PledPharma

PledPharma AB (publ)
Interim report January - June 2016
August 25, 2016

Important steps taken with the drug candidates PledOx® and Aladote®

January – June summary

- Net result for the first half year amounted to SEK -18 829 (-23 610) k
- Cash equivalents at the end of the period amounted to SEK 31 666 (69 586) k
- Cash flow from operating activities amounted to SEK -18 695 (-31 927) k
- Result per share amounted to SEK -0.7 (-0.8)

Second quarter summary

- Net result for the quarter amounted to SEK -11 984 (-11 447) k
- Cash equivalents at the end of the quarter amounted to SEK 31 666 (69 586) k
- Cash flow from operating activities amounted to SEK -12 018 (-17 942) k
- Result per share amounted to SEK -0.4 (-0.4)

Significant events during January - June

- PledPharma conducted a constructive meeting with the European Medicines Agency (EMA)
- Follow-up data confirms that PledOx® does not negatively interfere with the anti-cancer effect of chemotherapy
- PledPharma presented the Phase IIb PLIANT study data at the American Society of Clinical Oncology (ASCO) cancer meeting
- During the AGM the CEO reported that active discussions are being held with a number of potential partners in the ongoing process of finding one or more appropriate commercial partners for the continued development of PledOx®.

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CEO comment

During the second quarter, we continued our work to strengthen the projects through a number of important steps with our drug candidates PledOx® and Aladote®. In the PledOx project we have demonstrated additional clarifying data and made progress in our regulatory discussions.

The Aladote® project is progressing according to plan and a clinical study, with the aim to prevent liver damage associated with acetaminophen overdose, is expected to start in late 2016.

During the spring we completed a constructive meeting with the European Medicines Agency (EMA) regarding the remaining development and potential market introduction of PledOx®. The meeting was a joint meeting attended by representatives from NICE in the UK and NOMA in Norway, two national authorities who are responsible for health economic evaluations of new drugs. We conclude that the European Medicines Agency share our view regarding the structure and scope of the remaining clinical development of PledOx®.

We have previously completed a so-called end-of-Phase II/pre-Phase III meeting with the FDA. Also this meeting was held in a constructive and positive spirit and altogether has the contacts with the regulatory authorities established a basis for a clear regulatory strategy for the two largest markets, US and Europe and a good basis for the continued development. PledPharma's view is that these meetings have created a foundation for the way forward towards a market approval of PledOx® for the prevention of chemotherapy induced nerve damage in patients treated for colorectal cancer.

At ASCO in June, PledPharma presented the Phase IIb PLIANT study data demonstrating the preventing effect on chemotherapy-induced nerve damage of PledOx®. The results were presented in a Poster Discussion Session by the study's coordinating primary investigator, Professor Bengt Glimelius.

During the quarter we presented positive follow-up data from the Phase IIb study PLIANT where we reported that the so called Progression Free Survival (PFS) i.e., survival time without tumor growth after the end of treatment is approximately seven months, which is in line with what can be expected from this group of patients. No difference in PFS was noted between the patients who received PledOx® and those who received placebo. The results confirm that treatment with PledOx® has no negative effect on the efficacy of the cancer treatment.

As previously announced, active discussions are held with a number of potential partners for PledOx®.

In conclusion, we have strengthened the conditions for the drug candidates PledOx® and Aladote®.

Jacques Näsström
CEO, PledPharma AB (publ)

Significant events after the end of the period
No significant events to report after the end of the period

PledPharma in brief

PledPharma develops new drugs that protect the body against oxidative stress – a potentially disabling and sometimes life-threatening 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 and positive results from the Phase IIb study PLIANT were presented during the spring of 2015. 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 (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the company's Certified Adviser (tel +46 8 463 80 00). For more information, see www.pledpharma.se

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, where after 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 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, Japan, Canada, Mexico, Russia and South Africa with patent protection until 2030. For the third and most important, the compound patent for calmangafodipir, for the active ingredient of the drug candidates PledOx® and Aladote® is approved in the US with patent protection until December 2032. The fourth application has entered the national phase and is expected to provide patent protection until October 2033. In addition, PledPharma has four in-licensed patents covering therapeutic use of PLED therapeutics.

