



PledPharma AB (publ)

Interim report second quarter 2015

August 18, 2015

FDA meeting planned for the fall

Significant events during the quarter

- Net result for the period amounted to SEK -11 433 (-12 674) k
- Cash and cash equivalents at the end of the period amounted to SEK 69 586 (47 799) k
- Cash flow from operating activities for the period amounted to SEK -17 694 (-13 770) k
- Result per share for the period amounted to SEK -0.4 (-0.5)
- The Annual General Meeting held on April 14, 2015 re-elected Håkan Åström, Andreas Bunge, Martin Nicklasson, Sten Nilsson and Eva Redhe Ridderstad as members of the Board
- Aladote™ approved as a trademark in the EU
- Further clinically relevant and statistically significant results from the Phase IIb study with PledOx® presented at the scientific congress MASCC.

Other significant events during 2015

- Top-line results from phase IIb study presented in March - PledOx® reduces nerve damage in conjunction with chemotherapy by 43 percent



CEO comment

We are now approaching the next milestone on PledOx[®] way towards market registration. A meeting with the FDA is planned to take place during the fall. Along with US and Swedish registration experts, we are now working intensively with preparations for this important meeting. We have completed an interim report for the PLIANT-study and have developed a preliminary plan for the future development. FDA's comments and guidance at the forthcoming so-called End of Phase II/Pre Phase III-meeting will be important for the final design of the Phase III program. This is in turn an important basis of the negotiations with potential partners.

Interest for a drug that can help prevent the potentially debilitating neuropathic side effects of chemotherapy is great. It was obvious when we in June presented our clinical data at the scientific congress MASCC (Multinational Association of Supportive Care in Cancer) in Copenhagen. PledOx[®] has demonstrated a clinically relevant and statistically significant preventive effect against chemotherapy caused nerve damage in the treatment of colorectal cancer. Symptoms occur later and disappear faster after pretreatment with PledOx[®]. The hope now is to, as quickly as possible, make it available for patients worldwide to avoid the appearance of injuries that often can be irreversible and cause problems with pain and fine motor skills throughout life. At the same time an efficient prophylaxis against nerve damage could mean that cancer patients are less likely to have to cancel or reduce the dose - and thus the effect- of their chemotherapy.

We are engaged in a well-structured process for finding the ideal partner for the continued development and launch of PledOx[®]. During the year, we have deepened our analyzes of the market and its players, strengthened our team by additional internationally experienced business developers and continued the updating of a group of interested pharmaceutical companies on our progress. However, we have deliberately chosen to forego detailed discussions pending the outcome of the PLIANT study and the upcoming meeting with the FDA. The more well-founded information we have about the effect of PledOx[®] and the design of the Phase III program when we intensify the business discussions, the stronger our bargaining position will be.

Furthermore, we continue preparations to start the Aladote study during in 2016.

Jacques Näsström
CEO, PledPharma AB (publ)



PledPharma

PledPharma in brief

PledPharma develops new drugs that protect the body against oxidative stress – a condition that can be caused by chemotherapy treatment and acetaminophen (paracetamol) poisoning. The company's most advanced project PledOx[®] reduces nerve damage associated with chemotherapy. The drug candidate Aladote[™] is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. The project PP-099 seeks to limit the damage that occurs to the heart muscle during myocardial infarction. PledPharma's most advanced project with PledOx[®] has completed Phase II trial. Pledpharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bankaktiebolag is the company's Certified Adviser (tel +46 8 463 80 00). For more information, see www.pledpharma.se

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Vision

PledPharma will be a leading pharmaceutical company, which develops unique therapies with breakthrough therapy potential for life-threatening diseases.

Business idea, goals and strategy

PledPharma develops therapeutics to improve the treatment of life-threatening diseases based on the company's patented and clinically proven technology, PLED.

The primary goal is a successful transaction of the PledOx project with attractive commercial revenues and to develop Aladote[™] to commercialization together with a partner.

PledPharma conducts a partner-based development model focusing on taking project through phase IIb, whereafter the costly Phase III clinical trials and global marketing are sold, whereby the financial exposure is reduced. The typical compensation is anticipated to be received in the form of signing fees, milestone payments and royalties.

Patents and trademarks

PledPharma has four in-licensed patents covering therapeutic use of PLED therapeutics. In addition, PledPharma has four applications for a large number of countries aiming to get an exclusive market protection and broad commercial rights for the manufacture and use of PLED therapeutics. The first is so far approved in the US, China, Hong Kong, Russia, Australia and Japan with patent protection until 2028. The second was approved in 2013 in South Africa as the first country with patent protection until 2030.

PledPharma has trademark protection for PledOx[®] in the key markets and has recently been granted trademark protection for Aladote[™] in the EU.

