which is the result of intense work in 2012 where the focus has been on starting the PLIANT study.
During the year we conducted four preclinical safety studies, manufactured API with GMP standard and developed a finished product formulation of PledOx for clinical trials.
We have entered into an agreement with a CRO to run the PLIANT study and have obtained regulatory approval for the study in Sweden and the US.
Clinical trial centers are recruited in Sweden and the US for the initial dose-escalation phase of the study, and we have also recruited approximately 30 centers internationally for the 126 patients in the subsequent randomized part of the study.
Professor Bengt Glimelius at UAS, a world authority in research and treatment of colorectal cancer, has been appointed coordinating principal investigators.
During the autumn we initiated screening of patients at UAS and Karolinska University Hospital (KS) for inclusion in the initial part of PLIANT study. Measures to expand the patient base by adjustments to the study design have been implemented.
Progress has also been made on the company's patent position. A compositional matter patent application for PledOx has been submitted to strengthen and expand the patent protection and in February a patent in the US market was approved for the use of PLED compounds in cancer treatment.
During the year, three key papers on PLED compounds have been published in Translational Oncology.
We expect to be able to include the remaining 8-11 patients in the initial dose-escalation phase of the study in the next 4-5 months. Thereafter patients will be included at all clinics in the subsequent randomized portion of the study during mid-2013.
By the measures taken to broaden the patient base and by adding more clinics in the study, we hope to counteract the delay in the start of the study.
We have also gained an increasing awareness regarding PLED-compounds potential use in other medical indications which look very promising. "

Company profile

PledPharma is a Swedish specialty pharma company, which develops improved treatments of life-threatening diseases. We are focused on developing a medicine that reduces the serious side effects, which occur in connection with chemotherapy treatment In addition, we are evaluating an existing medicine’s ability to limit the reperfusion injuries to the heart after acute myocardial infarction treated with coronary angioplasty. Our projects meet significant medical needs and we have the opportunity to offer patients valuable supportive treatments in serious life-threatening diseases. This means that we also have the potential of offering our shareholders favorable value growth.

Considerable market potential

PledOx belongs to the group lowMEM (low Molecular Enzyme Mimetics) that mimic the endogenous enzyme Manganese Super Oxide Dismutase (MnSOD) which is our body’s key

protection against oxidative stress. Oxidative stress is caused by overproduction of harmful oxygen/nitrogen molecules, e.g. as a result of chemotherapy treatment.
Oxidative stress occurs in many diseases, and since PLED-compounds reduce the oxidative stress there is a potential to use these compounds in many different diseases. The global market in supportive cancer treatment alone is more than USD 10 billion.

Ongoing clinical programs
PledOx is developed to reduce chemotherapy-induced side effects in cancer treatment. The chemotherapy-induced side effects lead to a dose-reduction of the prescribed chemotherapy or, in the worst case, that the treatment must be discontinued completely. PLED-compound has previously shown to protect healthy cells and tissues in conjunction with chemotherapy and thus reducing the side effects. In the ongoing Phase IIb study, PledOx ability to prevent chemotherapy-induced side effects for colorectal cancer will be investigated. The ability to complete the planned treatment may lead to improved treatment results of cancer patients treated with chemotherapy.
The PLIANT study is divided in two parts with an initial dose-escalation phase, in order to determine the correct dose level, and a randomized phase, 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 phase, 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

In a small, externally financed, clinical Phase IIa study, we are examining another PLED-compound's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with coronary angioplasty. Results are expected during 2013. The development risks in this study are significantly higher than in the cancer study as this study constitutes an initial limited patient study for this indication, in an indication which also is difficult to study.

Our business model
We are developing drugs in areas where there are high medical needs and a good opportunity for investment returns. We focus on developing the existing clinical projects through Phase IIb and then out-license the continued development and commercialization for a consideration that includes upfront, milestone and royalty payments. Our technology is based on a proprietary and clinically proven PLED-compound.

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

Business goal
Out-licensing discussions of the PledOx project will be initiated in 2013. In the clinical program where PledOx preventive effects of chemotherapy induced side-effects in colorectal cancer treatment patients is investigated, we are now in clinical phase IIb.

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

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Financial summary

Fourth quarter 2012

Income
Revenue during the quarter amounted to SEK 115k (9k) and consisted of co-funding of SEK 100k from VINNOVA and foreign exchange gains. Interest income for the quarter amounted to SEK 255k (665k).

Costs
Operating expenses in the fourth quarter amounted to SEK 8 758k (26 099k).
In December 2011, the Board of Directors resolved to write-down capitalized expenses related to the cost of patents and work on own development resulting in a write-down of 17 094k in 2011.