PledPharma has trademark protection for PledOx® since 2010 and since 2015 for Aladote®.

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

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PledOx®

PledOx® (colorectal cancer)

PledOx® is developed to provide patients, that are treated adjuvantly or for metastatic colorectal cancer, protection against the nerve damage that often occurs in conjunction with chemotherapy treatment. The side-effects of chemotherapy often lead to a reduction of the planned dose or in worst case, treatment discontinuation. Unfortunately, it is common that the chemotherapy will induce permanent nerve damage. Patients may, for example, experience pain and dumbness in the hands and feet, difficulty with balance with risk of falling and problems with sensation during the rest of their lives.

This is the first time in a controlled clinical trial that one has succeeded in preventing chemotherapy caused nerve damage in a clinically significant manner without affecting the cancer treatment negatively. The results from the Phase IIb study PLIANT, where patients with colorectal cancer (colorectal cancer) treated with the chemotherapy combination FOLFOX and PledOx® (calmangafodipir), shows that the patients who received PledOx® had a lower risk than the placebo group to suffer from nerve damage.

Aladote®

Aladote® (hepatic/ALF)

Aladote® is a new formulation based on calmangafodipir 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.

PP-099

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

PledOx® – protects the nerves

Pre clinic | Phase I | Phase II | Phase III | Approval (USA/EU)

▶ Follow up – phase II study

Aladote® – protects the liver

Pre clinic | Phase I | Phase II | Phase III | Approval (US/EU)

▶ Preparation for phase II study

PP-099 – protects the heart

Pre clinic | Phase I | Phase II | Phase III | Approval (US/EU)

▶ Phase IIa studie completed

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Financial summary - Group
January - June 2016

Revenue
Revenue amounted to SEK 897 (205) k during the quarter and to SEK 945 (254) k for the six-month period. SEK 839k was related to a retroactive price adjustment in the PLIANT study. Other income consisted of rental revenues and foreign exchange gains. Interest income amounted to SEK 37 (60) k for the quarter and to SEK 75 (130) k for the six-month period.

Expenses
Operating expenses amounted to SEK 12 918 (11 702) k for the quarter and to SEK 19 849 (23 984) k for the six-month period. Of these, planned project costs amounted to SEK 7 511 (7 043) k for the quarter and to SEK 9 425 (14 549) k for the six-month period. The planned project cost mainly consisted of a single payment in the PLIANT study, regulatory costs and development costs.

Employee costs amounted to SEK 1 597 (1 186) k for the quarter and to SEK 3 187 (3 872) k for the six-month period. Other operating costs amounted to SEK 3 570 (3 464) k for the quarter and to SEK 6 983 (5 515) k for the six-month period. Depreciation amounted to SEK 0 (1) k for the quarter and to 0 (1) k for the six-month period.

Results
Operating result amounted to SEK -12 021 (-11 497) k for the quarter and to SEK -18 904 (-23 730) k for the six-month period. Result after financial items amounted to SEK -11 984 (-11 447) k for the quarter and to SEK -18 829 (-23 610) k for the six-month period.

No income tax was recorded for the quarter (-) or for the six-month period. Result per average share amounted to SEK -0.4 (-0.4) for the quarter and to SEK -0.7 (-0.8) for the six-month period.

Financial position

Cash
Cash at 30 June 2016 amounted to SEK 31 666 (69 586) k.

Cash flow
Cash flow from operating activities amounted to SEK -12 018 (-17 942) k for the quarter and to SEK -18 695 (-31 927) k for the six-month period. Cash flow amounted to SEK -12 018 (-16 732) k for the quarter and to SEK -18 695 (-30 717) k for the six-month period.

Equity and equity ratio
At June 30 2016 shareholders' equity amounted to SEK 29 203 (68 257) k. The company's equity ratio was 71 (92) %.

Debts
No long-term debts were outstanding (-), current liabilities amounted to SEK 12 020 (5 587) k and shareholders' equity per share amounted to SEK 1.0 (2.4), at the end of the period.

Investments, tangible and intangible assets
During the period, investments in tangible fixed assets corresponding to 0 (0) SEK.

