PledPharma

PledPharma AB (publ)
Interim report January - September 2016
October 20, 2016

With PledOx® to the next level

January – September summary

- Net result for the nine-month period amounted to SEK -26 761 (-35 041) k
- Cash equivalents at the end of the period amounted to SEK 23 590 (59 313) k
- Cash flow from operating activities amounted to SEK -26 770 (-42 201) k
- Result per share amounted to SEK -0.9 (-1.2)

Third quarter summary

- Net result for the quarter amounted to SEK -7 932 (-11 431) k
- Cash equivalents at the end of the quarter amounted to SEK 23 590 (59 313) k
- Cash flow from operating activities amounted to SEK -8 075 (-10 273) k
- Result per share amounted to SEK -0.3 (-0.4)

Significant events during January - September

- PledPharma conducted a constructive meeting with the European Medicines Agency (EMA)
- Follow-up data indicates 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

Significant events after the end of the period

- PledPharma announces a guaranteed rights issue of SEK 406 million in order to take PledOx® into phase III

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CEO comment - With PledOx® to the next level

The Board of Directors and management of PledPharma have decided to develop the Company's main product, PledOx®, all the way to application for market registration. This means that we change our strategy and develop the project through pivotal clinical trials, i.e. phase III trials that will form the basis for a new drug application (NDA) to the Food and Drug Administration ("FDA") in the US and for a marketing authorization application (MAA) to the European Medicines Agency ("EMA") in Europe. The reason we have chosen this path is that we expect to create significantly greater value for the shareholders, than what we can realize through a partnership today. The decision follows an over the past year, growing confidence in the project as well as feedback received in constructive discussions with several potential partners who want to see Phase III data. It does involve risk, but our assessment is that this step allows for a significantly increased value of PledOx®, both as a result of a higher value of completed Phase III studies, as well as that the proportion of the value attributed to PledPharma at a later out-licensing increases significantly.

From an economic stand point, the decision is supported by the assessment made by a reputable international research house after carrying out in-depth interviews with Key Opinion Leaders and representatives of health care payers. The research house estimates global peak sales of PledOx® to USD 1.8 billion, corresponding to approximately SEK 16 billion. The estimate is based solely on prescriptions to patients with colorectal cancer that are treated with the same chemotherapy agents as PledPharma has used in previous clinical trials. Hence, the estimate does not include patients treated for other cancers.

We enter into this with confidence after that the PLIANT study last spring demonstrated a clinically relevant reduction in neuropathy. Since then, our belief in the project has strengthened even further, first with long-term data from the study presented in December 2015 and the readout of survival data in May 2016, followed by both EMA and FDA in dialogue confirming that the next step for the project is Phase III trials.

As we move into Phase III we will, in addition to metastatic colorectal cancer patients, also include patients treated adjuvantly for colorectal cancer. These patients have great potential to be cured by surgery and chemotherapy. PledOx® aims to prevent these patients from receiving chronic and debilitating nerve injury.

Implementing these two phase III studies and taking PledOx® to market registration is estimated to cost approximately SEK 750 million, of which approximately SEK 400 million will be used to take these studies to top-line results in 2020. Top-line results will show treatment outcomes for chronic neuropathies when patients have completed chemotherapy.

Entering into phase III places increased and partly new demands on the organization. We will recruit senior specialists to manage the clinical studies which we expect to start in the middle of next year together with a renowned clinical contract research organization. We do not plan to build a large organization but to continue to work effectively.

Regarding Aladote® for the treatment of acute paracetamol poisoning, the plan is to out-license the project to commercial partners after clinical proof of concept. The first clinical study is expected to start in the first quarter of 2017. We have also taken the decision to discontinue the project PP 099 to focus on the development of PledOx® and Aladote®.

After the rights issue, we will begin preparations to apply for listing on Nasdaq Stockholm's main list. In summary, the decisions we have taken positions PledPharma to create significantly greater value for shareholders.

Jacques Näsström, CEO, PledPharma AB (publ)

PledPharma in brief

PledPharma develops new drugs that protect the body against oxidative stress – a potentially debilitating and sometimes life-threatening condition that can be caused by chemotherapy treatment and following acetaminophen (paracetamol) overdose. 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.

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 is a leading pharmaceutical company, developing new, unique therapies for debilitating and life-threatening conditions.

Business idea
PledPharma develops therapies to improve the treatment of debilitating and life-threatening conditions based on the company's patented and clinically proven technology, PLED.

Goals
PledPharma's goal is to create value for patients and society by developing effective new treatments for debilitating and life-threatening conditions.
PledPharma's primary business objective is:
• To successfully develop PledOx® to market registration
• To successfully develop Aladote® to clinical "proof of concept"

PledPharma financial goal is to achieve maximum value for shareholders.