Results and financial position
Operating result for the fourth quarter, amounted to SEK -8 643k (-26 090k). In 2011, 17 094k of the change was related to the change in the policy for impairment of capitalized costs described above. Result after financial items amounted to SEK -8 389k (-25 246k) and the result after tax was SEK -8 389k (-25 246k).
The cash flow during the quarter amounted to SEK -6 679k (-7 112k).
Cash flow from operating activities amounted to SEK -6 679k (-7 112k).

Full year 2012

Income
Revenue during the full year amounted to SEK 672k (9 699k) and consisted of co-funding of SEK 500k from VINNOVA and foreign exchange gains. In 2011, 9 401k of the change was related to capitalized costs described above.
Interest income for the period amounted to SEK 1 454k (1 017k).

Costs
Operating expenses in the full year amounted to SEK 35 981k (43 924). In 2011, 17 096k of the change was related to the change in the policy for impairment of capitalized costs described above.
The other cost increase came mainly from increased project costs.

Results
Operating result for the full year amounted to SEK -35 310k (-34 225k). Result after financial items amounted to SEK -33 857k (-33 246k) and the result after tax was SEK -33 857k (-33 246k).

Financial position
Cash and cash equivalents at December 31, 2012 amounted to SEK 58 808k (90 548k).

Shareholders' equity amounted to SEK 53 675k (87 532k) and the company's equity ratio was 89 percent (96). Shareholders' equity per share amounted to SEK 2.6 (4.3). No long-term debts were outstanding (-). Current liabilities at December 31, 2012 amounted to SEK 6 516k (3 893k).

The cash flow during the year amounted to SEK -31 740k (89 979k).
The positive cash flow during the previous year was a result of the proceeds from the share issues performed by the company in February and June 2011. Cash flow from

operating activities amounted to SEK -31 690k (-14 396k). The change came mainly from increased project costs.

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

Options Program
On March 29, the AGM approved the stock option program for executives and other employees for a maximum total of 400 000 options. All options have been subscribed per December 31, 2012 by the subsidiary PledPharma I AB which has the sole business to operate the handling of employee incentive programs in PledPharma. Per the same date the company had a share capital of SEK 50k and the cash position was SEK 312k. 131 000 call options were subscribed by employees in the company as of December 31, 2012.

Significant risks and uncertainties
Risks are described in the prospectus issued in connection with a right share issue which took place in June 2011. No changes in the company's risk assessment have taken place during the period.

Share
Number of shares at, December 2012 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.

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Income statement

SEKk	2012 Oct-Dec	2011 Oct-Dec	2012 Jan-Dec	2011 Jan-Dec
Revenue				
Activated work for own account	-	-	-	1 661
Capitalized costs	-	-	-	7 740
Other operating income	115	9	672	298
	115	**9**	**672**	**9 699**
Operating expenses				
Project costs	-3 702	-4 183	-18 601	-11 923
Employee benefit costs	-2 248	-2 421	-8 127	-6 624
Other operating costs	-2 807	-2 401	-9 249	-8 281
Depreciation and impairment, fixed assets	-1	-17 094	-4	-17 096
Operating result	**-8 643**	**-26 090**	**-35 310**	**-34 225**
Net financial items				
Interest income	255	665	1 454	1 017
Interest expense and similar items	-2	-1	-1	-38
Result after financial net	**-8 389**	**-25 426**	**-33 857**	**-33 246**
Result before tax	**-8 389**	**-25 426**	**-33 857**	**-33 246**
Tax	-	-	-	-
Result after tax	**-8 389**	**-25 426**	**-33 857**	**-33 246**
Share Data				
Number of shares at the end of period	20 247 775	20 247 775	20 247 775	20 247 775
Result per share before and after dilution (SEK)	-0,4	-1,3	-1,7	-2,0
Equity per share (SEK)	2,7	4,3	2,7	4,3
Equity per share after dilution (SEK)	2,6	4,3	2,6	4,3

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Balance sheet

KSEK	2012-12-31	2011-12-31
ASSETS		
Fixed assets		
Intangible assets		
Capitalized expenditure for research and development	-	-
Concessions, patents, licences, trademarks	-	-
	-	-
Property, plant and equipment		
Equipment, tools, fixtures and fittings	7	12
Financial assets		
Shares and participations in group companies	50	-
Total fixed assets	**57**	**12**
Current assets		
Current receivables		
Other receivables	629	330
Prepaid expenses and accrued income	697	536
	1 325	866
Cash and bank balances	58 808	90 548
Total current assets	**60 133**	**91 413**
Total assets	**60 190**	**91 425**

