PledPharma

PledPharma AB (publ)
Interim Report Second Quarter 2013

Significant events after the end of the period

- Four out of the six patients who are needed to start the second part of the Phase IIb study PLIANT have been treated and the results are in line with our expectations
- Patent for the use of PLED compounds in the treatment of cancer approved in China

Significant events during April - June

- Rights issue provided the company with 18.6 million SEK.
- IMS Consulting Group appointed advisor for the commercialization of PledOx®
- Sten Nilsson, MD, PhD Professor of Oncology at Karolinska University Hospital and Institutet in Stockholm elected as member of the board.
- All patients included in the small clinical phase IIa study MANAMI, examining a PLED-compound's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with percutaneous coronary intervention (PCI).
- PledOx® registered trademark in the US, Switzerland and Australia
- Net result amounted to SEK -6 048k (-10 548k)
- Cash and cash equivalents on June 30 amounted to SEK 59 116k (68 608k)
- Cash flow from operating activities amounted to SEK -7 708k (-13 038k)
- Result per share amounted to SEK -0.3 (-0.5)

Significant events during January – June

- Patent application for the use of PLED compounds in the treatment of cancer approved and issued in the US and Russia
- FDA approved IND application for the clinical trial PLIANT in the US
- The first patients treated in the PLIANT study
- Net result amounted to SEK -14 079k (-19 825k)
- Cash flow from operating activities amounted to SEK -18 252k (-21 889k)
- Result per share amounted to SEK -0.6 (-1.0)

CEO comments

" The rights issue in PledPharma completed in May was oversubscribed. The purpose of the rights issue was to expand the PLIANT study with more study centres worldwide to secure implementation, and to achieve greater flexibility to close the best possible licensing deal for PledPharma's drug candidate PledOx®.

Four out of six patients in the dose escalation phase are now treated with PledOx. In total, the patients have been treated with more than 20 doses of PledOx in conjunction with chemotherapy and all patients have tolerated PledOx well. With reservation to the small number of patients treated, the results are in line with our expectations, which we consider to be positive.

When all six patients are treated with PledOx we look forward to an approval from DSBM (Drug Safety Monitoring Board) to begin the inclusion of patients for the subsequent randomized part of the study. In the US, where PledOx is evaluated with FOLFOX in combination with the antibody Avastin, the three remaining patients for the US part of the study will be recruited in parallel with the last patients for the rest of the world. We expect to start the second part of the study during 2013 and the recruitment of the 126 patients included in the study can be done in parallel at the approximately 30 centres. Our ambition remains that we can attain "top line" results from the study in mid-2014.

Parallel to the PLIANT study we have made progress in preclinical development on a new life-threatening indication for PLED-derivatives where we believe that there are both medical need and a large commercial potential, "said CEO Jacques Näsström.

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 into 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 6 patients (3 on low dose and 3 on high dose) In the US, where PledOx is evaluated with FOLFOX in combination with the antibody Avastin, another 3 patients need to be included before the randomized part can start there.

In the next phase, the randomized part, aiming at 126 patients from approximately 30 centres 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

PledPharma 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

PledPharma 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 a successful out-licensing of PledOx®.

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 that 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 that 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.

OXIDATIVE 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.

IP

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 (and just recently for Russia and China) regarding the use of PLED compounds in the treatment of cancer with a patent protection until 2028.

OTHER

In the on going small clinical Phase IIa study MANAMI, examining a 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 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

Second quarter 2013

Income
Revenue during the quarter amounted to SEK 30k (434k) and consisted of foreign exchange gains. Interest income for the quarter amounted to SEK 0k (365k).

Costs
Operating expenses in the second quarter amounted to SEK 6 067k (11 347k). Of this, project costs amounted to 1 917k (7 342k) and employee costs to 1 600k (2 551k). Depreciation amounted to 1k (1k).

