



PledPharma

# PledPharma AB (publ)

## Full year report January – December 2011

Activities ahead of clinical phase IIb study are progressing according to plan

The period January - December

- **Cash flow from operating activities for 2011 amounted to SEK – 14.396k (-2.717k)**
- **Cash and cash equivalents at December 31 was SEK 90.548k (568k)**
- **Net profit, including impairment of capitalized costs, amounted to SEK -33.246k\* (-3.801k)**
- Two 1-month pre clinical toxicity studies with PledOx<sup>®</sup> showed positive results
- Two 3-month pre clinical toxicity studies with PledOx<sup>®</sup> initiated
- Clinical trial substance (mangafodipir) for the acute myocardial infarction study manufactured
- The PledPharma share listed on NASDAQ OMX First North
- A new share rights issue done resulting in SEK 109 million
- Håkan Åström (chairman), Peter Buhl Jensen, Rolf Andersson and Eva Redhe Ridderstad elected PledPharma board members
- Marie Bengtson was hired as Clinical Project Director, and Erik Kinnman, as medical expert and VP Investor Relations

The period October - December

- **Cash flow from operating activities amounted to SEK -7.112k (-613k)**
- **Net profit including impairment of capitalized costs amounted to SEK -25.426k\* (-1.609k)**
- The results in a preclinical model shows that PledOx<sup>®</sup> protects against white blood cell drop caused by the anticancer drug oxaliplatin.
- Results from the clinical phase IIa study in colorectal cancer patients treated with chemotherapy published. The study showed a reduced number of serious adverse events in the group that received PLED-derivative pre- treatment.
- The prospective clinical phase IIa acute myocardial infarction study ready to be restarted

### CEO comments

Jacques Näsström says: We have during 2011 taken major and exciting steps in our development towards becoming an important pharmaceutical company. The Board has been strengthened and we have also been able to make complementary additions to our organization. We are now listed on NASDAQ OMX First North, and have after the listing completed a 109 million SEK new share issue, which we expect to cover costs until the results of the important clinical cancer study. This study will start mid 2012 and results are expected by the end of 2013. The first clinical study in acute myocardial infarction is ready to restart and will be completed in mid 2012.

\* SEK17 092 k of the costs are related to impairment. The Board decided in December that the capitalized costs for patents and work on own development will be impaired. The decision to discontinue capitalization of costs in this stage of development was in order to make an adjustment to how other companies in the pharmaceutical industry has chosen to activate the cost of patents and for its own development.



## Company profile

PledPharma is a Swedish specialty pharma company, which develops new treatments of life threatening diseases. We are focused on developing a medicine that reduces the serious side effects, which develop in connection with chemotherapy treatment, and on developing a medicine that limits the damages on the heart that occurs when acute myocardial infarction is treated with coronary angioplasty. Our projects meets significant medical needs and we have the opportunity to offer patients valuable supportive treatments at serious and common life-threatening diseases. This means that we also have the potential of offering our shareholders strong return on investment.

### *Considerable market potential within cancer and coronary infarction treatments*

The global market for supportive cancer treatment is more than SEK 35 billion and 3.3 million doses of the chemotherapeutic oxaliplatin, which is the foundation in colorectal cancer treatments, are given per year.

1.2 million coronary angioplasties are done each year in connection with acute myocardial infarction treatment.

### *Ongoing clinical programs*

We are currently developing two drug development projects in clinical phase II with the patent protected substance class PLED-derivatives. We are investigating the preventive effect of PLED-derivative (PledOx<sup>®</sup>) on chemotherapy-induced side effects in colorectal cancer treatment in one of the studies.

In the other early and small clinical study, we are examining a PLED-derivative's ability to limit reperfusion injuries in patients with acute myocardial infarction going through coronary angioplasty.

## **Our Vision**

To become the leading specialty pharma company, which develops medicines that protect healthy cells from oxidative stress during treatment of life threatening diseases.

## **Our business model**

We develop medicines in areas where there are huge medical needs. The projects are based upon patented and clinically available PLED-derivatives, and thereby combines huge medical need with strong likelihood of success. We are mid-term focusing on developing our projects to phase IIb, and then to out-license continued development and commercialization against milestone and royalty payments for the rights.