Business model and strategy
PledPharma uses its patented and clinically proven technology, PLED, to develop treatments for debilitating and life-threatening conditions caused by oxidative stress. The company focuses on a few key projects. The projects are selected based on several criteria, the most important are the medical need, scientific rational and development path. That the potential treatments are in areas with limited competition is considered to be advantageous.

With a small number of projects in development PledPharma can give each project the attention and resources necessary for successful development. The company has an entrepreneurial approach and manage their projects in a resource efficient manner. The business is run by its own expert organization with expertise in preclinical and clinical development collaborating with partners, including conducting studies. PledPharma also intends to work with partners to manufacture, sale and distribute future approved products. Until profitable, the organization will mainly be financed through equity and licensing of projects to commercial partners.

Patents and trademarks
PledPharma's 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.

PledPharma portfolio of patents expands with new applications and approvals as applications are processed and new innovations are made, for example, regarding formulations and new application areas.

PledPharmas patent applications are approved in 16 countries. The first is so far approved in the US, EU, China, Hong Kong, Russia, Australia, Japan, South Korea and Israel 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.

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 two projects in or about to enter the clinical phase.

PledOx®

PledOx® (chemotherapy induced peripheral neuropathy)

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. PledOx® is a "first-in-class" treatment and there is a large medical need as there are currently no preventive or curative treatment for nerve damage from chemotherapy.

The results from the Phase IIb study PLIANT, where patients with metastatic 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 during the chemotherapy. Patients also showed a statistically significant and clinically meaningful reduction in chronic symptoms of nerve damage up to 6 months after treatment.

Aladote®

Aladote® (Acetaminophen poisoning)

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. Aladote® is a "first-in-class" treatment and there is a large medical need as there are currently no adequate treatment for patients arriving late to the hospital.

Status in PledPharma´s ongoing projects

PledOx® – protects the nerves

▶ Preparation for phase III study

Aladote® – protects the liver

▶ Preparation for phase II study

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Financial summary - Group
January - September 2016

Revenue
Revenue amounted to SEK 40 (67) k during the quarter and to SEK 985 (321) k for the nine-month period. The revenue consisted of rental revenues, foreign exchange gains and a retroactive price adjustment in the PLIANT study. Interest income amounted to SEK 32 (35) k for the quarter and to SEK 106 (165) k for the nine-month period.

Expenses
Operating expenses amounted to SEK 8 004 (11 532) k for the quarter and to SEK 27 853 (35 517) k for the nine-month period. Of these, planned project costs amounted to SEK 3 717 (7 551) k for the quarter and to SEK 13 142 (22 100) k for the nine-month period. A reduction that is primarily related to reduced costs for the PLIANT study in 2016.

Employee costs amounted to SEK 1 443 (1 218) k for the quarter and to SEK 4 631 (5 089) k for the nine-month period. Other operating costs amounted to SEK 2 809 (2 720) k for the quarter and to SEK 9 793 (8 235) k for the nine-month period. Depreciation amounted to SEK 0 (1) k for the quarter and to 0 (2) k for the nine-month period.

Results
Operating result amounted to SEK -7 964 (-11 465) k for the quarter and to SEK -26 868 (-35 196) k for the nine-month period. Result after financial items amounted to SEK -7 932 (-11 431) k for the quarter and to SEK -26 761(-35 041) k for the nine-month period.

No income tax was recorded for the quarter (-) or for the nine-month period. Result per average share amounted to SEK -0.3 (-0.4) for the quarter and to SEK -0.9 (-1.2) for the nine-month period.

Financial position

Cash
Cash at 30 September 2016 amounted to SEK 23 590 (59 313) k.

Cash flow
Cash flow from operating activities amounted to SEK -8 075 (-10 273) k for the quarter and to SEK -26 770 (-42 201) k for the nine-month period. Cash flow amounted to SEK -8 075 (-10 273) k for the quarter and to SEK -26 770 (-40 991) k for the nine-month period.

Equity and equity ratio
At September 30 2016 shareholders' equity amounted to SEK 21 271 (56 827) k. The company's equity ratio was 82 (91) %. Shareholders' equity per share amounted to SEK 0.7 (2.0), at the end of the period.

Debts
No long-term debts were outstanding (-), current liabilities amounted to SEK 4 769 (5 651) k.

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 September 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 8 004 (11 532) k and to 27 853 (35 500) k for the nine-month period.

Results
The parent company's result after financial items amounted to SEK -7 932 (-11 431) k for the quarter and to SEK -26 761 (-35 025) k for the nine-month period.

