PledPharma

PledPharma AB (publ)
Interim report third quarter 2014
24 October 2014

PLIANT study fully recruited and a new exciting project for acetaminophen-induced poisoning presented

Quarter summary

- Net result amounted to SEK -11 265k (-4 509k)
- Cash and cash equivalents on September 30 amounted to SEK 40 675k (54 910k)
- Cash flow from operating activities amounted to SEK -7 124k (-4 207k)
- Result per share amounted to SEK -0.5 (-0.2)

Significant events during July – September

- The first two futility analysis in the PLIANT study were approved by the DSMB
- Positive data from patients treated with the FOLFOX in combination with bevacizumab in the first part of the PLIANT study
- PledPharma was rewarded Nordic Star of the Year at the Nordic Life Science Days

Significant events after the end of the period

- The last patient was included in the PLIANT study
- The last futility analysis in the PLIANT study was approved by the DSMB
- The new project against acetaminophen induced poisoning is aimed to be financed by a rights issue

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CEO comments

The PLIANT study is fully recruited and all 126 patients have been included in part II. We expect to deliver top line results by the end of the first quarter 2015. An important objective of the study is to show that there is no negative impact on the anti-cancer effect. It is therefore utmost importance that the DSMB has announced that no further futility analyzes needs to be conducted. We will now intensify preparations for commercialization of the project through licensing.

We have during the year worked on a new project with expected great commercial potential based on the proprietary PLED-platform. Project PP-100 aims at reducing or preventing severe liver damage as a result of acetaminophen overdosing, one of the most common poisonings.

Because the compound in the PP-100 project is based on the same platform as PledOx, existing safety documentation can be used and the company believes that the project can go directly from preclinical stage to a Phase II study in patients. The compound is subject to the same composition of matter patent application as PledOx, with an expected patent protection up to 2033. We will also seek orphan drug status in both the EU and USA for this product.

The unpleasant thing with acetaminophen poisoning is that acetaminophen is generally considered as the gentlest among pain medications, furthermore, it can be difficult to detect poisoning at the onset for those that have inadvertently overdosed acetaminophen since the difference between normal and harmful dose is small and the symptoms can be quite vague or absent during the first 24h. Intentional overdose of acetaminophen is the most common method of attempted suicide among young people age 10-19 years, where girls dominate.

The existing treatment for overdose of acetaminophen (N-acetylcysteine) is effective if the patient seek medical care within 8 hours after ingestion of acetaminophen. Late arriving patients lack well-functioning treatments despite an increased risk of liver damage. About a quarter of those who overdose on acetaminophen come in to the emergency room later than 8 hours after the overdose.

Our preclinical results demonstrate that we have an opportunity to help late arriving patients. An extended treatment window will be able to save lives, reduce suffering and save significant healthcare costs. Data from IMS Health Capital allows us to estimate the commercial potential of the project to the same magnitude as for PledOx in treatment of colorectal cancer with FOLFOX.

Based on our preclinical results that clearly demonstrate that the PP-100 compound, PP 100-01A, with its unique formulation, can normalize the elevation of certain liver enzymes that are indicators of liver failure long after the N-acetylcysteine stopped working, we have decided to take PP-100 through clinical Phase II which will be financed by a rights issue that is supported by the largest shareholders. The Board of Directors intends to shortly convene an Extraordinary General Meeting to consider the Board's proposals regarding the rights issue with the right to subscribe one new share for every existing five at 16 SEK, which can provide the company with up to approximately 75 million SEK. The plan is that the rights issue will be carried out before the end of the year.

We look forward to deliver the topline data from the PLIANT-study, a licensing deal for PledOx and with the PP-100 project contribute with great clinical benefit in one of the most common forms of poisoning

Jacques Näsström, CEO, PledPharma AB (publ)

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Company profile

PledPharma is a Swedish pharmaceutical company that develops new therapies for the treatment of life threatening diseases. The initial objective is to develop a drug, PledOx®, which reduces severe side-effects associated with chemotherapy. The current market for supportive cancer care is some USD 10 billion.. In the most recently added project (PP-100), the ability of the compound (PP100-01A) in reducing or preventing acute liver failure due to paracetamol (acetaminophen) overdose is investigated. PledPharma has the potential to offer patients valuable and unique treatments for serious life-threatening diseases where there is an opportunity for earlier registration in the US through "breakthrough therapy" designation. Project PP-99 is based on limiting reperfusion injuries in patients with acute myocardial infarction undergoing percutaneous coronary intervention PledPharma (STO:PLED) is listed on NASDAQ OMX First North. Erik Penser Bankaktiebolag is the Certified Adviser. For further information, please visit www.pledpharma.se