Results and financial position
Operating result for the quarter, amounted to SEK -6 037k (-10 913k). Result after financial items amounted to SEK -6 048k (-10 548) and the result after tax was SEK -6 048k (-10 548k).
The cash flow during the quarter amounted to SEK 10 853k (-13 038k). This positive cash flow comes from the rights issue completed in June.
Cash flow from operating activities amounted to SEK -7 708k (-13 038k).
Cash at the end of the period amounted to 59 116k (68 608k).
Shareholders' equity amounted to SEK 58 422k (67 706k) and the company's equity ratio was 95 percent (95). Shareholders' equity per share amounted to SEK 2.7 (3.3). No long-term debts were outstanding (-). Current liabilities at March 31, 2013 amounted to SEK 2 903k (3 924k).

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 June 30, 2013.

Significant risks and uncertainties
Risks are described in the prospectus issued in connection with a right share issue that 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 June 30, 2013 were 21 935 089. After full dilution, the number of shares were 22 335 089. PledPharma shares were listed on NASDAQ OMX First North on 7 April 2011.

Rights issue
In May, a rights issue was carried out and 18, 6 MSEK were raised. The number of shares increased by 1 687 314 to 21 935 089 shares. The share capital increased by 88 806 SEK to 1 154 478 SEK.

Seasonal variations
PledPharma activity is not subject to seasonal variations.

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Income statement

SEKk	2013 April-June	2012 April-June	2013 Jan-June	2012 Jan-June	2012 Jan-Dec
Revenue					
Activated work for own account	-	-	-	-	-
Capitalized costs	-	-	-	-	-
Other operating income	30	434	119	523	672
	30	**434**	**119**	**523**	**672**
Operating expenses					
Project costs	(1 917)	(7 342)	(6 114)	(12 480)	(18 601)
Employee benefit costs	(1 600)	(2 551)	(3 151)	(4 193)	(8 127)
Other operating costs	(2 549)	(1 453)	(5 054)	(4 195)	(9 249)
Depreciation and impairment, fixed assets	(1)	(1)	(1)	(2)	(4)
Operating result	**-6 037**	**-10 913**	**-14 202**	**-20 348**	**-35 310**
Net financial items					
Interest income	0	365	138	522	1 454
Interest expense and similar items	(11)	(0)	(16)	0	(1)
Result after financial net	**(6 048)**	**(10 548)**	**(14 079)**	**(19 825)**	**(33 857)**
Result before tax	**(6 048)**	**(10 548)**	**(14 079)**	**(19 825)**	**(33 857)**
Tax	-	-	-	-	-
Result after tax	**(6 048)**	**(10 548)**	**(14 079)**	**(19 825)**	**(33 857)**
Share Data					
Number of shares at the end of period	21 935 089	20 247 775	21 935 089	20 247 775	20 247 775
Result per share before and after dilution (SEK)	-0,3	-0,5	-0,6	-1,0	-1,7
Equity per share (SEK)	2,7	3,3	2,7	3,3	2,7
Equity per share after dilution (SEK)	2,6	3,3	2,6	3,3	2,6

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Balance sheet

SEKk	2013-06-30	2012-06-30	2012-12-31
ASSETS			
Fixed assets			
Intangible assets			
Capitalized expenditure for research and development	-	-	-
Concessions, patents, licences, trademarks	-	-	-
	-	-	-
Property, plant and equipment			
Equipment, tools, fixtures and fittings	6	10	7
Financial assets			
Shares and participations in group companies	50	50	50
Total fixed assets	**56**	**60**	**57**
Current assets			
Current receivables			
Receivables group companies	0	-	266
Other receivables	763	1 538	629
Prepaid expenses and accrued income	1 389	1 425	697
	2 152	2 962	1 592
Cash and bank balances	59 116	68 608	58 808
Total current assets	**61 269**	**71 571**	**60 399**
Total assets	**61 325**	**71 630**	**60 457**