Our projects

PledPharma develops therapeutics based on PLED therapeutics and currently has three projects in or about to enter the clinical phase.

PledOx[®] (colorectal cancer)

PledOx[®] (calmangafodipir) is tested in an international phase IIb study in patients with colorectal cancer treated with the chemotherapy combination FOLFOX. The study goes according to plan and the first top-line results were presented at the end of the first quarter of 2015.

Aladote[™] (hepatic/ALF)

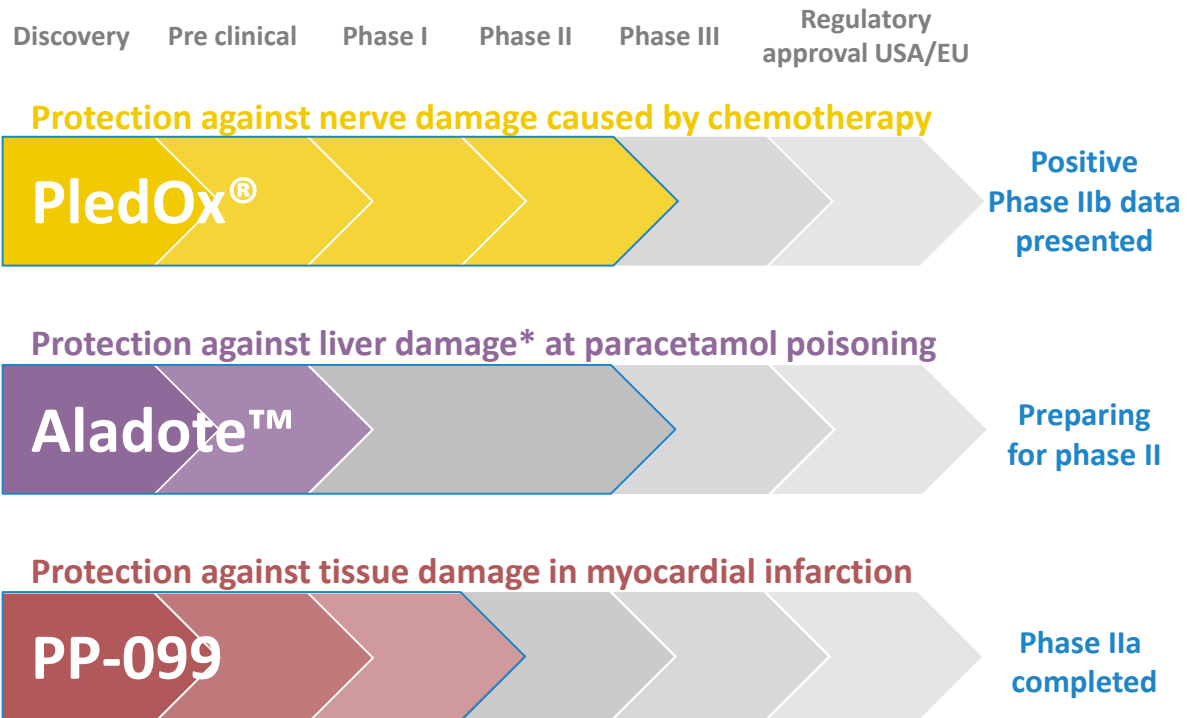


Aladote™ is a new formulation based on calmagafodipir evaluated and tested pre-clinically with promising results. A clinical trial for the prevention of acute liver failure (ALF) in patients with acetaminophen induced poisoning is under preparation.

Project PP-099 (myocardial infarction)

The PLED substance mangafodipir has been tested in a smaller national phase IIa study in heart attack patients undergoing angioplasty. The study indicated that PLED therapeutics can reduce reperfusion damage after acute myocardial infarction. No additional studies will be carried out without a partner.

Status in PledPharma's ongoing projects



* Acute liver failure means that the liver suddenly becomes so badly damaged that it can not function as it should. This is a very serious condition with a risk of death if treatment is not given

Financial summary Second quarter 2015

Revenue

Revenue amounted to SEK 205 (44) k during the quarter and to 254 (134) k for the six month period and consisted of rental revenues and foreign exchange gains. Interest income amounted to SEK 60 (85) k for the period and to 130 (179) for the six month period.

Expenses

Operating expenses amounted to SEK 11 698 (12 740) k for the quarter and to 23 968 (19 676) k for the six month period.

Of these, planned project costs, mainly related to the ongoing clinical study in PP95 project, amounted to SEK 7 043 (7 339) k for the period and to 14 549 (9 083) k for the six month period.

Employee costs amounted to SEK 1 186 (1 455) k for the quarter and to SEK 3 872 (2 702) k for the six month period.

Other operating costs amounted to SEK 3 468 (3 945) k for the quarter and to SEK 5 546 (7 890) k for the six month period.

