PledPharma

# PledPharma AB (publ)
# Year end report 2013

## Significant events after the end of the period

- Positive data from the first part of the PLIANT study
- A continuation in part of the first U.S. patent has been approved.
- A patent for the use of PLED pharmaceuticals in cancer treatment was approved in Japan

## Significant events during January- December

- The first patient in the second part of the Phase IIb study PLIANT has been included
- Promising results from the acute myocardial infarction study MANAMI
- Patent application for the use of PLED pharmaceuticals in the treatment of cancer approved and issued in the US, China and Russia
- FDA approved IND application for the clinical trial PLIANT in the US
- Rights issue provided the company with 18.6 million SEK.
- IMS Consulting Group appointed advisor for the commercialization of PledOx®
- Sten Nilsson, MD, PhD Professor of Oncology at Karolinska University Hospital and Institutet in Stockholm elected as member of the board.
- PledOx® registered as a trademark in the US, Switzerland, Japan and Australia
- Patent approved in South Africa

## October-December

- Net result amounted to SEK -6 961k (-8 389k)
- Cash and cash equivalents on December 31 amounted to SEK 49 302k (58 808k)
- Cash flow from operating activities amounted to SEK -5 607k (-6 679k)
- Result per share amounted to SEK -0.3 (-0.4)

## January – December

- Net result amounted to SEK -25 549k (-33 857k)
- Cash flow from operating activities amounted to SEK -28 066k (-31 957k)
- Result per share amounted to SEK -1.2 (-1.7)

## CEO comments

Our focus during 2013 has been on the oncology study PLIANT. The study examines whether PledOx® can reduce serious side effects in the treatment of colorectal cancer using the chemotherapy FOLFOX. During the first quarter of 2013 the first patient in the PLIANT study (part one) was included and all patients have now been treated. Part two of the study, where roughly 126 patients will be included started in November and a number of patients have now been treated according to plan and the majority of centers are actively recruiting patients.

As previously has been reported, the results of the first part of the PLIANT study shows that PledOx was well tolerated by patients treated with FOLFOX. Furthermore, the peripheral sensory disorders that may occur as a consequence of chemotherapy treatment did not occur in the patients pretreated with PledOx. The fact that it appears as PledOx can reduce the chemotherapy induced peripheral sensory nerve disorders known as neuropathies was what impressed most on the oncologists we talked to. The reason being that chemotherapy induced neuropathy is a major clinical problem and the main reason for discontinuing oxaliplatin-based chemotherapy.

We observed that patients pretreated with the lower dose of PledOx had fewer events of serious white blood cell-related side effects than patients treated with oxaliplatin normally are expected to get. Based on these positive data, PledPharma has applied to the regulatory authorities for reduction of the higher dose of 10 µmol/kg to 5 µmol/kg. The reduction is primarily based on the apparent better effect on white blood cell-related side effects with the lower dose of PledOx. This change in dose also means that the full number (i.e. 42) randomized patients must be included in order to be able to statistically evaluate the new dose, which results in an expansion of the study and an extension of the trial period. The current estimate is that all patients should be included in the study before the end of 2014 and that overall (top-line) data should be available towards the end of the first quarter of 2015. We will also investigate the possibility of getting a quicker registration in the United States for neuropathy indication by so called "breakthrough therapy designation" This means that PledOx has the potential to get registered as a pharmaceutical in the US based on the preliminary clinical top-line results from the PLIANT study.

During 2013 IMS Consulting Group (IMSCG) has been working to investigate the commercialization strategy for PledOx. IMSCG have concluded that PledOx will most likely be subsidized the U.S. and in the five largest European markets (EU5) and that PledOx will gain wide access to these markets, a major uptake and attractive pricing, meaning a potential multi-billion dollar market which can also be expanded with additional use in other types of cancers using other chemotherapies or radiotherapy.

During 2013, the myocardial infarction study MANAMI was completed and the results show that the PLED pharmaceutical was well tolerated by patients in the study and can be given safely to seriously ill cardiac patients without any side effects. Despite the study's limited size, a tendency towards clinical effect in reducing infarct size and improving the heart's pump function was seen. We are currently evaluating the commercial opportunity of this project (PP-099) and looking forward to an exciting 2014, says CEO Jacques Näsström.