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

Share
The number of shares at June 30 2016 were 28 388 883. PledPharma´s shares were listed on NASDAQ Stockholm First North on 7 April 2011.

Parent Company

Expenses
The parent company's expenses for the quarter amounted to SEK 12 918 (11 698) k and to 19 849 (23 968) k for the six-month period.

Results
The parent company's result after financial items amounted to SEK -11 984 (-11 443) k for the quarter and to SEK -18 829 (-23 594) k for the six month period.

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Consolidated statement of comprehensive income

SEKk	2016 April - June	2015 April - June	2016 Jan - June	2015 Jan - June	2015 Jan - Dec
Revenue					
Other operating income	897	205	945	254	378
	897	**205**	**945**	**254**	**378**
Operating expenses					
Project costs	-7 511	-7 043	-9 425	-14 549	-26 093
Other external costs	-3 570	-3 464	-6 983	-5 515	-11 274
Employee benefit costs	-1 597	-1 186	-3 187	-3 872	-6 909
Depreciation and impairment, fixed assets	0	-1	0	-1	-2
Other operating expenses	-239	-8	-253	-48	-128
Operating result	**-12 021**	**-11 497**	**-18 904**	**-23 730**	**-44 028**
Net financial items					
Interest income	37	60	75	130	203
Interest expense and similar items	-	-10	0	-10	-10
Result after financial net	**-11 984**	**-11 447**	**-18 829**	**-23 610**	**-43 836**
Result before tax	**-11 984**	**-11 447**	**-18 829**	**-23 610**	**-43 836**
Tax	-	-	-	-	-
Result after tax	**-11 984**	**-11 447**	**-18 829**	**-23 610**	**-43 836**
Statement of comprehensive income					
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	**-11 984**	**-11 447**	**-18 829**	**-23 610**	**-43 836**

Net earnings and comprehensive income is entirely attributable to parent company shareholders

Share Data					
Number of shares at the end of period	28 388 883	28 388 883	28 388 883	28 388 883	28 388 883
Average number of shares during period	28 388 883	28 367 883	28 388 883	28 357 383	28 373 133
Result per share before dilution (SEK)	-0,4	-0,4	-0,7	-0,8	-1,5
Result per share after dilution (SEK)	-0,4	-0,4	-0,7	-0,8	-1,5
Equity per share (SEK)	1,0	2,4	1,0	2,4	1,7
Equity per share after dilution (SEK)	1,0	2,4	1,0	2,4	1,7

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Consolidated statement of financial position

SEKk	2016-06-30	2015-06-30	2015-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	0	2	0
Total fixed assets	0	2	0
Current assets			
Current receivables			
Other receivables	6 589	1 010	788
Prepaid expenses and accrued income	2 969	3 246	1 213
	9 558	4 256	2 001
Cash and bank balances	31 666	69 586	50 360
Total current assets	**41 224**	**73 842**	**52 361**
Total assets	**41 224**	**73 844**	**52 361**
EQUITY AND LIABILITIES			
Equity			
Share capital	1 494	1 494	1 494
Other capital contributions	46 538	90 374	90 374
Accumulated loss including net loss	-18 829	-23 610	-43 836
Total equity	**29 203**	**68 257**	**48 032**
Short term liabilities			
Accounts payable	9 449	2 507	1 766
Other liabilities	196	185	177
Accrued expenses and deferred income	2 375	2 895	2 386
Total short term liabilities	12 020	5 587	4 329
Total equity and liabilities	**41 224**	**73 844**	**52 361**

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Consolidated statement of cash flows