## **Business goal**

Out-licensing of a first clinical project is planned when the study results are available at the end of 2013.

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



## Financial summary

### Fourth quarter 2011

#### Income

Operating revenue amounted to SEK 0 k (1108k) and refers to, for the previous year, capitalized costs. The Board decided in December that the capitalized costs for patents and work on own development should be written down. The decision to discontinue capitalization of costs in this stage of development was 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 PledPharma continue to do after the projects have undergone Phase III trials and commercial launches. Other operating income for the period amounted to 9 (1) thousand and consisted of foreign exchange gains. Interest income for the period amounted to 664 thousand.

#### Costs

Operating expenses in the fourth quarter amounted to SEK 9.005 (2.718k). The cost increase came mainly from increased project and personnel costs and transaction costs.

#### Impairments

The result is also explained by other operating expenses of SEK 17.092 k which relates to the impairment of capitalized costs, as a result of changes in the policy for timing of activation of the IPR. During the period, impairment of 1.1k has been made on tangible assets.

#### Results

Operating profit for the fourth quarter, including impairment of capitalized costs amounted to SEK -26.090 (-1.609k). The change in operating income is mainly due to impairments of capitalized cost but also due to increased costs. Profit after financial

items amounted to SEK -25.426k (- 1.609). Profit after tax was SEK -25.426k (-1.609k).

### Full year 2011

#### Revenues

Operating revenue amounted to SEK 0 (0). Capitalized costs amounted to SEK 9.401 k (2.248k). Other operating income amounted to SEK 298k (1k) and consisted of foreign exchange gains.

#### Costs

Operating expenses in the full year amounted to SEK 26.828 k (6.049k). The cost increase came mainly from increased project and personnel costs due to increased project investment, new employment but also from the costs associated with listing on First North, and transaction costs.

#### Impairments

The impairment of capitalized costs, as a result of changes in the policy for timing of activation of the IPR, amounted to SEK 17.092k. Impairment of tangible assets amounted to SEK 3,9k.

#### Results

Operating profit for the full year, including impairment of capitalized costs, amounted to SEK -34.225k (- 3.801k). The change in operating income is mainly due to impairments of capitalized cost but also due to increased costs. Profit after financial items amounted to SEK - 33.246k (-3.801k). Profit after tax was SEK -33.246k (-3.801k).

### Investments, liquidity and financial position

A total of capitalized expenses from 2011 of SEK 9.401k and SEK 7.691 k from previous years have been written down.



Total investment in capitalized expenses amounted to SEK 0 k.

Cash and cash equivalents at December 31, 2011 amounted to SEK 90.548k (568k).

Shareholders' equity as of 2011-12-31 was SEK 87.532k (6.990k), and the company's equity ratio is 96 percent (85).

Shareholders' equity per share amounted to SEK 4.3 (23.2). In 2011, there were no long-term debts (0). Current liabilities at December 31, 2011 were SEK 3.893 k (1502k).

The cash flow during 2011 amounted to SEK 89.979k (188k). The positive cash flow due to emissions of shares by the company conducted in February and June 2011.

Cash flow from operating activities for 2011 amounted to SEK – 14.396k (-2.717k).

#### **Loans**

The loan of 4.2 million from the former parent company Accelerator Nordic AB refunded after the registration of the right share issue in July.

The following funds are at the disposal of the AGM:

Share premium reserve	119712056
Net income	-33246055
<b>Totall</b>	<b>86466001</b>

The Board proposes that the loss of SEK 33.246.055 is counted against the share premium reserve and that the remaining share premium reserve shall be carried forward

#### **Tax**

The Company's unutilized loss of business for tax purposes in 2011 amounted to 5.968.952 SEK

#### **Employees**

The number of employees at December 31 was 6 (2) persons.

