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PledPharma AB (publ)
Interim report first quarter 2014
25 April 2014

Recruitment of patients in the PLIANT study proceeds according to expectations

"25 patients have so far been treated in Part 2. With the approval from the DSMB, we can now also include patients receiving the add-on therapy bevacizumab, which will increase the inclusion base " says CEO Jacques Näsström

Significant events during January- March

- Positive data from the first part of the PLIANT study
- Net result amounted to SEK -6 775k (-8 032k)
- Cash and cash equivalents on March 31 amounted to SEK 41 388k (48 264k)
- Cash flow from operating activities amounted to SEK -7 914k (-10 544k)
- Result per share amounted to SEK -0.3 (-0.4)

Significant events after the end of the period

- Approval from the DSMB (Drug Safety Monitoring Board) to also include Avastin (bevacizumab) patients in Part 2 of the PLIANT study
- Martin Nicklasson, Certified pharmacist, PhD and Associate Professor at the Department of Pharmaceutics at University of Uppsala was elected to the board of directors
- The extra general meeting approved a new share issue which can generate a maximum of 20,25 MSEK
- Patent approved in Hong Kong for the use of PLED drugs in the treatment of cancer

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CEO comments

Our ongoing cancer study PLIANT is running smoothly and currently all participating countries are actively recruiting patients to Part 2 of the study. At present, 25 patients have been treated in addition to those already treated the first part of the study.

The results from the first part of the study, in which 11 patients were included, show that PledOx was well tolerated by patients undergoing standard chemotherapy with FOLFOX. Furthermore, results indicate that the severe sensory disturbances, which may occur during FOLFOX chemotherapy, did not occur in the patients pretreated with PledOx in Part 1 of the study. That PledOx appears to reduce the risk on chemotherapy-induced sensory nerve disorders, known as neuropathies, is what impresses most on the oncologists we talked to since this is a major clinical problem and the main reason for oxaliplatin-based chemotherapy being discontinued. We also noted that patients who received the lower dose of PledOx displayed fewer serious blood cell-related adverse events than patients treated with FOLFOX normally are expected to get.

Based on these positive data, we have lowered the highest dose in this study to optimize the effect of PledOx on both blood cells and sensory disturbances, which results in an expansion of the study and hence increased costs. We are therefore conducting a smaller rights issue of 20.25 million SEK (if fully subscribed) at a price 12 SEK/share mainly to finance the additional patients in the study. We have beforehand received subscription commitments equivalent to more than 50% of the issued amount from some of the major shareholders.

Furthermore, it's positive that we have received approval from the independent Drug Safety Monitoring Board, to also include patients receiving the add-on therapy bevacizumab. This will increase the recruitment base, as this adjunctive therapy to chemotherapy is common.

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. PledPharma also evaluates an existing drugs possibility to reduce the damage that occurs on the heart muscle when patients suffer from acute myocardial infarction. In addition to these projects, the company is also evaluating opportunities of using our technology platform in additional areas where there is a significant unmet medical need. 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. This means that the company has the potential to offer shareholders a good return on their investment. 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

In the PLIANT-study the drug PledOx is tested to reduce serious side effects from FOLFOX treatment of colorectal cancer. The primary objective is to evaluate the reduction of adverse events related to 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. The dose-escalation part comprises of 6 patients (3 on the low dose and 3 on the high dose) and 5 patients with PledOx and FOLFOX in combination with the antibody bevacizumab. The combination with the antibody bevacizumab as adjunctive therapy to chemotherapy is common especially in the U.S. and Portugal, but occurs in all countries in the study.

In the next part, the randomized part, aiming at roughly 126 patients from approximately 30 centers in Europe and the United States, the patients will be divided into three equal groups to receive either placebo or PledOx in two different doses (2 µmol/kg or 5 µmol/kg) . Based on the positive data from part 1 of the study, PledPharma have reduced the higher dose of 10 µmol/kg to 5 µmol/kg to optimize PledOx effect on sensory disorders and white blood cell-related side effects. This change in dose also means that the full number (i.e. 42) randomized patients must be included on the new dose. However, patients to be treated with the new dose of 5 µmol / kg will replace the majority of patients that should have been treated with 10 µmol / kg. 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. The continued development of PledPharma's PLED drug could be within other cancer chemotherapy as well as radiation therapy.