SEKk	2016 April - June	2015 April - June	2016 Jan - June	2015 Jan - June	2015 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-11 984	-11 447	-18 829	-23 610	-43 836
Adjustments for non-cash items	0	1	0	1	2
Tax paid	-	-	-	-	-
Cash flow from operating activities before changes in working capital	**-11 984**	**-11 446**	**-18 829**	**-23 609**	**-43 833**
Changes in short term liabilities	-8 574	-2 137	-7 557	-1 094	1 161
Changes in account payables	8 347	-2 595	7 682	-7 460	-8 201
Changes in operating liabilities	193	-1 763	9	237	-280
Cash flow from operating activities	**-12 018**	**-17 942**	**-18 695**	**-31 927**	**-51 153**
INVESTING ACTIVITIES					
Cash flow from investing activities	**-**	**-**	**-**	**-**	**-**
FINANCING ACTIVITIES					
New share issue	**-**	1 210	-	1 210	1 210
Cost new share issue	-	-	-	-	-
Cash flow from financing activities	**-**	**1 210**	**-**	**1 210**	**1 210**
Cash flow for the period					
Balance at beginning of period	43 684	86 318	50 360	100 304	100 304
Change in cash	-12 018	-16 732	-18 695	-30 717	-49 943
CASH BALANCE AT THE END OF THE PERIOD	31 666	69 586	31 666	69 586	50 360

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Consolidates statement of changes in equity

kSEK	Share capital	Other capital contributions	Accumulated loss incl. net result for the period	Totalt equity
Opening balance 20150101	**1 492**	**137 586**	**(48 420)**	**90 658**
Loss allocation according to AGM	-	(48 420)	48 420	-
New share issue	2	1 208	-	1 210
Comprehensive income for period	-	-	(23 610)	(23 610)
Closing balance 20150630	**1 494**	**90 374**	**(23 610)**	**68 257**
Opening balance 20160101	**1 494**	**90 374**	**(43 836)**	**48 032**
Loss allocation according to AGM	-	(43 836)	43 836	-
Comprehensive income for period	-	-	(18 829)	(18 829)
Closing balance 20160630	**1 494**	**46 538**	**(18 829)**	**29 203**
Opening balance 20150101	**1 492**	**137 586**	**(48 420)**	**90 658**
Loss allocation according to AGM	-	(48 420)	48 420	-
New share issue	2	1 208	-	1 210
Comprehensive income for period	-	-	(43 836)	(43 836)
Closing balance 20151231	**1 494**	**90 374**	**(43 836)**	**48 032**

Consolidated key ratios

KSEK	2016 April - June	2015 April - June	2016 Jan-June	2015 Jan-June	2015 Jan-Dec
Operating result (EBIT)	-12 021	-11 497	-18 904	-23 730	-44 028
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-11 984	-11 447	-18 829	-23 610	-43 836
Cash flow from operating activities	-12 018	-17 942	-18 695	-31 927	-51 153
Total assets	41 224	73 844	41 224	73 844	52 361
Equity	29 203	68 257	29 203	68 257	48 032
Equity ratio %	71%	92%	71%	92%	92%
Return on equity %	neg.	neg.	neg.	neg.	neg.
Number of shares at the end of the period	28 388 883	28 388 883	28 388 883	28 388 883	28 388 883
Number of shares at the end of the period after dilution	28 388 883	28 388 883	28 388 883	28 388 883	28 388 883
Average number of shares under the period	28 388 883	28 367 883	28 388 883	28 357 383	28 373 133
Average number of shares under the period after dilution	28 388 883	28 367 883	28 388 883	28 357 383	28 373 133
Share Data					
Result per share	-0,4	-0,4	-0,7	-0,8	-1,5
Result per average share	-0,4	-0,4	-0,7	-0,8	-1,5
Cash flow from operating activities	-0,4	-0,6	-0,7	-1,1	-1,8
Equity per share	1,0	2,4	1,0	2,4	1,7
Equity per share after dilution	1,0	2,4	1,0	2,4	1,7
Dividend	-	-	-	-	-
Number of employees	4	4	4	4	4

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Parent company - Income statement

