



PledPharma AB (publ)

Interim report third quarter 2015

October 20, 2015

LICENSING PREPARATIONS CONTINUE ON SCHEDULE, BACKED BY STRONG PATENT PROTECTION

Significant events during the quarter

- Net result for the quarter amounted to SEK -11 431 (-11 265) k and to -35 025 (-30 714) k for the nine-month period
- Cash and cash equivalents at the end of the period amounted to SEK 59 313 (40 675) k
- Cash flow from operating activities for the quarter amounted to SEK -10 273 (-7 124) k and to -41 939 (-28 808) k for the nine-month period
- Result per share for the quarter amounted to SEK -0.4 (-0.5) and to -1.2 (-1.4) for the nine-month period
- PledPharma's key patent application for the active pharmaceutical ingredient of the drug candidates PledOx[®] and Aladote[®] has received a "Notice of Allowance" from the United States Patent and Trademark Office (USPTO) meaning that the USPTO intends to grant the application
- Patent for the anticancer-effect of PLED compounds approved by the European Patent Office and an important use patent for PLED compounds granted by authorities in Canada, Russia and Australia.
- Aladote[®] approved as a trademark in the US

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
- 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 MASCC scientific congress.



CEO comment

Earlier this year PledPharma presented groundbreaking results from a Phase IIb study of PledOx[®]. During the last quarter, intensive work has been ongoing on the completion of the comprehensive briefing package to be discussed at the upcoming meeting with the FDA. The goal of the meeting is to clarify the scope and design of the continued clinical development studies needed up to submission of a registration application. After this, we are ready to intensify discussions with potential commercial partners. Ahead of this important phase, we also commissioned a group of leading international experts, with extensive experience and deep knowledge of the global pharmaceutical industry's requirements, to perform an analysis of the project from a preclinical, clinical, pharmacological, manufacturing, and regulatory perspective. The analysis confirms that the PledOx[®] project confirms to a very high international standard and that no additional activities are deemed necessary before contract negotiations.

The commercial value of these results will of course be significantly higher if they can be combined with strong intellectual property protection. It is therefore rewarding that intellectual property protection for PledOx[®] has strengthened further during the past quarter. In September, the US Patent Office, USPTO, announced that it intends to grant a compound patent covering the active ingredient calmangafodipir. A composition of matter (compound) patent is normally the most desirable form of patents for pharmaceutical companies because it offers stronger protection than use patents. Getting our compound patent - which extends until December 2032 - issued on the world's largest pharmaceutical market is a very big step for PledPharma. Since another of our drug candidates - Aladote[®] - is based on the same active pharmaceutical ingredient as PledOx[®], the announcement from the patent authorities is also of great value for this project. Aladote[®] has been developed to prevent the severe liver damage that often occurs in connection with an overdose of acetaminophen - the most common method for suicide attempts among young people aged 10-19 years. A clinical phase II study is expected to be initiated during in 2016.

Furthermore, patent protection in other parts of the world has been strengthened by a series of positive official statements. The European Patent Office has approved a patent for the anti-cancer effect of PLED substances. Thus, this patent is now approved in all major pharmaceutical markets. Meanwhile, authorities in Canada, Russia and Australia granted an important use patent for PLED substances. Together, these two patents provide supplementary protection around the central and fundamental compound patent.

I look forward to the meeting with the FDA, which will give us guidance on how to present an attractive package to potential partners based on a professionally executed project with unique clinical results, a strong patent position, and a well-defined development plan. The aim is to achieve an agreement that maximizes our ability to quickly and effectively make PledOx[®] available for the long-suffering of cancer patients, while at the same time building significant value for our shareholders.

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, EU, China, Hong Kong, Russia, Australia and Japan with patent protection until 2028. The second is approved in Australia, Canada, Russia and South Africa with patent protection until 2030. For the third and most important, the compound patent for calmangafodipir, the United States Patent and Trademark Office (USPTO) in 2015 announced a "Notice of Allowance" for the active ingredient of the drug candidates PledOx[®] and Aladote[®]. A Notice of Allowance means that the USPTO intends to grant the application with patent protection until December 2032.

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

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.