PledPharma

Consolidated statement of comprehensive income

SEKk	2016 July - Sept	2015 July - Sept	2016 Jan - Sept	2015 Jan - Sept	2015 Jan - Dec
Revenue					
Other operating income	40	67	985	321	378
	40	**67**	**985**	**321**	**378**
Operating expenses					
Project costs	-3 717	-7 551	-13 142	-22 100	-26 093
Other external costs	-2 809	-2 720	-9 793	-8 235	-11 274
Employee benefit costs	-1 443	-1 218	-4 631	-5 089	-6 909
Depreciation and impairment, fixed assets	0	-1	0	-2	-2
Other operating expenses	-34	-43	-287	-91	-128
Operating result	**-7 964**	**-11 465**	**-26 868**	**-35 196**	**-44 028**
Net financial items					
Interest income	32	35	106	165	203
Interest expense and similar items	-	0	0	-10	-10
Result after financial net	**-7 932**	**-11 431**	**-26 761**	**-35 041**	**-43 836**
Result before tax	**-7 932**	**-11 431**	**-26 761**	**-35 041**	**-43 836**
Tax	-	-	-	-	-
Result after tax	**-7 932**	**-11 431**	**-26 761**	**-35 041**	**-43 836**
Statement of comprehensive income					
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	**-7 932**	**-11 431**	**-26 761**	**-35 041**	**-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	28 388 883	28 388 883	28 367 883	28 373 133
Result per share before dilution (SEK)	-0,3	-0,4	-0,9	-1,2	-1,5
Result per share after dilution (SEK)	-0,3	-0,4	-0,9	-1,2	-1,5
Equity per share (SEK)	0,7	2,0	0,7	2,0	1,7
Equity per share after dilution (SEK)	0,7	2,0	0,7	2,0	1,7

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Consolidated statement of financial position

SEKk	2016-09-30	2015-09-30	2015-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	0	1	0
Total fixed assets	**0**	**1**	**0**
Current assets			
Current receivables			
Other receivables	405	783	788
Prepaid expenses and accrued income	2 044	2 380	1 213
	2 449	3 164	2 001
Cash and bank balances	23 590	59 313	50 360
Total current assets	**26 040**	**62 477**	**52 361**
Total assets	**26 040**	**62 478**	**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	-26 761	-35 041	-43 836
Total equity	**21 271**	**56 827**	**48 032**
Short term liabilities			
Accounts payable	2 271	2 481	1 766
Other liabilities	202	164	177
Accrued expenses and deferred income	2 295	3 006	2 386
Total short term liabilities	**4 769**	**5 651**	**4 329**
Total equity and liabilities	**26 040**	**62 478**	**52 361**

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Consolidated statement of cash flows

SEKk	2016 July - Sept	2015 July - Sept	2016 Jan - Sept	2015 Jan - Sept	2015 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	-7 932	-11 431	-26 761	-35 041	-43 836
Adjustments for non-cash items	0	1	0	1	2
Tax paid	-	-	-	-	-
Cash flow from operating activities before changes in working capital	**-7 932**	**-11 430**	**-26 761**	**-35 040**	**-43 833**
Changes in short term liabilities	7 109	1 092	-448	-2	1 161
Changes in account payables	-7 178	-25	505	-7 486	-8 201
Changes in operating liabilities	-74	90	-66	327	-280
Cash flow from operating activities	**-8 075**	**-10 273**	**-26 770**	**-42 201**	**-51 153**
INVESTING ACTIVITIES					
Cash flow from investing activities	**-**	**-**	**-**	**-**	**-**
FINANCING ACTIVITIES					
New share issue	**-**	**-**	**-**	**1 210**	**1 210**
Cost new share issue	-	-	-	-	-
Cash flow from financing activities	**-**	**-**	**-**	**1 210**	**1 210**
Cash flow for the period					
Balance at beginning of period	31 666	69 586	50 360	100 304	100 304
Change in cash	-8 075	-10 273	-26 770	-40 991	-49 943
CASH BALANCE AT THE END OF THE PERIOD	23 590	59 313	23 590	59 313	50 360