KSEK	2012-12-31	2011-12-31
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	1 066	1 066
Non-restricted equity		
Share premium reserve	86 466	119 712
Result for the period	-33 857	-33 246
	52 609	86 466
Total equity	**53 675**	**87 532**
Accounts payable	2 331	1 432
Current tax liabilities	-	132
Other liabilities	403	306
Accrued expenses and deferred income	3 782	2 023
Total short term liabilities	**6 516**	**3 893**
Total equity and liabilities	**60 190**	**91 425**

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Cash flow statement

SEKk	2012 Oct-Dec	2011 Oct-Dec	2012 Jan-Dec	2011 Jan-Dec
OPERATING ACTIVITIES				
Result after financial net	-8 389	-25 426	-33 857	-33 246
Adjustments for non-cash items	1	17 094	4	17 096
Tax paid	4	1	-32	-11
Cash flow from operating activities before changes in working capital	**-8 384**	**-8 331**	**-33 885**	**-16 161**
Changes in short term liabilities	678	-437	-412	-637
Changes in account payables	-435	694	899	411
Changes in operating liabilities	1 462	962	1 708	1 991
Cash flow from operating activities	**-6 679**	**-7 112**	**-31 690**	**-14 396**
INVESTING ACTIVITIES				
Investment in intangible assets	-	-	-	-9 401
Investment in financial assets	-	-	-50	-
Purchase of property, plant and equipment	-	-	-	-11
Cash flow from investing activities	**-**	**-**	**-50**	**-9 413**
FINANCING ACTIVITIES				
New share issue	-	-	-	115 814
Share issue costs	-	-	-	-2 027
Cash flow from financing activities	**-**	**-**	**-**	**113 788**
Cash flow for the period				
Balance at beginning of period	65 487	97 659	90 548	568
Change in cash	-6 679	-7 112	-31 740	89 979
CASH BALANCE AT THE END OF THE PERIOD	58 808	90 548	58 808	90 548

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Change in Equity

KSEK	Share capital	Share premium reserve	Net income	Total equity
Opening balance 2011-01-01	**301**	**10 489**	**-3 801**	**6 990**
Bonus issue	301	-301	-	-
Registration share issue 2011-02-14	94	6 928	-	7 022
Registration share issue 2011-07-06	369	108 423	-	108 793
Issue expenses	-	-2 027	-	-2 027
Transfer of the 2010 year result	-	-3 801	3 801	-
Net result for the period	-	-	-33 246	-33 246
Closing balance 2011-12-31	**1 066**	**119 712**	**-33 246**	**87 532**

Opening balance 2012-01-01	**1 066**	**119 712**	**-33 246**	**87 532**
Transfer of 2011 year result	-	-33 246	33 246	-
Net result for the period	-	-	-33 857	-33 857
Closing balance 2012-12-31	**1 066**	**86 466**	**-33 857**	**53 675**

Key ratios

KSEK	2012 Oct-Dec	2011 Oct-Dec	2012 Jan-Dec	2011 Jan-Dec
Operating result (EBIT)	-8 643	-26 090	-35 310	-34 225
Operating margin %	neg.	neg.	neg.	neg.
Result for the period	-8 389	-25 426	-33 857	-33 246
Cash flow from operating activities	-6 679	-7 112	-31 690	-14 396
Total assets	60 190	91 425	60 190	91 425
Equity	53 675	87 532	53 675	87 532
Equity ratio %	89%	96%	89%	96%
Return on equity %	neg.	neg.	neg.	neg.
Number of shares at the end of the period	20 247 775	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	20 247 775
Average number of shares under the period	20 247 775	19 790 022	20 247 775	16 437 362
Average number of shares under the period after dilution	20 647 775	19 790 022	20 514 442	16 437 362
Share Data				
Result per share	-0,4	-1,3	-1,7	-1,6
Result per average share	-0,4	-1,3	-1,7	-2,0
Cash flow from operating activities	-0,3	-0,4	-1,6	-0,9
Equity per share	2,7	4,3	2,7	4,3
Equity per share after dilution	2,6	4,3	2,6	4,3
Dividend	-	-	-	-
Number of employees	6	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 2011 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.

Stockholm February 21, 2013

Jacques Näsström
CEO

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Next reports
The interim report for the period January-March 2013 will be published on April 18, 2013.
The interim report for the period January-June 2013 will be published on August 28, 2013.
The interim report for the period January-September 2013 will be published on October 24, 2013.

The Annual General Meeting will be held on April 18 at 17.00 in Erik Penser Bank's premises at Biblioteksgatan 9 in Stockholm.

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