PledPharma

# PledPharma AB (publ)
# Interim Report Third Quarter 2013

## Significant events after the end of the period

- All patients required to initiate the second part of the Phase IIb study PLIANT have been included
- Promising results from the acute myocardial infarction study MANAMI
- Patent from PledPharma's second series of worldwide applications has been approved in South Africa, as the first country.
- PledOx® registered as a trademark in Japan

## Significant events during July - September

- Patent for the use of PLED compounds in the treatment of cancer approved in China
- Net result amounted to SEK -4 509k (-5 642k)
- Cash and cash equivalents on September 30 amounted to SEK 54 910k (65 487k)
- Cash flow from operating activities amounted to SEK -4 207k (-3 121k)
- Result per share amounted to SEK -0.2 (-0.3)

## Significant events during January – September

- Patent application for the use of PLED compounds in the treatment of cancer approved and issued in the US 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 and Australia
- Net result amounted to SEK -18 588k (-25 467k)
- Cash flow from operating activities amounted to SEK -22 459k (-25 010k)
- Result per share amounted to SEK -0.8 (-1.3)

## CEO comments

The myocardial infarction study MANAMI is completed and the results show that the PLED substance 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 was seen.

MANAMI is a small study in a very large and difficult disease area. As PledPharma has previously communicated, we have chosen to focus our resources on the oncology project. However, based on these results we will now evaluate the commercial potential of the myocardial infarction indication.

In the oncology study PLIANT the last out of six patients in the dose escalation part, is under treatment with PledOx. When this sixth patient has been treated with the third dose and the Drug Safety Monitoring Board (DSMB) once again concur, then the randomized part of the study with 126 patients from approximately 30 centers in Europe and the United States can start. If everything goes according to plan, a decision by the DSMB to start the second part can be expected during the week commencing with November 11.

When the dose escalation part has been completed, the data from this open part of the study will be analyzed and presented separately. Overall, patients have then been treated with more than 40 doses PledOx in conjunction with chemotherapy and all patients have tolerated PledOx well, says CEO Jacques Näsström.

## COMPANY PROFILE

PledPharma is a Swedish specialty pharma company that develops PledOx® in order to prevent serious side effects during chemotherapy treatment of cancer. These side effects are often so severe that the treatment cannot be completed as planned. The global market for supportive cancer care is about SEK 70 billion. PledOx is a drug candidate in the patented substance class PLED, which protects the body's normal cells against oxidative stress. PledOx is a lowMEM (Low Molecular Enzyme Mimetic) that mimics the body's own enzyme manganese superoxide dismutase (MnSOD), which is our main protection against oxidative stress. Oxidative stress is caused by overproduction of harmful oxygen/nitrogen molecules, e.g. as a result of chemotherapy treatment. PledPharma is also evaluating the possibility of using PLED substances during the treatment of other life-threatening diseases.

## ABOUT THE PLIANT-STUDY

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 a low dose and 3 on a high dose) Before PledOx can be evaluated with FOLFOX in combination with the antibody Avastin in the randomized part, another 3 patients will be needed on this regimen.

In the next part, the randomized part, aiming at 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

## ABOUT THE MANAMI-STUDY

The results of the small clinical Phase IIa study MANAMI, examining a PLED-compound's ability to limit reperfusion injuries in patients with acute myocardial infarction treated with balloon dilatation have been presented. Results show that PLED substance 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.

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## 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 specialty pharma company, which develops drugs that protect healthy cells from oxidative stress during treatment of life-threatening diseases.

## 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.

## MARKET

The market for the treatment of loss of white blood cells in cancer was more than US$ 5 billion in 2010 according to Datamonitor. PledOx has the potential to dramatically reduce the side effects in the treatment of colorectal cancer with oxaliplatin, the base of FOLFOX used in colorectal cancer treatment that in 2010 was given in 3.3 million doses globally according to IMS. IMS has in a focus group study in the United States estimated a price of 2,000 USD per dose. Since our aim is that PledOx is to be used at each dose of oxaliplatin a very large market potential is assumed even with a limited market penetration. Furthermore, PledOx has the possibility not only to be used in case of loss of white blood cells, but can also reduce nerve damage and has the potential to be used in other chemotherapies as well as radiation. This may implicate that PledOx can contribute to growth in the market segment where currently there is no treatment.

## OXIDATIVE STRESS AND PLED SUBSTANCES

Oxidative stress is caused by the overproduction of harmful oxygen/nitrogen molecules. PledOx is a drug candidate in the patented substance class PLED, which protects the body's normal cells against oxidative stress. As the PLED substances 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-compounds, 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 compounds 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

## Third quarter 2013

**Income**
Revenue during the quarter amounted to SEK 9k (34k) and consisted of foreign exchange gains. Interest income for the quarter amounted to SEK 288k (677k).