About the PLIANT study

The PLIANT-study investigates PledOx's ability to reduce serious FOLFOX-induced side effects during treatment of colorectal cancer. The primary objective is to evaluate the reduction of adverse events such as a decrease in white blood cells (neutrophils) and sensory nerve disorders (neuropathy). 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. For further details please see www.clinicaltrials.gov

Significant patient benefits with PledOx

PledOx is a new drug that protects the body's normal cells against oxidative stress caused by the overproduction of harmful nitrogen / oxygen molecules (free radicals). This overproduction arises for example during chemotherapy treatment of cancer. Initially PledOx is developed to reduce severe side-effects of chemotherapy treatment and currently PledPharma has an ongoing phase IIb study, PLIANT. The study focuses on the treatment of colorectal cancer, the third most common cancer worldwide, and side-effects caused by the cancer drugs in FOLFOX. PledOx is given to the patient as a pretreatment to FOLFOX. A possible development of PledPharma's PLED drug could be within other cancer chemotherapy as well as radiation therapy.

Project PP-100 – against acetaminophen-induced poisoning

Project PP-100 aims at reducing or preventing severe liver damage as a result of acetaminophen overdosing, one of the most common poisonings. Acetaminophen is the most widely used drug in the world for the treatment of painful conditions and it is available both as an over-the-counter and as a prescription drug. Acetaminophen overdose is also one of the most frequent causes of drug poisonings either intentionally or unintentionally. The difference between normal and harmful dose is small and the symptoms can be quite vague or absent during the first 24h. Overdose of acetaminophen can among other things lead to acute liver failure, which in turn may result in the need for a liver transplant and in the worst case, result in death.

The problem with acetaminophen overdose is huge worldwide. In Sweden, the number of questions about acetaminophen poisoning at Poisons Information Center has grown three-fold since 2000. In the United States acetaminophen overdose is behind 56,000 emergency room visits, 2,600 hospitalizations and 500 deaths annually.

The existing treatment for overdose of acetaminophen (N-acetylcysteine) is effective if the patient seek medical care within 8 hours after ingestion of acetaminophen. Late arriving patients lack well-functioning treatments despite an increased risk of liver damage. About a quarter of those who overdose on acetaminophen come in to the emergency room later than 8 hours after the overdose.

Preclinical results clearly demonstrate that the PP-100 compound, PP 100-01A, with its unique formulation, can normalize the elevation of certain liver enzymes that are indicators of liver failure long after the N-acetylcysteine stopped working. PledPharma will also seek orphan drug status in both the EU and USA for this product and is planning a clinical phase II study.

Mechanism of action
N-acetylcysteine acts as antidote by replenishing glutathione stores. Acetaminophen metabolites bind to glutathione after which the conjugate is excreted via the kidneys. More recent research has indicated that the hepatotoxic effects of acetaminophen is due to that when the glutathione stores in the liver are depleted, acetaminophen metabolites bind to proteins in the liver, which induces severe oxidative stress that can lead to acute liver failure. Since PledPharma's PLED compounds are potent low molecular enzyme mimetics (low MEM) of the body's own manganese-containing superoxide dismutase (MnSOD), these compounds can by their mechanism of action reduce the oxidative stress in the liver and thereby prevent acute liver failure.

Orphan drugs
Orphan drugs, are drugs aimed to treat serious and rare disease-areas of significant medical interest. Orphan drug designation conveys a number of advantages, including market exclusivity for a certain period of time, certain tax credits, assistance with applications and accelerated market approval.

Vision, Business Idea, goal and strategy

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

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

Goal
The primary goal is a successful out-licensing of PledOx® with attractive commercial revenues.

Strategy
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 licensed out, whereby the financial exposure is reduced. The compensation is anticipated to be received in the form of signing fees, milestone payments and royalties.

Operations are conducted with a small focused internal organization that has extensive industry experience ensuring that the company has the expertise needed to cost-effectively drive value growth in clinical programs in collaboration with our external partners.

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IP

PledPharma has four in-licensed patents covering therapeutic use of PLED pharmaceuticals. Additionally PledPharma has filed 3 series of worldwide patent applications aiming to achieve exclusive and broad commercial rights for manufacturing and use of PLED-pharmaceuticals, including among others PledOx® (calmangafodipir). The third series, a compositional matter patent application regarding PledOx was filed to strengthen and extend PledPharma's patent protection and in February 2013, a patent from the first series was approved for the US market and more recently in Russia, China, Japan and Hong Kong, regarding the use of PLED pharmaceuticals in the treatment of cancer with a patent protection until 2028. Furthermore, the second series "Pharmaceutical composition and therapeutic methods employing a combination of a manganese complex compound and a non-manganese complexed form of the compound" was recently approved in South Africa as the first country.