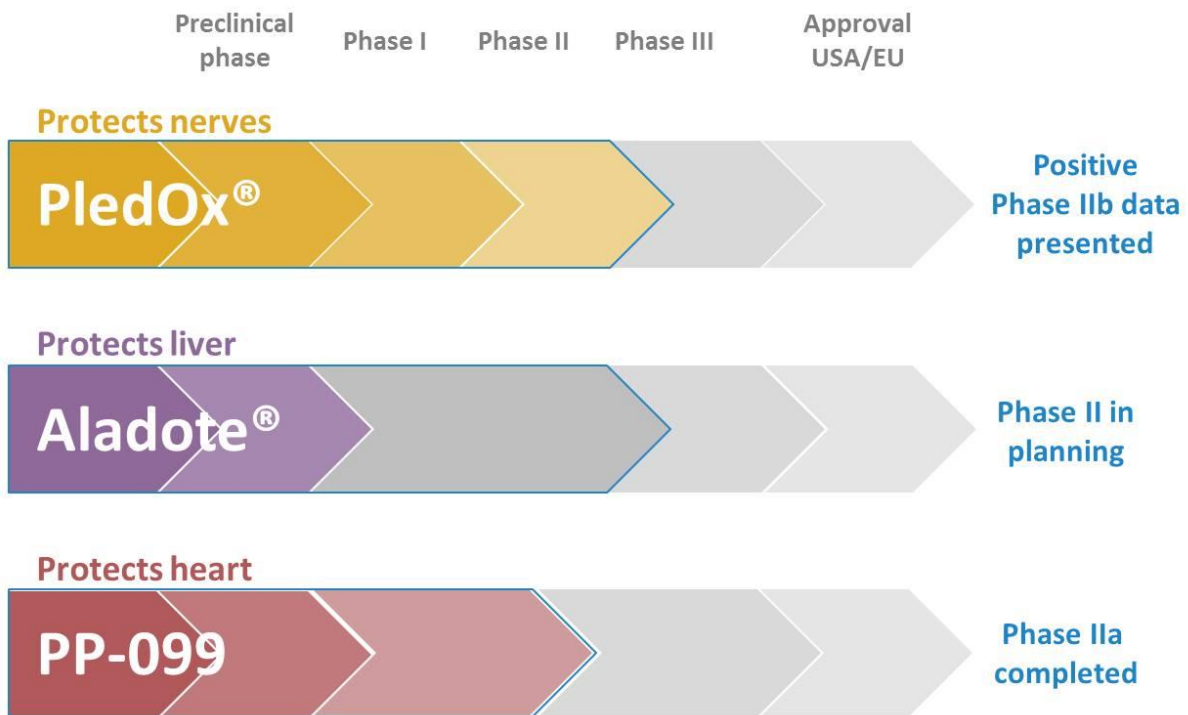
Aladote[®] (hepatic/ALF)

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



Financial summary Third quarter 2015

Revenue

Revenue amounted to SEK 67 (42) k during the quarter and to 321 (177) k for the nine month period and consisted of rental revenues and foreign exchange gains. Interest income amounted to SEK 35 (130) k for the period and to 165 (309) k for the nine month period.

Expenses

Operating expenses amounted to SEK 11 532 (11 426) k for the quarter and to 35 500 (31 102) k for the nine month period.

Of these, planned project costs, mainly related to the ongoing clinical study in PP95 project, amounted to SEK 7 551 (6 799) k for the period and to 22 100 (15 882) k for the nine month period.

Employee costs amounted to SEK 1 218 (1 672) k for the quarter and to SEK 5 089 (4 373) k for the nine month period.

Other operating costs amounted to SEK 2 763 (2 945) k for the quarter and to SEK 8 309 (10 845) k for the nine month period.

Depreciation amounted to SEK 1 (1) k for the quarter and to 2 (2) k for the nine month period.

Results and financial position

Operating result amounted to SEK -11 465 (-11 383) k for the quarter and to SEK -35 179 (-30 925) k for the nine month period.

Result after financial items amounted to SEK -11 431 (-11 265) k for the quarter and to SEK -35 025 (-30 714) k for the nine month period.

No income tax was recorded for the quarter (-) or for the nine month period (-).

Cash flow from operating activities amounted to SEK -10 273 (-7 124) k for the quarter and to SEK -41 939 (-28 808) k for the nine month period.

Cash flow, affected by a share issue in the comparative period, amounted to SEK -10 273

(-7 124) k for the quarter and to SEK -40 729 (-8 628) k for the nine month period.

Cash at 30 September 2015 amounted to SEK 59 313 (40 675) k and shareholders' equity amounted to SEK 56 843 (36 419) k. The company's equity ratio was 91 (82) %. Result per average share amounted to SEK -0.4 (-0.5) for the quarter and to SEK -1.2 (-1.4) for the nine month period.

No long-term debts were outstanding (-), current liabilities amounted to SEK 5 680 (7 810) k and shareholders' equity per share amounted to SEK 2.0 (1.5), at the end of the period.

Employees

Average number of employees during the period 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 September 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.