## COMPANY PROFILE

PledPharma is a Swedish pharmaceutical company that develops new therapies for prevention of life threatening diseases related to oxidative stress. The initial objective is to develop a drug, PledOx®, which reduces the serious side effects associated with chemotherapy. The current market for supportive cancer care is some USD 10 billion. PledPharma also evaluates an existing medicines possibility to reduce the damage that occurs on the heart muscle when a patient suffers from myocardial infarction in the project PP-099. In addition to these projects, the company is also evaluating opportunities of using the technology-platform in other medical conditions 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 "breakthrough therapy designation2. It also 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 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). Before PledOx can be evaluated with FOLFOX in combination with the antibody bevacizumab in the randomized part, another 3 patients will be needed on this regimen.

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. For further details please see www.clinicaltrials.gov

## POSITIVE RESULTS FROM THE MANAMI-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. Results show that the PLED pharmaceutical was well tolerated by patients in the study and 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.

## MISSION

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

## BUSINESS MODEL

PledPharma focus on developing clinical projects through Phase IIb and then out-license the continued development and commercialization for traditional consideration including signing fees, milestone payments and royalty payments.

## VISION

PledPharma will be a leading pharmaceutical company, which develops unique therapies with breakthrough therapy potential for life-threatening diseases related to oxidative stress. .

## BUSINESS GOALS

The goal is a successful out-licensing of PledOx®.

## STRATEGY

PledPharma conducts a partner-based development model aiming to maximize project performance, while financial exposure is reduced. Operations are conducted with a small focused internal organization that has extensive industry experience ensuring that the

company has the expertise needed to very cost-effectively drive value growth in clinical programs in collaboration with our external partners.

## OXIDATIVE STRESS AND PLED PHARMACEUTICALS

Oxidative stress is caused by the overproduction of harmful oxygen/nitrogen molecules. PledOx is a drug candidate in the patented class PLED, which protects the body's normal cells against oxidative stress. As the PLED pharmaceuticals reduce the oxidative stress there is a potential to use the substance at various diseases. The world market only in supportive cancer treatment is over 10 billion USD.

## IP

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 and China, 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 a non-manganese complexed form of the compound" was recently approved in South Africa as the first country.

PledPharma (STO:PLED) is listed on NASDAQ OMX First North. For more information, please visit: www.pledpharma.se

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# Financial summary

## Fourth quarter 2013

**Income**
Revenue during the quarter amounted to SEK 159k (115k) and consisted of foreign exchange gains. Interest income for the quarter amounted to SEK 142k (255k).

**Costs**
Operating expenses in the fourth quarter amounted to SEK 7 221k (8 758k). Of this, project costs amounted to 2 981k (3 702k) and employee costs to 1 488k (2 248k). Depreciation amounted to 1k (1k).

**Results and financial position**
Operating result for the quarter amounted to SEK -7 062k (-8 643k). Result after financial items amounted to SEK -6 961k (-8 389) and the result after tax was SEK -6 961k (-8 389k).

The cash flow during the quarter amounted to SEK -5 607k (-6 679k).
Cash flow from operating activities amounted to SEK -5 607k (-6 679k).
Cash at the end of the period amounted to 49 302k (58 808k).

Shareholders' equity amounted to SEK 46 954k (53 941k) and the company's equity ratio was 92 percent (89). Shareholders' equity per share amounted to SEK 2.1 (2.7). No long-term debts were outstanding (-). Current liabilities at 31 December 2013 amounted to SEK 4 057k (6 516k).

**Employees**
Average number of employees during the period was 5 (6) persons.

**Options Program**
131 000 call options, in the in 2012 decided options scheme, were subscribed by employees in the company as of December 31, 2013.

**Significant risks and uncertainties**
Risks are described in the prospectus issued in connection with a right share issue that took place in June 2011 as well as in the Annual Report for 2012. No changes in the company's risk assessment have taken place during the period.

**Share**
Number of shares at December 31, 2013 were 21 935 089. After full dilution, the number of shares were 22 335 089. PledPharma shares were listed on NASDAQ OMX First North on 7 April 2011.

**Rights issue**
In May, a rights issue was carried out and 18.6 MSEK were raised. The number of shares increased by 1 687 314 to 21 935 089 shares. The share capital increased by 88 806 SEK to 1 154 478 SEK.

