



PledPharma AB (publ) Interim report January-September 2012

Patient screening ongoing ahead of inclusion in the PledOx™ Phase IIb study

The period July – September

- **The design of the clinical study for PledOx has been approved by the Swedish Medical Products Agency (MPA)**
- **Selection of patients ongoing at Uppsala University Hospital and Karolinska University Hospital in Solna and for inclusion in the PledOx Phase IIb study in colorectal cancer**
- **Participating clinics in the PledOx study have been chosen. Around 30 high-quality clinics in eight countries, including Sweden and the US, will participate in the study**
- **Net result amounted to SEK -5 642k (-2 485k)**
- **Cash and cash equivalents on Sept 30 was SEK 65 487k (97 659k)**
- **Cash flow from operating activities amounted to SEK -3 121k (-5 659k)**
- **Result per share amounted to SEK -0.28 (-0.12)**

The period January – September in summary

- Net result amounted to SEK -25 467k (-7 820k)
- Cash flow from operating activities amounted to SEK -25 010k (-7 284k)
- Result per share amounted to SEK -1.26 (-0.39)
- Professor Bengt Glimelius at Uppsala University Hospital, a world authority within research and treatment of cancer, coordinating principal investigator of the PledOx study
- Positive results in the long term preclinical PledOx safety studies
- A new composition of matter patent application for PledOx provides additional strong and extended patent protection opportunities
- Positive and supportive meetings with the MPA and the US regulatory authority (FDA) regarding the PledOx study
- Publication of clinical study, showing a decreased number of serious adverse events due to chemotherapy in patients pretreated with PLED-substance, in a scientific journal

CEO comments

“Patient screening is ongoing in the open dose-escalation phase of the study at Karolinska University Hospital in Solna and Uppsala University Hospital. We expect to include the first patient in the coming month. Nine to twelve patients will be included in this part of the PledOx study until the beginning of 2013. The other clinics will start thereafter”, says CEO Jacques Näsström.



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 damages on the heart that occurs when acute myocardial infarction is 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

Oxidative stress occurs in many different diseases, and as PLED-substances reduce the oxidative stress there is a potential to use the substance in various diseases. The global market in supportive cancer treatment alone is more than USD 10 billion.

Ongoing clinical programs

The substance PledOx is developed to reduce chemotherapy-induced side effects in cancer treatment. The chemotherapy-induced side effects lead to a reduction in the dose of the prescribed chemotherapy or, in the worst case, treatment must be discontinued completely. PLED-substance has previously shown its ability 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 overall results are expected in the end of 2013.

In a small, externally financed, clinical Phase IIa study, we are examining another PLED-substance's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with coronary angioplasty. Results are expected in the first half of 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, 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 driving 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-substance.

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

Financial summary

Third quarter 2012

Income

Revenue during the quarter amounted to SEK 34k (5 278k) and consisted of foreign exchange gains. For the previous year, revenue mainly consisted of capitalized costs. Decision has been made to discontinue capitalization of costs in this stage of development to make an adjustment to how other companies in the pharmaceutical industry has chosen to activate the cost of patents and work on own development. Activation of costs of this kind will continue after the projects have undergone Phase III trials and commercial launches. Interest income for the period amounted to SEK 677k (331k).

Costs

Operating expenses in the third quarter amounted to SEK 6 353k (8 064k).

Results

Operating result for the third quarter, amounted to SEK -6 319k (-2 786k). The change in operating income is mainly due to the change in the policy for impairment of capitalized costs. Result after financial items amounted to SEK -5 642k (-2 485k) and the result after tax was SEK -5 642k (-2 485k).

First nine months 2012

Income

Revenue during the first nine months amounted to SEK 557k (9 690k) and consisted of co-funding of SEK 400k from VINNOVA and foreign exchange gains. Regarding the previous year, see comment regarding the third quarter. Interest income for the period amounted to SEK 1 199k (353k).

Costs

Operating expenses in the first nine months amounted to SEK 27 224k (17 825). The cost increase came mainly from increased project- and personnel costs.

Results

Operating result for the first nine months amounted to SEK -26 667k (-8 135k). The change in operating result was due to increased costs and to the change in the policy for impairment of capitalized costs. Result after financial items amounted to SEK -25 467k (-7 820k) and the result after tax was SEK -25 467k (-7 820k).

Investments, liquidity and financial position

Cash and cash equivalents at September 30, 2012 amounted to SEK 65 487k (97 659k). Shareholders' equity amounted to SEK 62 064k (112 957k) and the company's equity ratio was 92 percent (98). Shareholders' equity per share amounted to SEK 3.07 (5.58). No long-term debts were outstanding (-). Current liabilities at September 30, 2012 amounted



to SEK 5 436k (2 065k).

The cash flow during the first nine months amounted to SEK -25 060k (97 091k).

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 -25 010k (-7 284k).

Employees

Average number of employees during the first nine months 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 on the balance day 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 317k. 131 000 call options were subscribed by employees in the company as of September 30, 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 September 30, 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.