PledOx is a registered trademark in EU, U.S., Switzerland, Australia, Norway and Japan and pending in China and Russia.

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Financial summary
Third quarter 2014

Income
Revenue during the quarter amounted to SEK 42k (9k) and consisted of foreign exchange gains and rental revenues. Interest income for the quarter amounted to SEK 130k (288k).

Costs
Operating expenses for the quarter amounted to SEK 11 425k (4 805k).

Of this, project costs amounted to 6 799k (1 462k) which mainly consisted of costs for ongoing clinical study in PP95 project. Employee costs amounted to 1 672k (1 387k). Depreciation amounted to 1k (1k).

Results and financial position
Operating result for the quarter amounted to SEK -11 383k (-4 796k). Result after financial items amounted to SEK -11 265k (- 4 509k) and the result after tax was SEK -11 265k (-4 509k).

The cash flow during the quarter amounted to SEK - 7124k (4 207k).

Cash flow from operating activities amounted to SEK -7 124k (-4 207k). Cash at the end of the period amounted to 40 675k (54 910k).

Shareholders' equity amounted to SEK 36 419k (53 914k) and the company's equity ratio was 82 percent (95). Shareholders' equity per share amounted to SEK 1.5 (2.5). No long-term debts were outstanding (-). Current liabilities at the end of the quarter amounted to SEK 7 810k (3 015k).

Employees
Average number of employees during the period was 4 (5) persons.

Options Program
As of September 30, 2014, 131 000 call options, in the in 2012 decided options scheme, were subscribed by employees in the company.

Significant risks and uncertainties
Risks are described in the Annual Report for 2013. No changes in the company's risk assessment have taken place during the period.

Share
Number of shares at September 30, 2014 were 23 622 403. After full dilution, the number of shares will be 24 022 403. PledPharma shares were listed on NASDAQ OMX First North on 7 April 2011.

Seasonal variations
PledPharma activity is not subject to seasonal variations.

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Income statement

SEKk	2014 July-Sept	2013 July-Sept	2014 Jan-Sept	2013 Jan-Sept	2013 Jan-Dec
Revenue					
Other operating income	42	9	177	128	287
	42	**9**	**177**	**128**	**287**
Operating expenses					
Project costs	(6 799)	(1 462)	(15 882)	(7 576)	(10 558)
Employee benefit costs	(1 672)	(1 387)	(4 373)	(4 538)	(6 025)
Other operating costs	(2 954)	(1 956)	(10 845)	(7 010)	(9 785)
Depreciation and impairment, fixed assets	(1)	(1)	(2)	(2)	(2)
Operating result	**(11 383)**	**(4 796)**	**(30 925)**	**(18 997)**	**(26 084)**
Net financial items					
Depreciation of investment in subsidiaries					(32)
Interest income	130	288	309	426	568
Interest expense and similar items	(12)	(1)	(97)	(17)	(1)
Result after financial net	**(11 265)**	**(4 509)**	**(30 714)**	**(18 588)**	**(25 549)**
Result before tax	**(11 265)**	**(4 509)**	**(30 714)**	**(18 588)**	**(25 549)**
Tax	-	-	-	-	-
Result after tax	**(11 265)**	**(4 509)**	**(30 714)**	**(18 588)**	**(25 549)**
Share Data					
Number of shares at the end of period	23 622 403	21 935 089	23 622 403	21 935 089	21 935 089
Result per share before dilution (SEK)	(0,5)	(0,2)	(1,3)	(0,8)	(1,2)
Result per share after dilution (SEK)	(0,5)	(0,2)	(1,3)	(0,8)	(1,2)
Equity per share (SEK)	1,5	2,5	1,5	2,5	2,1
Equity per share after dilution (SEK)	1,5	2,4	1,5	2,4	2,1

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Balance sheet

SEKk	2014-09-30	2013-09-30	2013-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	3	6	5
Financial assets			
Shares and participations in group companies	50	50	50
Total fixed assets	**53**	**56**	**55**
Current assets			
Current receivables			
Receivables group companies	234	0	234
Other receivables	1 985	667	991
Prepaid expenses and accrued income	1 282	1 296	428
	3 501	1 963	1 653
Cash and bank balances	40 675	54 910	49 302
Total current assets	**44 176**	**56 873**	**50 956**
Total assets	**44 229**	**56 928**	**51 011**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1 243	1 154	1 154
Non-restricted equity			
Share premium reserve	65 890	71 347	71 348
Result for the period	(30 714)	(18 588)	(25 549)
	35 176	52 759	45 799
Total equity	**36 419**	**53 914**	**46 954**
Accounts payable	4 782	434	1 278
Current tax liabilities	317	163	-
Other liabilities	352	228	539
Accrued expenses and deferred income	2 359	2 190	2 240
Total short term liabilities	**7 810**	**3 015**	**4 057**
Total equity and liabilities	**44 229**	**56 928**	**51 011**