SEKk	2013-06-30	2012-06-30	2012-12-31
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1 154	1 066	1 066
Non-restricted equity			
Received group contributions	-	-	266
Share premium reserve	71 347	86 466	86 466
Result for the period	(14 079)	(19 825)	(33 857)
	57 268	66 641	52 876
Total equity	**58 422**	**67 706**	**53 941**
Accounts payable	809	2 003	2 331
Current tax liabilities	153	179	-
Other liabilities	192	457	403
Accrued expenses and deferred income	1 749	1 285	3 782
Total short term liabilities	**2 903**	**3 924**	**6 516**
Total equity and liabilities	**61 325**	**71 630**	**60 457**

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Cash flow statement

Cash flow statement

SEKk	2013 April-June	2012 April-June	2013 Jan-June	2012 Jan-June	2012 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-6 048	-10 548	-14 079	-19 825	-33 857
Adjustments for non-cash items	1	1	1	2	4
Tax paid	41	-13	72	-23	-32
Cash flow from operating activities before changes in working capital	-6 007	-10 560	-14 006	-19 846	-33 885
Changes in short term liabilities	-105	-2 306	-753	-2 097	-678
Changes in account payables	-175	273	-1 522	571	899
Changes in operating liabilities	-1 421	-444	-1 971	-517	1 708
Cash flow from operating activities	-7 708	-13 038	-18 252	-21 889	-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	**0**	**0**	**0**	**-50**	**216**
FINANCING ACTIVITIES					
New share issue	18 560	-	18 560	-	-
Share issue costs	-	-	-	-	-
Cash flow from financing activities	**18 560**	**0**	**18 560**	**0**	**0**
Cash flow for the period					
Balance at beginning of period	48 264	81 646	58 808	90 548	90 548
Change in cash	10 853	-13 038	308	-21 939	-31 740
CASH BALANCE AT THE END OF THE PERIOD	59 116	68 608	59 116	68 608	58 808

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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	-	-	-	-19 825	-19 825
Closing balance 2012-06-30	**1 066**	-	**86 466**	**-19 825**	**67 706**

Opening balance 2013-01-01	**1 066**	**266**	**86 466**	**-33 857**	**53 941**
Transfer of 2012 year result		-266	-33 590	33 857	
Share issue	89		18 472		
Net result for the period				-14 079	-14 079
Closing balance 2013-06-30	**1 154**	-	**71 347**	**-14 079**	**58 422**

Key ratios

KSEK	2013 April-June	2012 April-June	2013 Jan-June	2012 Jan-June	2012 Jan-Dec
Operating result (EBIT)	-6 037	-10 913	-14 202	-20 348	-35 310
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-6 048	-10 548	-14 079	-19 825	-33 857
Cash flow from operating activities	-7 708	-13 038	-18 252	-21 889	-31 956
Total assets	61 325	71 630	61 325	71 630	60 457
Equity	58 422	67 706	58 422	67 706	53 941
Equity ratio %	1	1	1	1	1
Return on equity %	neg.	neg.	neg.	neg.	neg.
Number of shares at the end of the period	21 935 089	20 247 775	21 935 089	20 247 775	20 247 775
Number of shares at the end of the period after dilution	22 335 089	20 247 775	22 335 089	20 247 775	20 647 775
Average number of shares under the period	20 637 155	20 247 775	20 566 997	20 247 775	20 247 775
Average number of shares under the period after dilution	21 037 155	20 247 775	20 966 997	20 547 775	20 547 775
Share Data					
Result per share	-0,3	-0,5	-0,6	-1,0	-1,7
Result per average share	-0,3	-0,5	-0,7	-1,0	-1,7
Cash flow from operating activities	-0,4	-0,6	-0,8	-1,1	-1,6
Equity per share	2,7	3,3	2,7	3,3	2,7
Equity per share after dilution	2,6	3,3	2,6	3,3	2,6
Dividend	-	-	-	-	-
Number of employees	6	6	6	6	6

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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.

The company's auditors have not reviewed this report.

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 that took place in June 2011 as well as in the Annual Report for 2012.

Stockholm August 29, 2013

Jacques Näsström
CEO

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Next reports
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 through Erik Penser Access.
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