#### **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**

The number of shares at December 31 2011 were 20 247 775. 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

SEK	2011	2010	2011	2010
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
Net sales	-	-	-	2 666
Work performed by the company for its own use and capitalized	-	426 883	1 661 387	1 064 148
Capitalized costs	-	681 575	7 740 070	1 180 775
Other operating income	9 115	714	297 624	714
	<b>9 115</b>	<b>1 109 172</b>	<b>9 699 081</b>	<b>2 248 303</b>
<b>Operating expenses</b>				
Project costs	-4 183 318	-681 581	-11 923 388	-1 183 440
Other external costs	-2 372 519	-1 014 654	-8 073 798	-2 956 882
Employee benefit expenses	-2 420 900	-1 020 190	-6 623 681	-1 904 596
Depreciation/amortization and impairment (as well as reversals) of property, plant and equipment and intangible assets	-17 093 563	-525	-17 096 410	-2 100
Other operating expenses	-28 486	-1 378	-206 848	-1 864
<b>Operating result (EBIT)</b>	<b>-26 089 671</b>	<b>-1 609 156</b>	<b>-34 225 044</b>	<b>-3 800 579</b>
Interest income	664 528	5	1 017 165	5
Interest expense and similar profit(loss) items	-554	-50	-38 176	-50
<b>Result after financial net</b>	<b>-25 425 697</b>	<b>-1 609 201</b>	<b>-33 246 055</b>	<b>-3 800 624</b>
<b>Result before taxes</b>	<b>-25 425 697</b>	<b>-1 609 201</b>	<b>-33 246 055</b>	<b>-3 800 624</b>
Tax on profit for the period	-	-	-	-
<b>Result after tax</b>	<b>-25 425 697</b>	<b>-1 609 201</b>	<b>-33 246 055</b>	<b>-3 800 624</b>
<b>Share Data</b>				
Number of shares at the end of period	20 247 775	301 316	20 247 775	301 316
Result after tax	-1,3	-5,3	-1,6	-12,6
Equity	4,3	23,2	4,3	23,2

## Balance sheet

SEK	2011-12-31	2010-12-31
<b>ASSETS</b>		
<i>Intangible assets</i>		
Capitalized expenditure for research and development and similar	0	3 567 068
Concessions, patents, licences, trademarks and similar rights	0	4 123 946
	0	7 691 014
<i>Property, plant and equipment</i>		
Equipment ,tools, fixtures and fittings	11 781	4 404
<b>Total fixed assets</b>	<b>11 781</b>	<b>7 695 418</b>
<i>Current assets</i>		
<i>Current receivables</i>		
Receivables from group companies	-	64 362
Other receivables	329 731	159 089
Prepaid expenses and accrued income	535 860	5 185
	865 591	228 636
Cash and bank balances	90 547 600	568 269
<b>Total current assets</b>	<b>91 413 191</b>	<b>796 905</b>
<b>Total assets</b>	<b>91 424 972</b>	<b>8 492 323</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
<i>Restricted equity</i>		
Share capital	1 065 672	301 316
<i>Non-restricted equity</i>		
Share premium reserve	119 712 056	10 489 147
Result for the period	-33 246 055	-3 800 624
	86 466 001	6 688 523
<b>Total equity</b>	<b>87 531 673</b>	<b>6 989 839</b>
Accounts payable	1 431 792	1 020 850
Current tax liabilities	132 049	42 870
Other liabilities	306 414	168 800
Accrued expenses and deferred income	2 023 044	269 964
<b>Total short term liabilities</b>	<b>3 893 299</b>	<b>1 502 484</b>
<b>Total equity and liabilities</b>	<b>91 424 972</b>	<b>8 492 323</b>