Positive results from acute myocardial infarction study

The results of the small clinical Phase IIa study MANAMI, examining a PLED-pharmaceutical's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with balloon dilatation have been presented. The results show that the PLED drug can be given to patients suffering from serious heart disease without any side effects. Despite the study's limited size, a tendency towards clinical effect was seen.

Further projects

In addition to the above projects, based on the company's technology platform, additional opportunities with unmet medical needs are evaluated. PledPharma has the potential to offer patients valuable and unique treatments for serious life-threatening diseases where there is also an opportunity for faster registration process of the drug in the United States through a process known as "breakthrough therapy". This means that PledPharma has the potential to offer shareholders a good return on their investment.

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 out 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.

IP

PledPharma has four inlicensed 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 and Japan and pending in China and Norway.

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Financial summary
First quarter 2014

Income
Revenue during the quarter amounted to SEK 90k (89k) and consisted of foreign exchange gains and rental revenues. Interest income for the quarter amounted to SEK 95k (140k).

Costs
Operating expenses in the fourth quarter amounted to SEK 6960k (8 260k). Of this, project costs amounted to 1 744k (4 197k) and employee costs to 1 246k (1 551k). Depreciation amounted to 1k (1k).

Results and financial position
Operating result for the quarter amounted to SEK -6 870k (-8 171k). Result after financial items amounted to SEK -6 775k (-8 032) and the result after tax was SEK -6 775k (-8 032k).

The cash flow during the quarter amounted to SEK -7 914k (-10 544k).

Cash flow from operating activities amounted to SEK -7 914k (-10 544). Cash at the end of the period amounted to 41 388k (48 264k).

Shareholders' equity amounted to SEK 40 178k (45 910k) and the company's equity ratio was 94 percent (91). Shareholders' equity per share amounted to SEK 1.8 (2.3). No long-term debts were outstanding (-). Current liabilities at 31 March 2014 amounted to SEK 2 434k(4 536k).

Employees
Average number of employees during the period was 4 (6) persons.

Options Program
As of March 31, 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 March 31, 2014 were 21 935 089. After full dilution, the number of shares will be 22 335 089. 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 Jan-March	2013 Jan-March	2013 Jan-Dec
Revenue			
Other operating income	90	89	287
	90	**89**	**287**
Operating expenses			
Project costs	(1 744)	(4 197)	(10 558)
Employee benefit costs	(1 246)	(1 551)	(6 025)
Other operating costs	(3 969)	(2 512)	(9 785)
Depreciation and impairment, fixed assets	(1)	(1)	(2)
Operating result	**-6 870**	**-8 171**	**-26 084**
Net financial items			
Depreciation of investment in subsidiaries			(32)
Interest income	95	140	568
Interest expense and similar items	-	(0)	(1)
Result after financial net	**(6 775)**	**(8 032)**	**(25 549)**
Result before tax	**(6 775)**	**(8 032)**	**(25 549)**
Tax	-	-	-
Result after tax	**(6 775)**	**(8 032)**	**(25 549)**
Share Data			
Number of shares at the end of period	21 935 089	20 247 775	21 935 089
Result per share before dilution (SEK)	(0,3)	(0,4)	(1,2)
Result per share after dilution (SEK)	(0,3)	(0,4)	(1,2)
Equity per share (SEK)	1,8	2,3	2,1
Equity per share after dilution (SEK)	1,8	2,2	2,1