SEKk	2016 April - June	2015 April - June	2016 Jan - June	2015 Jan - June	2015 Jan-Dec
Revenue					
Other operating income	897	205	945	254	378
	897	**205**	**945**	**254**	**378**
Operating expenses					
Project costs	-7 511	-7 043	-9 425	-14 549	-26 093
Other external costs	-3 570	-3 460	-6 983	-5 498	-11 258
Employee benefit costs	-1 597	-1 186	-3 187	-3 872	-6 909
Depreciation and impairment, fixed assets	0	-1	0	-1	-2
Other operating expenses	-239	-8	-253	-48	-128
Operating result	**-12 021**	**-11 493**	**-18 904**	**-23 714**	**-44 012**
Net financial items					
Depreciation of investment in subsidiaries	-	-	-	-	-16
Interest income	37	60	75	130	203
Interest expense and similar items	-	-10	0	-10	-10
Result after financial net	**-11 984**	**-11 443**	**-18 829**	**-23 594**	**-43 836**
Result before tax	**-11 984**	**-11 443**	**-18 829**	**-23 594**	**-43 836**
Tax	-	-	-	-	-
Result after tax	**-11 984**	**-11 443**	**-18 829**	**-23 594**	**-43 836**

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Parent company - Balance sheet

SEKk	2016-06-30	2015-06-30	2015-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	-	2	0
Financial assets			
Shares and participations in group companies	50	50	50
Total fixed assets	**50**	**52**	**50**
Current assets			
Current receivables			
Other receivables	6 589	1 005	787
Prepaid expenses and accrued income	2 969	3 246	1 213
	9 558	4 251	2 001
Cash and bank balances	31 666	69 586	50 360
Total current assets	**41 224**	**73 837**	**52 361**
Total assets	**41 274**	**73 889**	**52 411**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1 494	1 494	1 494
Non-restricted equity			
Share premium reserve	46 538	90 374	90 374
Result for the period	-18 829	-23 594	-43 836
Total equity	**29 203**	**68 274**	**48 032**
Short term liabilities			
Debt to group company	50	28	51
Accounts payable	9 449	2 507	1 766
Other liabilities	196	185	177
Accrued expenses and deferred income	2 375	2 895	2 386
Total short term liabilities	**12 071**	**5 615**	**4 380**
Total equity and liabilities	**41 274**	**73 889**	**52 411**

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Notes

NOTE 1 - Accounting principles

PledPharma applies International Financial Reporting Standards (IFRS) as adopted by the EU. This report is prepared in accordance with IAS 34 Interim Financial Reporting and the Annual Accounts Act. The parent company's interim report is prepared in accordance with the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and the Swedish Annual Accounts Act. Applied accounting principles and calculation methods are the same as in the latest annual report for 2015.

NOTE 2 – Additional information

Other information in accordance with IAS 34.16A are found on pages before the income statement and statement of comprehensive income. Information on earnings, cash flow and financial position, see page 5. For events after the period, see page 3.

NOTE 3 – Financial assets and debts

Group 30 June 2016

The fair value and carrying value are shown in the table below:

	Account and loan receivables	**Financial debts**	**Total carrying amount**	**Fair value**
Accounts receivable	-	-	**-**	**-**
Accrued but not invoiced income	-	-	**-**	**-**
Cash	31 666	-	31 666	31 666
Total assets	**31 666**	**-**	**31 666**	**31 666**
Accounts payable	-	9 449	9 449	9 449
Other liabilities	-	-	**-**	**-**
Total debts	**-**	**9 449**	**9 449**	**9 449**

Group 31 December 2015

The fair value and carrying value are shown in the table below:

	Account and loan receivables	**Financial debts**	**Total carrying amount**	**Fair value**
Accounts receivable	-	-	**-**	**-**
Accrued but not invoiced income	-	-	**-**	**-**
Cash	50 360	-	50 360	50 360
Total assets	**50 360**	**-**	**50 360**	**50 360**
Accounts payable	-	1 766	1 766	1 766
Other liabilities	-	-	**-**	**-**
Total debts	**-**	**1 766**	**1 766**	**1 766**

NOTE 4- Related parties transactions

No transactions with related parties have occurred during the period.

Other information

Next reports
Interim report January-September, 20 October 2016

PledPharma is required to publish the information in this report under Swedish Securities Market Act. The information was submitted for publication on 25 August, 2016.

This report, and further information is available on the website, www.pledpharma.se

This report has not been audited.

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PledPharma

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.

Stockholm, August 25, 2016

Håkan Åström	Andreas Bunge	Martin Nicklasson
Chairman of the board	*Board member*	*Board member*

Sten Nilsson	Eva Redhe
Board member	*Board member*