**Seasonal variations**
PledPharma activity is not subject to seasonal variations.

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# Income statement

| SEKk | 2013 Oct-Dec | 2012 Oct-Dec | 2013 Jan-Dec | 2012 Jan-Dec |
|---|---|---|---|---|
| **Revenue** | | | | |
| Activated work for own account | - | - | - | - |
| Capitalized costs | - | - | - | - |
| Other operating income | 159 | 115 | 287 | 672 |
| | **159** | **115** | **287** | **672** |
| **Operating expenses** | | | | |
| Project costs | (2 981) | (3 702) | (10 558) | (18 601) |
| Employee benefit costs | (1 488) | (2 248) | (6 025) | (8 127) |
| Other operating costs | (2 751) | (2 807) | (9 785) | (9 249) |
| Depreciation and impairment, fixed assets | (1) | (1) | (2) | (4) |
| **Operating result** | **-7 062** | **-8 643** | **-26 084** | **-35 310** |
| | | | | |
| **Net financial items** | | | | |
| Depreciation of investment in subsidiaries | -32 | | | |
| Interest income | 142 | 255 | 568 | 1 454 |
| Interest expense and similar items | (9) | (2) | (1) | (1) |
| **Result after financial net** | **(6 961)** | **(8 389)** | **(25 549)** | **(33 857)** |
| | | | | |
| **Result before tax** | **(6 961)** | **(8 389)** | **(25 549)** | **(33 857)** |
| | | | | |
| Tax | - | - | - | - |
| **Result after tax** | **(6 961)** | **(8 389)** | **(25 549)** | **(33 857)** |
| | | | | |
| **Share Data** | | | | |
| Number of shares at the end of period | 21 935 089 | 20 247 775 | 21 935 089 | 20 247 775 |
| Result per share before dilution (SEK) | (0,3) | (0,4) | (1,2) | (1,7) |
| Result per share after dilution (SEK) | (0,3) | (0,4) | (1,1) | (1,6) |
| Equity per share (SEK) | 2,1 | 2,7 | 2,1 | 2,7 |
| Equity per share after dilution (SEK) | 2,1 | 2,6 | 2,1 | 2,6 |

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# Balance sheet

| SEKk | 2013-12-31 | 2012-12-31 |
|---|---|---|
| ASSETS | | |
| **Fixed assets** | | |
| *Intangible assets* | | |
| Capitalized expenditure for research and development | - | - |
| Concessions, patents, licences, trademarks | - | - |
| | - | - |
| | | |
| *Property, plant and equipment* | | |
| Equipment, tools, fixtures and fittings | 5 | 7 |
| | | |
| *Financial assets* | | |
| Shares and participations in group companies | 50 | 50 |
| **Total fixed assets** | **55** | **57** |
| | | |
| **Current assets** | | |
| *Current receivables* | | |
| Receivables group companies | 234 | 266 |
| Other receivables | 991 | 629 |
| Prepaid expenses and accrued income | 428 | 697 |
| | 1 653 | 1 592 |
| | | |
| *Cash and bank balances* | 49 302 | 58 808 |
| **Total current assets** | **50 956** | **60 399** |
| | | |
| **Total assets** | **51 011** | **60 457** |
| | | |
| EQUITY AND LIABILITIES | | |
| | | |
| **Equity** | | |
| *Restricted equity* | | |
| Share capital | 1 154 | 1 066 |
| | | |
| *Non-restricted equity* | | |
| Received group contributions | - | 266 |
| Share premium reserve | 71 348 | 86 466 |
| Result for the period | (25 549) | (33 857) |
| | 45 799 | 52 876 |
| | | |
| **Total equity** | **46 954** | **53 941** |
| | | |
| Accounts payable | 1 278 | 2 331 |
| Current tax liabilities | 0 | - |
| Other liabilities | 539 | 403 |
| Accrued expenses and deferred income | 2 240 | 3 782 |
| **Total short term liabilities** | **4 057** | **6 516** |
| | | |
| **Total equity and liabilities** | **51 011** | **60 457** |