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Balance sheet

SEKk	2014-03-31	2013-03-31	2013-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	4	7	5
Financial assets			
Shares and participations in group companies	50	50	50
Total fixed assets	**54**	**57**	55
Current assets			
Current receivables			
Receivables group companies	234	266	234
Other receivables	443	997	991
Prepaid expenses and accrued income	491	861	428
	1 169	2 125	1 653
Cash and bank balances	41 388	48 264	49 302
Total current assets	**42 557**	**50 389**	**50 956**
Total assets	**42 612**	**50 445**	**51 011**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1 154	1 066	1 154
Non-restricted equity			
Received group contributions			
Share premium reserve	45 798	52 876	71 348
Result for the period	(6 775)	(8 032)	(25 549)
	39 024	44 844	45 799
Total equity	**40 178**	**45 910**	**46 954**
Accounts payable	189	984	1 278
Current tax liabilities	27	143	-
Other liabilities	-	171	539
Accrued expenses and deferred income	2 218	3 238	2 240
Total short term liabilities	**2 434**	**4 536**	**4 057**
Total equity and liabilities	**42 612**	**50 445**	**51 011**

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Cash flow statement

SEKk	2014 Jan-March	2013 Jan-March	2013 Jan-Dec
OPERATING ACTIVITIES			
Result after financial net	-6 775	-8 032	-25 549
Adjustments for non-cash items	1	1	2
Tax paid	59	31	101
Cash flow from operating activities before changes in working capital	-6 715	-7 999	-25 445
Changes in short term liabilities	217	-648	-162
Changes in account payables	-1 088	-1 347	-1 053
Changes in operating liabilities	-327	-549	-1 406
Cash flow from operating activities	-7 914	-10 544	-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**
FINANCING ACTIVITIES			
New share issue	-	-	18 560
Share issue costs	-	-	-
Cash flow from financing activities	**0**	**0**	**18 560**
Cash flow for the period			
Balance at beginning of period	49 302	58 808	58 808
Change in cash	-7 914	-10 544	-9 506
CASH BALANCE AT THE END OF THE PERIOD	41 388	48 264	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	0	-266	-33 590	33 857	0
Net result for the period	0	0	0	-8 032	-8 032
Closing balance 2013-03-31	**1 066**	**0**	**52 876**	**-8 032**	**45 910**

Opening balance 2014-01-01	**1 154**	**0**	**71 347**	**-25 549**	**46 953**
Loss allocation according AGM resolution	-	-	(25 549)	25 549	-
Net result for the period	-	-	-	(6 775)	(6 775)
Closing balance 2014-03-31	**1 154**	**0**	**45 798**	**-6 775**	**40 178**

Key ratios

KSEK	2014 Jan-March	2013 Jan-March	2013 Jan-Dec
Operating result (EBIT)	-6 870	-8 171	-26 084
Operating margin %	neg.	neg.	neg.
Result for the period	-6 775	-8 032	-25 549
Cash flow from operating activities	-7 914	-10 544	-28 066
Total assets	42 612	50 445	51 011
Equity	40 178	45 910	46 954
Equity ratio %	94%	91%	92%
Return on equity %	neg.	neg.	neg.
Number of shares at the end of the period	21 935 089	20 247 775	21 935 089
Number of shares at the end of the period after dilution	22 335 089	20 647 775	22 335 089
Average number of shares under the period	21 935 089	20 247 775	21 190 579
Average number of shares under the period after dilutio	22 335 089	20 647 775	21 590 579
Share Data			
Result per share	-0,3	-0,4	-1,2
Result per average share	-0,3	-0,4	-1,2
Cash flow from operating activities	-0,4	-0,5	-1,3
Equity per share	1,8	2,3	2,1
Equity per share after dilution	1,8	2,2	2,1
Dividend	-	-	-
Number of employees	4	6	5

Accounting principles

This report has been prepared in compliance with the Swedish Financial Accounting Standards Council's recommendation RR 20 on Interim Financial Reporting and the Annual accounts Act. 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 not 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 April 25, 2014

Jacques Näsström
CEO

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Next reports

The interim report for the period April - June 2014 will be published on August 28, 2014.

Certified Advisor

The company´s Certified Advisor is Erik Penser Bankaktiebolag.

Analysts who follow PledPharma

Erik Penser Bankaktiebolag through Erik Penser Access.
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