## Cash flow statement

SEK	2011	2010	2011	2010
	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
<b>Operating activities</b>				
Result after financial net	-25 425 698	-1 609 201	-33 246 055	-3 800 624
Adjustments	17 093 563	525	17 096 410	2 100
Tax paid	939	-1 098	-10 879	-4 774
<b>Cash flow from operating activities before changes in working capital</b>	<b>-8 331 196</b>	<b>-1 609 774</b>	<b>-16 160 524</b>	<b>-3 803 298</b>
Changes in short term liabilities	-437 330	-80 772	-636 955	-147 176
Changes in account payables	694 424	871 233	410 942	870 430
Changes in operating liabilities	962 432	206 811	1 990 755	362 845
<b>Cash flow from operating activities</b>	<b>-7 111 670</b>	<b>-612 502</b>	<b>-14 395 782</b>	<b>-2 717 199</b>
<b>Investing activities</b>				
Investment in intangible assets	0	-1 108 464	-9 401 457	-2 244 922
Purchase of property, plant and equipment	-	-	-11 316	-
<b>Cash flow from investing activities</b>	<b>0</b>	<b>-1 108 464</b>	<b>-9 412 773</b>	<b>-2 244 922</b>
<b>Financing activities</b>				
New share issue	0	0	115 814 481	5 149 950
Costs of new share issue	0	0	-2 026 595	-
<b>Cash flow from financing activities</b>			<b>113 787 886</b>	<b>5 149 950</b>
Cash flow for the period				
Balance at beginning of period	97 659 270	2 289 236	568 269	380 440
Exchange differences	-7 111 670	-1 720 966	89 979 331	187 829
Balance at end of the period	90 547 600	568 270	90 547 600	568 269

## Change in Equity

	Share capital	Share premium reserve	Net income	Total equity
<b>Opening balance 2011-01-01</b>	301 316	10 489 147	-3 800 624	6 989 841
Bonus issue	301 316	-301 316		
Registration new share issue 2011-02-14	93 626	6 928 325		
Registration new share issue 2011-07-06	369 414	108 423 117		
Issue expenses		-2 026 595		
Transfer of the 2010 year result		-3 800 622	3 800 624	
Net profit			-33 246 055	
<b>Closing balance 2011-09-30</b>	<b>1 065 672</b>	<b>119 712 056</b>	<b>-33 246 055</b>	<b>87 531 673</b>
<b>Opening balance 2010-01-01</b>	232 650	6 753 512	-1 345 648	5 640 514
New share issue	68 666	5 081 284		
Transfer of 2009 year result		-1 345 648	1 345 648	
Net profit			-3 800 624	
<b>Closing balance 2010-09-30</b>	<b>301 316</b>	<b>10 489 148</b>	<b>-3 800 624</b>	<b>6 989 840</b>

## Key ratios

SEK	2011 Oct-Dec	2010 Oct-Dec	2011 Jan-Dec	2010 Jan-Dec
Net sales	-	-	-	2 666
Operating result (EBIT)	-26 089 671	-1 609 156	-34 225 044	-3 800 579
Operating margin %	neg.	neg.	neg.	neg.
Result for the period	-25 425 697	-1 609 201	-33 246 055	-3 800 624
Total assets	91 424 972	8 492 323	91 424 972	8 492 323
Equity	87 531 673	6 989 839	87 531 673	6 989 839
Equity ratio %	1	1	1	1
Return on equity %	neg.	neg.	neg.	neg.
Number of shares at the end of the period	20 247 775	301 316	20 247 775	301 316
Average number of shares under the period	20 247 775	301 316	15 093 411	266 513
<b>Share Data</b>				
Result after tax	-1,3	-5,3	-1,6	-12,6
Result per average share	-1,3	-5,3	-2,2	-14,3
Cash flow from operating activities	-0,4	-2,0	-0,7	-9,0
Equity	4,3	23,2	4,3	23,2
Dividend	-	-	-	-
Number of employees	6	4	6	4

### Definitions

Operating margin

Operating result as a percentage of net income

Equity ratio

Equity as a percentage of total assets

Return on equity

Result for the year as a percentage of average equity



## 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 2010 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

Amounts are expressed in SEK (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

In this interim report includes statements that are forward looking. Actual results may differ from those indicated. Internal factors such as the successful management of research and intellectual property rights may affect future results. There are also external conditions such as economic environment, political changes and competing research programs, which may affect PledPharma results.

Stockholm February 17, 2012

Jacques Näsström  
CEO

### **Contacts for further information**

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### **Next report**

April 27, 2012, quarterly report for the period January-March 2012

### **Analysts who follow PledPharma**

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