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# Cash flow statement

| SEKk | 2013 Oct-Dec | 2012 Oct-Dec | 2013 Jan-Dec | 2012 Jan-Dec |
|---|---|---|---|---|
| OPERATING ACTIVITIES | | | | |
| Result after financial net | -6 961 | -8 389 | -25 549 | -33 857 |
| Adjustments for non-cash items | 1 | 1 | 2 | 4 |
| Tax paid | -12 | 4 | 101 | -32 |
| **Cash flow from operating activities before changes in working capital** | -6 972 | -8 384 | -25 445 | -33 885 |
| Changes in short term liabilities | 483 | 678 | -162 | -726 |
| Changes in account payables | 843 | -435 | -1 053 | 899 |
| Changes in operating liabilities | 38 | 1 462 | -1 406 | 1 755 |
| **Cash flow from operating activities** | -5 607 | -6 679 | -28 066 | -31 957 |
| INVESTING ACTIVITIES | | | | |
| Investment in intangible assets | - | - | - | - |
| Received group contribution | - | - | - | 266 |
| Investment in financial assets | - | - | - | (50) |
| Purchase of property, plant and equipment | - | - | - | - |
| **Cash flow from investing activities** | **0** | **0** | **0** | **216** |
| FINANCING ACTIVITIES | | | | |
| New share issue | - | - | 18 560 | - |
| Share issue costs | - | - | - | - |
| **Cash flow from financing activities** | **0** | **0** | **18 560** | **0** |
| Cash flow for the period | | | | |
| Balance at beginning of period | 54 910 | 65 487 | 58 808 | 90 548 |
| Change in cash | -5 607 | -6 679 | -9 506 | -31 740 |
| CASH BALANCE AT THE END OF THE PERIOD | 49 302 | 58 808 | 49 302 | 58 808 |

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# Change in Equity

| SEKk | Share capital | Other | Share premium reserve | Net income | Total equity |
|---|---|---|---|---|---|
| **Opening balance 2012-01-01** | **1 066** | **-** | **119 712** | **-33 246** | **87 532** |
| Transfer of the 2010 year result | - | - | -33 246 | 33 246 | - |
| Group contribution received | | 266 | | | 266 |
| Net result for the period | - | - | - | -33 857 | -33 857 |
| **Closing balance 2012-12-31** | **1 066** | **266** | **86 466** | **-33 857** | **53 941** |
| | | | | | |
| **Opening balance 2013-01-01** | **1 066** | **266** | **86 466** | **-33 857** | **53 941** |
| Transfer of 2012 year result | | -266 | -33 590 | 33 857 | |
| Share issue | 88 | | 18 472 | | |
| Net result for the period | | | | -25 549 | -25 549 |
| **Closing balance 2013-12-31** | **1 154** | - | **71 348** | **-25 549** | **46 954** |

# Key ratios

| KSEK | 2013 Oct-Dec | 2012 Oct-Dec | 2013 Jan-Dec | 2012 Jan-Dec |
|---|---|---|---|---|
| Operating result (EBIT) | -7 062 | -8 643 | -26 084 | -35 310 |
| Operating margin % | neg. | neg. | neg. | neg. |
| Result for the period | -6 961 | -8 389 | -25 549 | -33 857 |
| Cash flow from operating activities | -5 607 | -6 679 | -28 066 | -31 957 |
| Total assets | 51 011 | 60 457 | 51 011 | 60 457 |
| Equity | 46 954 | 53 941 | 46 954 | 53 941 |
| Equity ratio % | 92% | 89% | 92% | 89% |
| Return on equity % | neg. | neg. | neg. | neg. |
| Number of shares at the end of the period | 21 935 089 | 20 247 775 | 21 935 089 | 20 247 775 |
| Number of shares at the end of the period after dilution | 22 335 089 | 20 647 775 | 22 335 089 | 20 647 775 |
| Average number of shares under the period | 21 935 089 | 20 247 775 | 21 190 579 | 20 247 775 |
| Average number of shares under the period after dilutio | 22 335 089 | 20 647 775 | 21 590 579 | 20 547 775 |
| **Share Data** | | | | |
| Result per share | -0,3 | -0,4 | -1,2 | -1,7 |
| Result per average share | -0,3 | -0,4 | -1,2 | -1,7 |
| Cash flow from operating activities | -0,3 | -0,3 | -1,3 | -1,6 |
| Equity per share | 2,1 | 2,7 | 2,1 | 2,7 |
| Equity per share after dilution | 2,1 | 2,6 | 2,1 | 2,6 |
| Dividend | - | - | - | - |
| Number of employees | 5 | 6 | 5 | 6 |

## 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 2012 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 prospectus issued in connection with the right share issue that took place in June 2011 as well as in the Annual Report for 2012.

Stockholm February 19, 2014

Jacques Näsström
CEO

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**Next reports**
The interim report for the period January-March 2014 will be published on April 25, 2014.

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

**Analysts who follow PledPharma**
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