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Cash flow statement

SEKk	2014 July-Sept	2013 July-Sept	2014 Jan-Sept	2013 Jan-Sept	2013 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	(11 265)	(4 509)	(30 714)	(18 588)	(25 549)
Adjustments for non-cash items	1	1	2	2	2
Tax paid	45	41	135	113	101
Cash flow from operating activities before changes in working capital	**(11 219)**	**(4 467)**	**(30 578)**	**(18 474)**	**(25 445)**
Changes in short term liabilities	(109)	108	(1 984)	(645)	(162)
Changes in account payables	3 261	(375)	3 505	(1 897)	(1 053)
Changes in operating liabilities	943	527	248	(1 444)	(1 406)
Cash flow from operating activities	**(7 124)**	**(4 207)**	**(28 808)**	**(22 459)**	**(28 066)**
INVESTING ACTIVITIES					
Investment in intangible assets	-	-	-	-	-
Received group contribution	-	-	-	-	-
Investment in financial assets	-	-	-	-	-
Purchase of property, plant and equipment	-	-	-	-	-
Cash flow from investing activities	**0**	**0**	**0**	**0**	**0**
FINANCING ACTIVITIES					
New share issue	-	-	20 180	18 560	18 560
Cash flow from financing activities	**0**	**0**	**20 180**	**18 560**	**18 560**
Cash flow for the period					
Balance at beginning of period	47 799	59 116	49 302	58 808	58 808
Change in cash	-7 124	-4 207	(8 628)	-3 898	(9 506)
CASH BALANCE AT THE END OF THE PERIOD	40 675	54 910	40 675	54 910	49 302

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Change in Equity

SEKk	Share capital	Other	Share premium reserve	Net income	Total equity
Opening balance 2013-01-01	**1 066**	**266**	**86 466**	**(33 857)**	**53 941**
Loss allocation according AGM resolution	-	(266)	(33 590)	33 857	-
New share issue	89	-	18 472	-	18 560
Net result for the period	-	-	-	(18 588)	(18 588)
Closing balance 2013-09-30	**1 154**	**0**	**71 347**	**(18 588)**	**53 914**

Opening balance 2014-01-01	**1 154**	**0**	**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 2014-09-31	**1 243**	**0**	**65 890**	**(30 714)**	**36 419**

Key ratios

KSEK	2014 July-Sept	2013 July-Sept	2014 Jan-Sept	2013 Jan-Sept	2013 Jan-Dec
Operating result (EBIT)	-11 383	-4 796	-30 925	-18 997	-26 084
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-11 265	-4 509	-30 714	-18 588	-25 549
Cash flow from operating activities	-7 124	-4 207	-28 808	-22 459	-28 066
Total assets	44 229	56 928	44 229	56 928	51 011
Equity	36 419	53 914	36 419	53 914	46 954
Equity ratio %	82%	95%	82%	95%	92%
Return on equity %	neg.	neg.	neg.	neg.	neg.
Number of shares at the end of the period	23 622 403	21 935 089	23 622 403	21 935 089	21 935 089
Number of shares at the end of the period after dilution	24 022 403	22 335 089	24 022 403	22 335 089	22 335 089
Average number of shares under the period	22 602 598	20 618 613	22 276 344	20 437 361	21 190 579
Average number of shares under the period after dilutio	23 002 598	21 018 613	22 676 344	20 837 361	21 590 579
Share Data					
Result per share	-0,5	-0,2	-1,3	-0,8	-1,2
Result per average share	-0,5	-0,2	-1,4	-0,9	-1,2
Cash flow from operating activities	-0,3	-0,2	-1,2	-1,0	-1,3
Equity per share	1,5	2,5	1,5	2,5	2,1
Equity per share after dilution	1,5	2,4	1,5	2,4	2,1
Dividend	-	-	-	-	-
Number of employees	4	5	4	5	5

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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 2013 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 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 Annual Report for 2013.

Stockholm October 24, 2014

Jacques Näsström
CEO

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Next reports
The Year End report for 2014 will be published on February 17, 2015.

Certified Advisor
The company´s Certified Advisor is Erik Penser Bankaktiebolag.

Analysts who follow PledPharma
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