Depreciation amounted to SEK 1 (1) k for the quarter and to 1 (1) k for the six month period.

Results and financial position

Operating result amounted to SEK -11 493 (-12 696) k for the quarter and to SEK -23 714 (-19 542) k for the six month period.

Result after financial items amounted to SEK -11 433 (-12 674) k for the quarter and to SEK -23 594 (-19 449) k for the six month period. No income tax was recorded for the quarter (-) or for the six month period (-).

Cash flow from operating activities amounted to SEK -17 694 (-13 770) k for the quarter and to SEK -31 666 (-21 684) k for the six month period.

Cash flow, affected by a share issue in the comparative period, amounted to SEK -16 484 (6 411) k for the quarter and to SEK -30 456 (-1 503) k for the six month period.

Cash at 30 June 2015 amounted to SEK 69 586 (47 799) k and shareholders' equity amounted to SEK 68 274 (47 685) k. The company's equity ratio was 92 (93) %. No long-term debts were outstanding (-), current liabilities at the end of the period amounted to SEK 5 615 (3 368) k and shareholders' equity per share amounted to SEK 2.4 (2.0).

Employees

Average number of employees during the quarter was four (four) persons.

Options Program

In April 42,000 new shares were subscribed for, based on the in 2012 decided options scheme, while the remaining warrants expired unexercised.

Significant risks and uncertainties

Risks are described in the Annual Report for 2014. No changes in the company's risk assessment have taken place during the period.

Share

The number of shares at June 30, 2015, after the subscription of shares in the Options Program, as described above, were 28 388 883. PledPharma's shares were listed on NASDAQ Stockholm First North on 7 April 2011.

Seasonal variations

PledPharma's activity is not subject to seasonal variations.



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Income statement

SEKk	2015 Apr-June	2014 Apr-June	2015 Jan-June	2014 Jan-June	2014 Jan-Dec
Revenue					
Other operating income	205	44	254	134	233
	205	44	254	134	233
Operating expenses					
Project costs	-7 043	-7 339	-14 549	-9 083	-29 459
Employee benefit costs	-1 186	-1 455	-3 872	-2 702	-6 271
Other operating costs	-3 468	-3 945	-5 546	-7 890	-13 067
Depreciation and impairment, fixed assets	-1	-1	-1	-1	-2
Operating result	-11 493	-12 696	-23 714	-19 542	-48 566
Net financial items					
Depreciation of investment in subsidiaries	-	-	-	-	-19
Interest income	60	85	130	179	312
Interest expense and similar items	-	-63	-10	-85	-147
Result after financial net	-11 433	-12 674	-23 594	-19 449	-48 420
Result before tax	-11 433	-12 674	-23 594	-19 449	-48 420
Tax	-	-	-	-	-
Result after tax	-11 433	-12 674	-23 594	-19 449	-48 420
Share Data					
Number of shares at the end of period	28 388 883	23 622 403	28 388 883	23 622 403	28 346 883
Average number of shares during period	28 381 883	22 602 598	28 385 383	22 276 344	22 649 770
Result per share before and after dilution (SEK)	-0,4	-0,5	-0,8	-0,8	-1,7
Result per average share (SEK)	-0,4	-0,6	-0,8	-0,9	-2,1
Equity per share (SEK)	2,4	2,0	2,4	2,0	3,2
Equity per share after dilution (SEK)	2,4	2,0	2,4	2,0	3,2



PledPharma

Balance sheet

SEKk	2015-06-30	2014-06-30	2014-12-31
ASSETS			
Fixed assets			
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	2	4	3
<i>Financial assets</i>			
Shares and participations in group companies	50	50	50
Total fixed assets	52	54	53
Current assets			
<i>Current receivables</i>			
Receivables group companies	-	234	216
Other receivables	1 005	1 079	2 727
Prepaid expenses and accrued income	3 246	1 886	430
	4 251	3 200	3 373
<i>Cash and bank balances</i>			
	69 586	47 799	100 043
Total current assets	73 837	50 998	103 415
Total assets	73 889	51 052	103 468

SEKk	2015-06-30	2014-06-30	2014-12-31
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	1 494	1 243	1 492
<i>Non-restricted equity</i>			
Share premium reserve	90 374	65 890	137 586
Result for the period	-23 594	-19 449	-48 420
	66 780	46 441	89 166
Total equity	68 274	47 685	90 658
Liabilities			
Accounts payable	2 507	1 521	9 967
Current tax liabilities	-	32	-
Other liabilities	214	167	292
Accrued expenses and deferred income	2 895	1 647	2 551
Total short term liabilities	5 615	3 368	12 810
Total equity and liabilities	73 889	51 052	103 468

