

## PledPharma AB (publ) Interim report January – June 2012

### *PledOx™ clinical study design approved*

The period April – June

- **Net result amounted to SEK -10 548k (-2 488k)**
- **Cash flow from operating activities amounted to SEK -13 038k ( 1 837k)**
- **Result per share amounted to SEK -0.52 (-0.19)**

Significant events after the end of the period

- The design of the clinical study for PledOx was approved by the Swedish Medical Products Agency (MPA) August 1
- Professor Bengt Glimelius at Uppsala University Hospital, a world authority within research and treatment of cancer, especially cancer in the gastrointestinal canal, coordinating principal investigator of the PledOx study
- Positive results achieved 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

The first half Year in summary

- **Net result amounted to SEK -19 825k (-5 336k)**
- **Cash flow from operating activities amounted to SEK -21 889k (-1 625k)**
- **Cash and cash equivalents on June 30 was SEK 68 608k (106 165k)**
- **Result per share amounted to SEK -0.98 (-0.40)**
- 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 incidences due to chemotherapy in patients pretreated with PLED-substance, in a scientific journal

CEO comments

“We are very pleased to have delivered all necessary interim goals necessary to initiate our important clinical PledOx Phase IIb trial in colorectal cancer patients. The study design is now approved by the Swedish MPA and we expect to recruit the first patient in September/October 2012. This is a very important milestone in the development of the company”, says CEO Jacques Näsström.



## **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 occur in connection with chemotherapy treatment, and on 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 strong returns on investment.

## **Considerable market potential within cancer**

The global market for supportive cancer treatment is more than USD 10 billion and 3.3 million doses of the chemotherapeutic oxaliplatin, which is the foundation in colorectal cancer treatments, are given each year.

## **Ongoing clinical programs**

Our focus is on the Phase IIb study where PledOx™ ability to prevent chemotherapy-induced side effects for colorectal cancer is investigated. This clinical study design is approved by the Swedish MPA and the first patient is expected to be recruited in September/October 2012. The results are expected in the end of 2013.

In a small and early clinical study, we are examining a PLED-substance's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with coronary angioplasty. This study is slightly delayed due to unpredictable patient influx. We now expect to recruit the remaining patients during the remainder of the year and results are expected in the first half of 2013.

## **Our business model**

We are developing drugs in areas where there are high unmet 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**

To become 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 when study results are available during the end of 2013. In the clinical program where PledOx preventive effects on chemotherapy induced side-effects in colorectal cancer treatment patients is investigated, we now are in clinical phase IIb.

In the clinical program regarding PLED-derivative's (mangafodipir) ability to reduce reperfusion injuries in patients with acute coronary infarction treated with angioplasty, results are expected to be presented in the first half of 2013. The development risks involved in this study are considerably higher than in the cancer study since this is a first and limited patient study in this indication, which in addition is difficult to study.

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

## Financial summary

### Second quarter 2012

#### Income

Revenue during the quarter amounted to SEK 434k (2 531k) and consisted of co-funding of SEK 400k from VINNOVA and foreign exchange gains. For the previous year, revenue consisted of capitalized costs and other operating income. 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 365k (20k).

#### Costs

Operating expenses in the second quarter amounted to SEK 11 347k (5 040k). The cost increase came mainly from increased project and personnel costs.

#### Results

Operating result for the first quarter, amounted to SEK -10 913k (-2 508k). The change in operating income is due to increased costs and to the change in the policy for impairment of capitalized costs. Result after financial items amounted to SEK -10 548k (-2 488k). Result after tax was SEK -10 548k (-2 488k).

### First half 2012

#### Income

Revenue during the first six months amounted to SEK 523k (4 412k) and consisted of co-funding of SEK 400k from VINNOVA and foreign exchange gains. Regarding the previous year, see comment above regarding the second quarter. Interest income for the period amounted to SEK 522k (22k).

#### Costs

Operating expenses in the first half of 2012 amounted to SEK 20 871k (9 761k). The cost increase came mainly from increased project and personnel costs.

#### Results

Operating result for the first half of 2012 amounted to SEK -20 348k (-5 349k). 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 -19 825k (- 5 336k) and the result after tax was SEK -19 825k (- 5 336k).

#### Investments, liquidity and financial position

Cash and cash equivalents at June 30, 2012 amounted to SEK 68 608k (106 165k). Shareholders' equity amounted to SEK 67 706k (113 050k) and the company's equity ratio was 95 percent (96). Shareholders' equity per share amounted to SEK 3.34 (8.55). No long-term debts were outstanding (-). Current liabilities at June 30, 2012 amounted to SEK 3 924k (5 194k).