Consolidates statement of changes in equity

kSEK	Share capital	Other capital contributions	Accumulated loss incl. net result for the period	Total 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	-	-	(35 041)	(35 041)
Closing balance 20150930	**1 494**	**90 374**	**(35 041)**	**56 827**
Opening balance 20160101	**1 494**	**90 374**	**(43 836)**	**48 032**
Loss allocation according to AGM	-	(43 836)	43 836	-
Comprehensive income for period	-	-	(26 761)	(26 761)
Closing balance 20160930	**1 494**	**46 538**	**(26 761)**	**21 271**
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 July - Sept	2015 July - Sept	2016 Jan-Sept	2015 Jan-Sept	2015 Jan-Dec
Operating result (EBIT)	-7 964	-11 465	-26 868	-35 196	-44 028
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-7 932	-11 431	-26 761	-35 041	-43 836
Cash flow from operating activities	-8 075	-10 273	-26 770	-42 201	-51 153
Total assets	26 040	62 478	26 040	62 478	52 361
Equity	21 271	56 827	21 271	56 827	48 032
Equity ratio %	82%	91%	82%	91%	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	28 388 883	28 388 883	28 367 883	28 373 133
Average number of shares under the period after dilution	28 388 883	28 388 883	28 388 883	28 367 883	28 373 133
Share Data					
Result per share	-0,3	-0,4	-0,9	-1,2	-1,5
Result per average share	-0,3	-0,4	-0,9	-1,2	-1,5
Cash flow from operating activities	-0,3	-0,4	-0,9	-1,5	-1,8
Equity per share	0,7	2,0	0,7	2,0	1,7
Equity per share after dilution	0,7	2,0	0,7	2,0	1,7
Dividend	-	- -	-		-
Number of employees	4	4	4	4	4

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Parent company - Income statement

SEKk	2016 July - Sept	2015 July - Sept	2016 Jan - Sept	2015 Jan - Sept	2015 Jan-Dec
Revenue					
Other operating income	40	67	985	321	378
	40	**67**	**985**	**321**	**378**
Operating expenses					
Project costs	-3 717	-7 551	-13 142	-22 100	-26 093
Other external costs	-2 809	-2 720	-9 793	-8 219	-11 258
Employee benefit costs	-1 443	-1 218	-4 631	-5 089	-6 909
Depreciation and impairment, fixed assets	0	-1	0	-2	-2
Other operating expenses	-34	-43	-287	-91	-128
Operating result	**-7 964**	**-11 465**	**-26 868**	**-35 179**	**-44 012**
Net financial items					
Depreciation of investment in subsidiaries	-	-	-	-	-16
Interest income	32	35	106	165	203
Interest expense and similar items	-	0	0	-10	-10
Result after financial net	**-7 932**	**-11 431**	**-26 761**	**-35 025**	**-43 836**
Result before tax	**-7 932**	**-11 431**	**-26 761**	**-35 025**	**-43 836**
Tax	-	-	-	-	-
Result after tax	**-7 932**	**-11 431**	**-26 761**	**-35 025**	**-43 836**

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Parent company - Balance sheet

SEKk	2016-09-30	2015-09-30	2015-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	0	1	0
Financial assets			
Shares and participations in group companies	50	50	50
Total fixed assets	**50**	**51**	**50**
Current assets			
Current receivables			
Other receivables	405	778	787
Prepaid expenses and accrued income	2 044	2 380	1 213
	2 449	3 158	2 001
Cash and bank balances	23 590	59 313	50 360
Total current assets	**26 040**	**62 472**	**52 361**
Total assets	**26 090**	**62 523**	**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	-26 761	-35 025	-43 836
Total equity	**21 271**	**56 843**	**48 032**
Short term liabilities			
Debt to group company	50	28	51
Accounts payable	2 271	2 481	1 766
Other liabilities	202	164	177
Accrued expenses and deferred income	2 295	3 006	2 386
Total short term liabilities	**4 819**	**5 680**	**4 380**
Total equity and liabilities	**26 090**	**62 523**	**52 411**

PledPharma

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 6. For events after the period, see page 1.

NOTE 3 – Financial assets and debts

Group 30 September 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	-	-	-	-
Cash	23 590	-	23 590	23 590
Total assets	**23 590**	**-**	**23 590**	**23 590**
Accounts payable	-	2 271	2 271	2 271
Other liabilities	-	-	-	-
Total debts	**-**	**2 271**	**2 271**	**2 271**

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	-	-	-	-
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

Consulting agreements exist with Board members Håkan Åström, Sten Nilsson and Martin Nicklasson who receives maximum compensation on an annual basis as follows: Håkan Åström SEK 582K, Sten Nilsson SEK 204K and Martin Nicklasson SEK 100K. During the period the Board member Martin Nicklasson invoiced SEK 25K in consulting fees.

Other information

Next reports
Year end report, 24 February 2016

PledPharma is required to publish the information in this report in accordance with Market Abuse Act. and Swedish Securities Market Act. The information was submitted for publication on 20 October, 2016.

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

This is a translation of the Swedish interim report that has been reviewed by the company's auditor.

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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, October 20, 2016

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

Sten Nilsson	Eva Redhe
Board member	*Board member*