Cash flow statement

SEKk	2015 Apr-June	2014 Apr-June	2015 Jan-June	2014 Jan-June	2014 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-11 443	-12 674	-23 594	-19 449	-48 420
Adjustments for non-cash items	1	1	1	1	21
Tax paid	-	30	-	89	-
Cash flow from operating activities before changes in working capital	-11 443	-12 643	-23 593	-19 358	-48 399
Changes in short term liabilities	-1 921	-2 031	-878	-1 696	-1 888
Changes in account payables	-2 595	1 332	-7 461	244	8 690
Changes in operating liabilities	-1 734	-428	265	-873	213
Cash flow from operating activities	-17 694	-13 770	-31 666	-21 684	-41 385
INVESTING ACTIVITIES					
Cash flow from investing activities	-	-	-	-	-
FINANCING ACTIVITIES					
New share issue	1 210	20 248	1 210	20 248	95 839
Cost new share issue	-	-67	-	-67	-3 714
Cash flow from financing activities	1 210	20 180	1 210	20 180	92 125
Cash flow for the period					
Balance at beginning of period	86 070	41 388	100 043	49 302	49 302
Change in cash	-16 484	6 411	-30 456	-1 503	50 740
CASH BALANCE AT THE END OF THE PERIOD	69 586	47 799	69 586	47 799	100 043



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Change in Equity

SEKk	Share capital	Share premium reserve	Net income	Total equity
Opening balance 2014-01-01	1 154	71 347	-25 549	46 953
Loss allocation according AGM resolution	-	-25 549	25 549	-
New share issue	89	20 092	-	20 180
Net result for the period	-	-	-19 449	-19 449
Closing balance 2014-06-30	1 243	65 890	-19 449	47 685
Opening balance 2015-01-01	1 492	137 586	-48 420	90 658
Loss allocation according AGM resolution	-	-48 420	48 420	-
New share issue warrants	2	1 208	-	1 210
Net result for the period	-	-	-23 594	-23 594
Closing balance 2015-06-30	1 494	90 374	-23 594	68 274

Key ratios

KSEK	2015	2014	2015	2014	2014
	Apr-June	Apr-June	Jan-June	Jan-June	Jan-Dec
Operating result (EBIT)	-11 493	-12 696	-23 714	-19 542	-48 566
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-11 433	-12 674	-23 594	-19 449	-48 420
Cash flow from operating activities	-17 694	-13 770	-31 666	-21 684	-41 385
Total assets	73 889	51 052	73 889	51 052	103 468
Equity	68 274	47 685	68 274	47 685	90 658
Equity ratio %	92%	93%	92%	93%	88%
Return on equity %	neg.	neg.	neg.	neg.	neg.
Number of shares at the end of the period	28 388 883	23 622 403	28 388 883	23 622 403	28 346 883
Number of shares at the end of the period after	28 388 883	24 022 403	28 388 883	24 022 403	28 746 883
Average number of shares under the period	28 381 883	22 602 598	28 385 383	22 276 344	22 649 770
Average number of shares under the period afi	28 381 883	23 002 598	28 385 383	22 676 344	23 049 770
Share Data					
Result per share	-0,4	-0,5	-0,8	-0,8	-1,7
Result per average share	-0,4	-0,6	-0,8	-0,9	-2,1
Cash flow from operating activities	-0,6	-0,6	-1,1	-0,9	-1,5
Equity per share	2,4	2,0	2,4	2,0	3,2
Equity per share after dilution	2,4	2,0	2,4	2,0	3,2
Dividend	-	-	-	-	-
Number of employees	4	4	4	4	4

Accounting principles

This report is prepared in accordance with the Annual Accounts Act and the Accounting Standards Board. In preparation of the interim reports the BFNAR 2007: 1 is used and additionally guidance from the Swedish Financial Accounting Standards Council's recommendation RR 20 for Interim Reports. The company's Annual Report for 2014 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 prepared. Amounts are expressed in KSEK (thousands Swedish kronor). Figures in parentheses refer to the corresponding period last year.

This report has not been subject to review 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.

Other

The Annual General Meeting was held on April 14, 2015 where the General Meeting resolved in accordance with the submitted proposals. Håkan Åström, Andreas Bunge, Martin Nicklasson, Sten Nilsson and Eva Redhe Ridderstad were re-elected as members of the Board.

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 Annual Report for 2014.

Stockholm August 18, 2015

Jacques Näsström
CEO

Next reports

The interim report for the period January-September 2015 will be published on October 20, 2015.

Certified Advisor

The company's Certified Advisor is Erik Penser Bankaktiebolag (tel +46 8 463 80 00).

Analysts who follow PledPharma

Erik Penser Bankaktiebolag, through Erik Penser Access
Pareto, Yilmaz Mahshid
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