The cash flow during the first six months amounted to SEK -21 939k (105 597k). 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 21 889k (-1 625k).

### **Employees**

The average number of employees during the first six months was 6 (5) 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 318k. 131 000 call options were subscribed by

employees in the company as of June 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**

The number of shares at June 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

<b>KSEK</b>	<b>2012</b> <b>April-June</b>	<b>2011</b> <b>April-June</b>	<b>2012</b> <b>Jan-June</b>	<b>2011</b> <b>Jan-June</b>	<b>2011</b> <b>Jan-Dec</b>
<b>Revenue</b>					
Activated work for own account	-	583	-	935	1 661
Capitalized costs	-	1 796	-	3 227	7 740
Other operating income	434	152	523	250	298
	<b>434</b>	<b>2 531</b>	<b>523</b>	<b>4 412</b>	<b>9 699</b>
<b>Operating expenses</b>					
Project costs	-7 342	-1 796	-12 480	-3 227	-11 923
Employee benefit costs	-2 551	-1 415	-4 193	-2 445	-6 624
Other operating costs	-1 453	-1 827	-4 195	-4 087	-8 281
Depreciation and impairment, fixed assets	-1	-1	-2	-2	-17 096
<b>Operating result</b>	<b>-10 913</b>	<b>-2 508</b>	<b>-20 348</b>	<b>-5 349</b>	<b>-34 225</b>
Interest income	365	20	522	22	1 017
Interest expense and similar items	0	0	0	-8	-38
<b>Result after financial net</b>	<b>-10 548</b>	<b>-2 488</b>	<b>-19 825</b>	<b>-5 336</b>	<b>-33 246</b>
<b>Result before tax</b>	<b>-10 548</b>	<b>-2 488</b>	<b>-19 825</b>	<b>-5 336</b>	<b>-33 246</b>
Tax	-	-	-	-	-
<b>Result after tax</b>	<b>-10 548</b>	<b>-2 488</b>	<b>-19 825</b>	<b>-5 336</b>	<b>-33 246</b>
<b>Share Data</b>					
Number of shares at the end of period	20 247 775	13 228 902	20 247 775	13 228 902	20 247 775
Result after tax before and after dilution (SEK)	-0,52	-0,19	-0,98	-0,40	-1,64
Equity per share (SEK)	3,34	8,55	3,34	8,55	4,32
Equity per share after dilution (SEK)	3,28	8,55	3,28	8,55	4,32

## Balance sheet

KSEK	<u>2012-06-30</u>	<u>2011-06-30</u>	<u>2011-03-31</u>
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Intangible assets</i>			
Capitalized expenditure for research and development	-	7 669	-
Concessions, patents, licences, trademarks	-	4 185	-
	-	11 853	-
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	10	14	12
<i>Financial assets</i>			
Shares and participations in group companies	50	-	-
<b>Total fixed assets</b>	<b>60</b>	<b>11 867</b>	<b>12</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Other receivables	1 538	-	330
Prepaid expenses and accrued income	1 425	211	536
	2 962	211	866
<i>Cash and bank balances</i>			
	68 608	106 165	90 548
<b>Total current assets</b>	<b>71 571</b>	<b>106 376</b>	<b>91 413</b>
<b>Total assets</b>	<b>71 630</b>	<b>118 243</b>	<b>91 425</b>
KSEK	<u>2012-06-30</u>	<u>2011-06-30</u>	<u>2011-12-31</u>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	1 066	696	1 066
<i>Non-restricted equity</i>			
Share premium reserve	86 466	11 689	119 712
Unregistered share capital	-	106 000	-
Result for the period	-19 825	-5 336	-33 246
	66 641	112 353	86 466
<b>Total equity</b>	<b>67 706</b>	<b>113 050</b>	<b>87 532</b>
<b>Liabilities</b>			
Accounts payable	2 003	730	1 432
Current tax liabilities	179	94	132
Other liabilities	457	3 852	306
Accrued expenses and deferred income	1 285	518	2 023
<b>Total short term liabilities</b>	<b>3 924</b>	<b>5 194</b>	<b>3 893</b>
<b>Total equity and liabilities</b>	<b>71 630</b>	<b>118 243</b>	<b>91 425</b>