Income statement

KSEK	2012 July-Sept	2011 July-Sept	2012 Jan-Sept	2011 Jan-Sept	2011 Jan-Dec
Revenue					
Activated work for own account	-	726	-	1 661	1 661
Capitalized costs	-	4 513	-	7 740	7 740
Other operating income	34	39	557	289	298
	34	5 278	557	9 690	9 699
Operating expenses					
Project costs	-2 419	-4 513	-14 899	-7 740	-11 923
Employee benefit costs	-1 686	-1 758	-5 880	-4 203	-6 624
Other operating costs	-2 247	-1 793	-6 442	-5 880	-8 281
Depreciation and impairment, fixed assets	-1	-1	-3	-3	-17 096
Operating result	-6 319	-2 786	-26 667	-8 135	-34 225
Interest income	677	331	1 199	353	1 017
Interest expense and similar items	0	-30	0	-38	-38
Result after financial net	-5 642	-2 485	-25 467	-7 820	-33 246
Result before tax	-5 642	-2 485	-25 467	-7 820	-33 246
Tax	-	-	-	-	-
Result after tax	-5 642	-2 485	-25 467	-7 820	-33 246
Share Data					
Number of shares at the end of period	20 247 775	20 247 775	20 247 775	20 247 775	20 247 775
Result after tax before and after dilution (SEK)	-0,3	-0,1	-1,3	-0,5	-2,0
Equity per share (SEK)	3,1	5,6	3,1	5,6	4,3
Equity per share after dilution (SEK)	3,0	5,6	3,0	5,6	4,3

Balance sheet

KSEK	2012-09-30	2011-09-30	2011-12-31
ASSETS			
Fixed assets			
<i>Intangible assets</i>			
Capitalized expenditure for research and development	-	12 760	-
Concessions, patents, licences, trademarks	-	4 332	-
	-	17 092	-
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	9	13	12
<i>Financial assets</i>			
Shares and participations in group companies	50	-	-
Total fixed assets	59	17 105	12
Current assets			
<i>Current receivables</i>			
Other receivables	562	64	330
Prepaid expenses and accrued income	1 393	194	536
	1 955	258	866
<i>Cash and bank balances</i>	65 487	97 659	90 548
Total current assets	67 442	97 917	91 413
Total assets	67 501	115 023	91 425
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	1 066	1 066	1 066
<i>Non-restricted equity</i>			
Share premium reserve	86 466	119 712	119 712
Result for the period	-25 467	-7 820	-33 246
	60 999	111 892	86 466
Total equity	62 064	112 957	87 532
Accounts payable	2 766	737	1 432
Current tax liabilities	233	133	132
Other liabilities	515	118	306
Accrued expenses and deferred income	1 922	1 076	2 023
Total short term liabilities	5 436	2 065	3 893
Total equity and liabilities	67 501	115 023	91 425

Cash flow statement

KSEK	2012	2011	2012	2011	2011
	July-Sept	July-Sept	Jan-Sept	Jan-Sept	Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-5 642	-2 485	-25 467	-7 820	-33 246
Adjustments for non-cash items	1	1	3	3	17 096
Tax paid	-13	-4	-36	-12	-11
Cash flow from operating activities before changes in working capital	-5 654	-2 488	-25 501	-7 829	-16 161
Changes in short term liabilities	1 007	273	-1 089	-200	-637
Changes in account payables	763	8	1 334	-283	411
Changes in operating liabilities	763	-3 452	245	1 028	1 991
Cash flow from operating activities	-3 121	-5 659	-25 010	-7 284	-14 396
INVESTING ACTIVITIES					
Investment in intangible assets	-	-5 239	-	-9 401	-9 401
Investment in financial assets	-	-	-50	-	-
Purchase of property, plant and equipment	-	-	-	-11	-11
Cash flow from investing activities	-	-5 239	-50	-9 413	-9 413
FINANCING ACTIVITIES					
New share issue	-	2 793	-	115 814	115 814
Share issue costs	-	-400	-	-2 027	-2 027
Cash flow from financing activities	-	2 393	-	113 788	113 788
Cash flow for the period					
Balance at beginning of period	68 608	106 165	90 548	568	568
Change in cash	-3 121	-8 506	-25 060	97 091	89 979
CASH BALANCE AT THE END OF THE PERIOD	65 487	97 659	65 487	97 659	90 548

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	-	-	-7 820	-7 820
Closing balance 2011-09-30	1 066	119 712	-7 820	112 957
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	-	-	-25 467	-25 467
Closing balance 2012-09-30	1 066	86 466	-25 467	62 064

Key ratios

KSEK	2012 July-Sept	2011 July-Sept	2012 Jan-Sept	2011 Jan-Sept	2011 Jan-Dec
Operating result (EBIT)	-6 319	-2 786	-26 667	-8 135	-34 225
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-5 642	-2 485	-25 467	-7 820	-33 246
Cash flow from operating activities	-3 121	-5 659	-25 010	-7 284	-14 396
Total assets	67 501	115 023	67 501	115 023	91 425
Equity	62 064	112 957	62 064	112 957	87 532
Equity ratio %	92%	98%	92%	98%	96%
Return on equity %	neg.	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	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	20 247 775
Average number of shares under the period	20 247 775	19 790 022	20 247 775	15 153 267	16 437 362
Average number of shares under the period after dilution	20 647 775	19 790 022	20 514 442	15 153 267	16 437 362
Share Data					
Result after tax	-0,3	-0,1	-1,3	-0,4	-1,6
Result per average share	-0,3	-0,1	-1,3	-0,5	-2,0
Cash flow from operating activities	-0,2	-0,3	-1,2	-0,5	-0,9
Equity per share	3,1	5,6	3,1	5,6	4,3
Equity per share after dilution	3,0	5,6	3,0	5,6	4,3
Dividend	-	-	-	-	-
Number of employees	6	6	6	6	6



Accounting principles

The interim 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 interim 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 interim 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.

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Next report

The Year End report for January-December 2012 will be published on February 21, 2013

Analysts who follow PledPharma

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