PledPharma

PledPharma AB (publ)
Interim report second quarter 2014
28 August 2014

Over 100 patients included in the PLIANT cancer study
“70 patients have so far been treated with the new dosing in the PLIANT study. Together with the already treated 39 patients according to previous protocol, a total of over 100 patients have now been treated in Part 2 of the study. " says CEO Jacques Näsström

Quarter summary
- Net result amounted to SEK -12 674k (-6 048k)
- Cash and cash equivalents on June 30 amounted to SEK 47 799k (59 116k)
- Cash flow from operating activities amounted to SEK -13 770k (-7 708k)
- Result per share amounted to SEK -0.5 (-0.3)

Significant events during April – June

- Approval from the DSMB (Drug Safety Monitoring Board) to also include Avastin (bevacizumab) patients in Part 2 of the PLIANT study
- A rights issue was conducted which generated approximately 20 MSEK
- Patent approved in Hong Kong for the use of PLED-substances in the treatment of cancer
- Martin Nicklasson was elected to the board of directors

Significant events after the end of the period

- Futility analysis in PLIANT study completed and approved by the DSMB
- Positive data from patients treated with the FOLFOX in combination with bevacizumab in the first part of the PLIANT study

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CEO comments

We have now been able to significantly increase the recruitment rate in the PLIANT study and to date we have included 70 of the 126 patients that need to be included.

Additionally, 39 patients were treated according to the previous protocol (where about one third of the patients received a dose of 10 µmol/kg). This means that within the PLIANT study's second part, we have up until today treated at least 109 patients. The results from these first 39 patients will help us to build up a better dose-response curve and also strengthens the statistical evaluation together with the other 126 patients.

Recently the DSMB reported that the futility analysis for the first 30 patients in the study who have completed four treatment cycles with the chemotherapy mixture FOLFOX after pretreatment with either PledOx or placebo has been completed and that no negative impact on the anti-cancer effect of the chemotherapy was observed. This approval means that the PLIANT trial can proceed as planned. The safety analysis is important since there has been a concern that the PledOx drug not only protects healthy cells but also the cancer cells. The DSMB has therefore had an extra focus on this during the analysis but no negative impact on the anti-cancer effect of the chemotherapy has been observed. Additional safety analyzes will be conducted for every 30 patients enrolled that have completed four treatment cycles with chemotherapy. The next analysis will be preformed in the beginning of September.

We have now received data from an additional 5 patients in the first part of the PLIANT study. The data showed that PledOx was well tolerated by these 5 patients who were treated with the antibody Avastin (bevacizumab) in combination with FOLFOX chemotherapy. In total 11 patients have been treated in this open part of the study and preliminary analysis of the raw data indicated that PledOx® reduced the severe chemotherapy-induced side effects. Nine of these 11 patients underwent at least 6 treatment cycles of FOLFOX and none of these patients showed any grade 2 or worse neuropathy against an expected outcome of at least two patients. These data also indicated a reduction of serious blood-related side effects with the 5 µmol/kg dose of PledOx.

In summary, I feel that we have now taken a major step forward in our main study PLIANT and I'm confident that we will keep the goal that all patients should be included in the study at the end of the year. We now look forward to an exciting fall for PledPharma.

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. 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 as pretreatment to 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. 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's effect on both 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. However, due to randomization reasons the study was "restarted" after 39 patients, meaning that the total number of patients will be 39 +126. The 39 patients will be analyzed separately, but also together with the 126 to support the statistics of the 126 patients. 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".

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.

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
Second quarter 2014

Income
Revenue during the quarter amounted to SEK 44k (30k) and consisted of foreign exchange gains and rental revenues. Interest income for the quarter amounted to SEK 85k (0k).

Costs
Operating expenses for the quarter amounted to SEK 12 740k (6 067k). Of this, project costs amounted to 7 339k (1 917k) whereof 5 198k were milestone payments to GE Healthcare and CRO company Pharma Consulting Group. Employee costs amounted to 1 455k (1 600k). Depreciation amounted to 1k (1k).

Results and financial position
Operating result for the quarter amounted to SEK -12 696k (-6 037k). Result after financial items amounted to SEK -12 674k (-6 048k) and the result after tax was SEK -12 674k (-6 048k).

The cash flow during the quarter amounted to SEK 6 411k (10 853k). This positive cash flow comes from the rights issue completed in May.

Cash flow from operating activities amounted to SEK -13 770k (-7 708k). Cash at the end of the period amounted to 47 799k (59 116k).

Shareholders' equity amounted to SEK 47 685k (58 422k) and the company's equity ratio was 93 percent (95). Shareholders' equity per share amounted to SEK 2.0 (2.7). No long-term debts were outstanding (-). Current liabilities at 30 June 2014 amounted to SEK 3 368k (2 908k).

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

Options Program
As of June 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.

Rights issue
In May, a rights issue was carried out and 20 MSEK were raised. The number of shares increased by 1 687 314 to 23 622 403 shares. The share capital increased by 88 806 SEK to 1 243 284 SEK.