## Cash flow statement

KSEK	2012	2011	2012	2011	2011
	April-June	April-June	Jan-June	Jan-June	Jan-Dec
<b>Operating activities</b>					
Result after financial net	-10 548	-2 488	-19 825	-5 336	-33 246
Adjustments for non-cash items	1	1	2	2	17 096
Tax paid	-13	-4	-23	-8	-11
<b>Cash flow from operating activities before changes in working capital</b>	<b>-10 560</b>	<b>-2 491</b>	<b>-19 846</b>	<b>-5 341</b>	<b>-16 161</b>
Changes in short term liabilities	-2 306	-452	-2 097	-473	-637
Changes in account payables	273	353	571	-291	411
Changes in operating liabilities	-444	4 427	-517	4 480	1 991
<b>Cash flow from operating activities</b>	<b>-13 038</b>	<b>1 837</b>	<b>-21 889</b>	<b>-1 625</b>	<b>-14 396</b>
<b>Investing activities</b>					
Investment in intangible assets	-	-2 379	-	-4 162	-9 401
Investment in financial assets	-	-	-50	-11	-
Purchase of property, plant and equipment	-	-	-	-	-11
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-2 379</b>	<b>-50</b>	<b>-4 174</b>	<b>-9 413</b>
<b>Financing activities</b>					
New share issue	-	106 000	-	113 022	115 814
Share issue costs	-	-1 627	-	-1 627	-2 027
<b>Cash flow from financing activities</b>	<b>-</b>	<b>104 373</b>	<b>-</b>	<b>111 395</b>	<b>113 788</b>
Cash flow for the period					
Balance at beginning of period	81 646	2 334	90 548	568	568
Change in cash	-13 038	103 830	-21 939	105 597	89 979
Cash balance at end of the period	68 608	106 165	68 608	106 165	90 548

## Change in Equity

SEK	Share capital	Share capital under registration	Share premium reserve	Net income	Total equity
<b>Opening balance 2011-01-01</b>	<b>301</b>		<b>10 489</b>	<b>-3 801</b>	<b>6 990</b>
Bonus issue	301		-301		
Registration share issue 2011-02-1	94		6 928		
New share issue		106 000			
Issue expenses			-1 627		
Transfer of the 2010 year result			-3 801	3 801	
Net result for the period				-5 336	
<b>Closing balance 2011-06-30</b>	<b>696</b>	<b>106 000</b>	<b>11 689</b>	<b>-5 336</b>	<b>113 050</b>

<b>Opening balance 2012-01-01</b>	<b>1 066</b>		<b>119 712</b>	<b>-33 246</b>	<b>87 532</b>
Transfer of 2011 year result			-33 246	33 246	
Net result for the period				-19 825	
<b>Closing balance 2012-06-30</b>	<b>1 066</b>		<b>86 466</b>	<b>-19 825</b>	<b>67 706</b>

## Key ratios

KSEK	2012 April-June	2011 April-June	2012 Jan-June	2011 Jan-June	2011 Jan-Dec
Operating result (EBIT)	-10 913	-2 508	-20 348	-5 349	-34 225
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-10 548	-2 488	-19 825	-5 336	-33 246
Cash flow from operating activities	-13 038	1 837	-21 889	-1 625	-14 396
Total assets	71 630	118 243	71 630	118 243	91 425
Equity	67 706	113 050	67 706	113 050	87 532
Equity ratio %	95%	96%	95%	96%	96%
Return on equity %	neg.	neg.	neg.	neg.	neg.
Number of shares at the end of the period	20 247 775	13 228 902	20 247 775	13 228 902	20 247 775
Number of shares at the end of the period after dilution	20 647 775	13 228 902	20 647 775	13 228 902	20 247 775
Average number of shares under the period	20 247 775	13 228 902	20 247 775	6 908 749	15 093 411
Average number of shares under the period after dilution	20 647 775	13 228 902	20 447 775	13 228 902	20 247 775
<b>Share Data</b>					
Result after tax	-0,52	-0,19	-0,98	-0,40	-1,64
Result per average share	-0,52	-0,19	-0,98	-0,77	-2,20
Cash flow from operating activities	-0,64	0,14	-1,08	-0,24	-0,95
Equity per share	3,34	8,55	3,34	8,55	4,32
Equity per share after dilution	3,28	8,55	3,28	8,55	4,32
Dividend	-	-	-	-	-
Number of employees	6	5	6	5	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.

Stockholm August 24, 2012

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## Next report

The interim report for the period January-September 2012 will be published on October 26, 2012

## Analysts who follow PledPharma

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