PledPharma

Income statement

SEKk	2015 Jul-Sept	2014 Jul-Sept	2015 Jan-Sept	2014 Jan-Sept	2014 Jan-Dec
Revenue					
Other operating income	67	42	321	177	233
	67	42	321	177	233
Operating expenses					
Project costs	-7 551	-6 799	-22 100	-15 882	-29 459
Employee benefit costs	-1 218	-1 672	-5 089	-4 373	-6 271
Other operating costs	-2 763	-2 954	-8 309	-10 845	-13 067
Depreciation and impairment, fixed assets	-1	-1	-2	-2	-2
Operating result	-11 465	-11 383	-35 179	-30 925	-48 566
Net financial items					
Depreciation of investment in subsidiaries	-	-	-	-	-19
Interest income	35	130	165	309	312
Interest expense and similar items	-	-12	-10	-97	-147
Result after financial net	-11 431	-11 265	-35 025	-30 714	-48 420
Result before tax	-11 431	-11 265	-35 025	-30 714	-48 420
Tax	-	-	-	-	-
Result after tax	-11 431	-11 265	-35 025	-30 714	-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	28 388 883	22 602 598	28 367 883	22 276 344	22 649 770
Result per share before and after dilution (SEK)	-0,4	-0,5	-1,2	-1,3	-1,7
Result per average share (SEK)	-0,4	-0,5	-1,2	-1,4	-2,1
Equity per share (SEK)	2,0	1,5	2,0	1,5	3,2
Equity per share after dilution (SEK)	2,0	1,5	2,0	1,5	3,2



PledPharma

Balance sheet

SEKk	2015-09-30	2014-09-30	2014-12-31
ASSETS			
Fixed assets			
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	1	3	3
<i>Financial assets</i>			
Shares and participations in group companies	50	50	50
Total fixed assets	51	53	53
Current assets			
<i>Current receivables</i>			
Receivables group companies	-	234	216
Other receivables	778	1 985	2 727
Prepaid expenses and accrued income	2 380	1 282	430
	3 158	3 501	3 373
<i>Cash and bank balances</i>			
	59 313	40 675	100 043
Total current assets	62 472	44 176	103 415
Total assets	62 523	44 229	103 468

SEKk	2015-09-30	2014-09-30	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	-35 025	-30 714	-48 420
	55 349	35 176	89 166
Total equity	56 843	36 419	90 658
Liabilities			
Accounts payable	2 481	4 782	9 967
Current tax liabilities	-	317	-
Other liabilities	192	352	292
Accrued expenses and deferred income	3 006	2 359	2 551
Total short term liabilities	5 680	7 810	12 810
Total equity and liabilities	62 523	44 229	103 468

Cash flow statement

SEKk	2015 Jul-Sept	2014 Jul-Sept	2015 Jan-Sept	2014 Jan-Sept	2014 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-11 431	-11 265	-35 025	-30 714	-48 420
Adjustments for non-cash items	1	1	2	2	21
Tax paid	-	45	-	135	-
Cash flow from operating activities before changes in working capital	-11 430	-11 219	-35 023	-30 578	-48 399
Changes in short term liabilities	1 092	-109	214	-1 984	-1 888
Changes in account payables	-25	3 261	-7 486	3 505	8 690
Changes in operating liabilities	90	943	356	248	213
Cash flow from operating activities	-10 273	-7 124	-41 939	-28 808	-41 385
INVESTING ACTIVITIES					
Cash flow from investing activities	-	-	-	-	-
FINANCING ACTIVITIES					
New share issue	-	-	1 210	20 180	95 839
Cost new share issue	-	-	-	-	-3 714
Cash flow from financing activities	-	-	1 210	20 180	92 125
Cash flow for the period					
Balance at beginning of period	69 586	47 799	100 043	49 302	49 302
Change in cash	-10 273	-7 124	-40 729	-8 628	50 740
CASH BALANCE AT THE END OF THE PERIOD	59 313	40 675	59 313	40 675	100 043

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	-	-	-30 714	-30 714
Closing balance 2014-09-30	1 243	65 890	-30 714	36 419
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	-	-	-35 025	-35 025
Closing balance 2015-09-30	1 494	90 374	-35 025	56 843

Key ratios

KSEK	2015 Jul-Sept	2014 Jul-Sept	2015 Jan-Sept	2014 Jan-Sept	2014 Jan-Dec
Operating result (EBIT)	-11 465	-11 383	-35 179	-30 925	-48 566
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-11 431	-11 265	-35 025	-30 714	-48 420
Cash flow from operating activities	-10 273	-7 124	-41 939	-28 808	-41 385
Total assets	62 523	44 229	62 523	44 229	103 468
Equity	56 843	36 419	56 843	36 419	90 658
Equity ratio %	91%	82%	91%	82%	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 dilution	28 388 883	24 022 403	28 388 883	24 022 403	28 746 883
Average number of shares under the period	28 388 883	22 602 598	28 367 883	22 276 344	22 649 770
Average number of shares under the period after dilution	28 388 883	23 002 598	28 367 883	22 676 344	23 049 770
Share Data					
Result per share	-0,4	-0,5	-1,2	-1,3	-1,7
Result per average share	-0,4	-0,5	-1,2	-1,4	-2,1
Cash flow from operating activities	-0,4	-0,3	-1,5	-1,2	-1,5
Equity per share	2,0	1,5	2,0	1,5	3,2
Equity per share after dilution	2,0	1,5	2,0	1,5	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 on October 20, 2015

Jacques Näsström
CEO

Next reports

The Year End report for 2015 will be published on February 29, 2016.

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, Daniel Thorsson and Finlay Heppenstall
Redeye, Klas Palin.

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