Share
Number of shares at June 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 April-June	2013 April-June	2014 Jan-June	2013 Jan-.June	2013 Jan-Dec
Revenue					
Other operating income	44	30	134	119	287
	44	**30**	**134**	**119**	**287**
Operating expenses					
Project costs	(7 339)	(1 917)	(9 083)	(6 114)	(10 558)
Employee benefit costs	(1 455)	(1 600)	(2 702)	(3 151)	(6 025)
Other operating costs	(3 945)	(2 549)	(7 890)	(5 054)	(9 785)
Depreciation and impairment, fixed assets	(1)	(1)	(1)	(1)	(2)
Operating result	**(12 696)**	**(6 037)**	**(19 542)**	**(14 202)**	**(26 084)**
Net financial items					
Depreciation of investment in subsidiaries					(32)
Interest income	85	0	179	138	568
Interest expense and similar items	(63)	(11)	(85)	(16)	(1)
Result after financial net	**(12 674)**	**(6 048)**	**(19 449)**	**(14 079)**	**(25 549)**
Result before tax	**(12 674)**	**(6 048)**	**(19 449)**	**(14 079)**	**(25 549)**
Tax	-	-	-	-	-
Result after tax	**(12 674)**	**(6 048)**	**(19 449)**	**(14 079)**	**(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)	(0,3)	(0,8)	(0,6)	(1,2)
Result per share after dilution (SEK)	(0,5)	(0,3)	(0,8)	(0,6)	(1,2)
Equity per share (SEK)	2,0	2,7	2,0	2,7	2,1
Equity per share after dilution (SEK)	2,0	2,6	2,0	2,6	2,1

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Balance sheet

SEKk	2014-06-30	2013-06-30	2013-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	4	6	5
Financial assets			
Shares and participations in group companies	50	50	50
Total fixed assets	**54**	**56**	**55**
Current assets			
Current receivables			
Receivables group companies	234	0	234
Other receivables	1 079	763	991
Prepaid expenses and accrued income	1 886	1 389	428
	3 200	2 152	1 653
Cash and bank balances	47 799	59 116	49 302
Total current assets	**50 998**	**61 269**	**50 956**
Total assets	**51 052**	**61 325**	**51 011**
Equity			
Restricted equity			
Share capital	1 243	1 154	1 154
Non-restricted equity			
Received group contributions			
Share premium reserve	65 890	71 347	71 348
Result for the period	(19 449)	(14 079)	(25 549)
	46 441	57 268	45 799
Total equity	**47 685**	**58 422**	**46 954**
Accounts payable	1 521	809	1 278
Current tax liabilities	32	153	-
Other liabilities	167	192	539
Accrued expenses and deferred income	1 647	1 749	2 240
Total short term liabilities	**3 368**	**2 903**	**4 057**
Total equity and liabilities	**51 052**	**61 325**	**51 011**

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Cash flow statement

SEKk	2014 April-June	2013 April-June	2014 Jan-June	2013 Jan-June	2013 Jan-Dec
OPERATING ACTIVITIES					
Result after financial net	(12 674)	(6 048)	(19 449)	(14 079)	(25 549)
Adjustments for non-cash items	1	1	1	1	2
Tax paid	30	41	89	72	101
Cash flow from operating activities before changes in working capital	**(12 643)**	**(6 007)**	**(19 358)**	**(14 006)**	**(25 445)**
Changes in short term liabilities	(2 031)	(105)	(1 696)	(753)	(162)
Changes in account payables	1 332	(175)	244	(1 522)	(1 053)
Changes in operating liabilities	(428)	(1 421)	(873)	(1 971)	(1 406)
Cash flow from operating activities	**(13 770)**	**(7 708)**	**(21 684)**	**(18 252)**	**(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	20 248	18 560	20 248	18 560	18 560
Share issue costs	(67)	-	(67)	-	-
Cash flow from financing activities	**20 180**	**18 560**	**20 180**	**18 560**	**18 560**
Cash flow for the period					
Balance at beginning of period	41 388	48 264	49 302	58 808	58 808
Change in cash	6 411	10 853	(1 503)	308	(9 506)
CASH BALANCE AT THE END OF THE PERIOD	47 799	59 116	47 799	59 116	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	(0)
New share issue	89	-	18 472	-	18 560
Net result for the period	-	-	-	(14 079)	(14 079)
Closing balance 2013-06-30	**1 154**	**0**	**71 347**	**(14 079)**	**58 422**

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				(19 449)	(19 449)
Closing balance 2014-03-31	**1 243**	**0**	**65 890**	**(19 449)**	**47 685**

Key ratios

KSEK	2014 April-June	2013 April-June	2014 Jan-June	2013 Jan-June	2013 Jan-Dec
Operating result (EBIT)	-12 696	-6 037	-19 542	-14 202	-26 084
Operating margin %	neg.	neg.	neg.	neg.	neg.
Result for the period	-12 674	-6 048	-19 449	-14 079	-25 549
Cash flow from operating activities	-13 770	-7 708	-21 684	-18 252	-28 066
Total assets	51 052	61 325	51 052	61 325	51 011
Equity	47 685	58 422	47 685	58 422	46 954
Equity ratio %	93%	95%	93%	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	21 204 690
Average number of shares under the period after dilutio	23 002 598	21 018 613	22 676 344	20 837 361	21 604 690
Share Data					
Result per share	-0,5	-0,3	-0,8	-0,6	-1,2
Result per average share	-0,6	-0,3	-0,9	-0,7	-1,2
Cash flow from operating activities	-0,6	-0,4	-0,9	-0,8	-1,3
Equity per share	2,0	2,7	2,0	2,7	2,1
Equity per share after dilution	2,0	2,6	2,0	2,6	2,1
Dividend	-	-	-	-	-
Number of employees	4	6	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 August 28, 2014

Jacques Näsström
CEO

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Next reports

The interim report for the period July - September 2014 will be published on October 24, 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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