**Costs**
Operating expenses in the second quarter amounted to SEK 4 805k (6 349k). Of this, project costs amounted to 1 462k (2 419k) and employee costs to 1 387k (1 686k). Depreciation amounted to 1k (1k).

**Results and financial position**
Operating result for the quarter amounted to SEK -4 796k (-6 315k). Result after financial items amounted to SEK -4 509k (-5 642) and the result after tax was SEK -4 509k (-5 642k).
The cash flow during the quarter amounted to SEK -4 207k (-3 121k).
Cash flow from operating activities amounted to SEK -4 207k (-3 121k).
Cash at the end of the period amounted to 54 910k (65 487k).

Shareholders' equity amounted to SEK 53 914k (62 064k) and the company's equity ratio was 95 percent (92). Shareholders' equity per share amounted to SEK 2.5 (3.1). No long-term debts were outstanding (-). Current liabilities at 30 September 2013 amounted to SEK 3015k (5 436k).

**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 September 30, 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 September 30, 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 July-Sept | 2012 July-Sept | 2013 Jan-Sept | 2012 Jan-Sept | 2012 Jan-Dec |
|---|---|---|---|---|---|
| **Revenue** | | | | | |
| Activated work for own account | - | - | - | - | - |
| Capitalized costs | - | - | - | - | - |
| Other operating income | 9 | 34 | 128 | 557 | 672 |
| | **9** | **34** | **128** | **557** | **672** |
| **Operating expenses** | | | | | |
| Project costs | (1 462) | (2 419) | (7 576) | (14 899) | (18 601) |
| Employee benefit costs | (1 387) | (1 686) | (4 538) | (5 880) | (8 127) |
| Other operating costs | (1 956) | (2 243) | (7 010) | (6 422) | (9 249) |
| Depreciation and impairment, fixed assets | (1) | (1) | (2) | (3) | (4) |
| **Operating result** | **-4 796** | **-6 315** | **-18 997** | **-26 647** | **-35 310** |
| | | | | | |
| **Net financial items** | | | | | |
| Interest income | 288 | 677 | 426 | 1 199 | 1 454 |
| Interest expense and similar items | (1) | (4) | (17) | (20) | (1) |
| **Result after financial net** | **(4 509)** | **(5 642)** | **(18 588)** | **(25 467)** | **(33 857)** |
| | | | | | |
| **Result before tax** | **(4 509)** | **(5 642)** | **(18 588)** | **(25 467)** | **(33 857)** |
| | | | | | |
| Tax | - | - | - | - | - |
| **Result after tax** | **(4 509)** | **(5 642)** | **(18 588)** | **(25 467)** | **(33 857)** |
| | | | | | |
| **Share Data** | | | | | |
| Number of shares at the end of period | 21 935 089 | 20 247 775 | 21 935 089 | 20 247 775 | 20 247 775 |
| Result per share before and after dilution (SEK) | (0,2) | (0,3) | (0,8) | (1,3) | (1,7) |
| Equity per share (SEK) | 2,5 | 3,1 | 2,5 | 3,1 | 2,7 |
| Equity per share after dilution (SEK) | 2,4 | 3,1 | 2,4 | 3,1 | 2,6 |

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# Balance sheet

| SEKk | 2013-09-30 | 2012-09-30 | 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 | 6 | 9 | 7 |
| | | | |
| *Financial assets* | | | |
| Shares and participations in group companies | 50 | 50 | 50 |
| **Total fixed assets** | **56** | **59** | **57** |
| | | | |
| **Current assets** | | | |
| *Current receivables* | | | |
| Receivables group companies | - | - | 266 |
| Other receivables | 667 | 562 | 629 |
| Prepaid expenses and accrued income | 1 296 | 1 393 | 697 |
| | 1 963 | 1 955 | 1 592 |
| | | | |
| *Cash and bank balances* | 54 910 | 65 487 | 58 808 |
| **Total current assets** | **56 873** | **67 442** | **60 399** |
| | | | |
| **Total assets** | **56 928** | **67 501** | **60 457** |
| **Equity** | | | |
| *Restricted equity* | | | |
| Share capital | 1 154 | 1 066 | 1 066 |
| | | | |
| *Non-restricted equity* | | | |
| Received group contributions | - | - | 266 |
| Share premium reserve | 71 347 | 86 466 | 86 466 |
| Result for the period | (18 588) | (25 467) | (33 857) |
| | 52 759 | 60 999 | 52 876 |
| | | | |
| **Total equity** | **53 914** | **62 064** | **53 941** |
| | | | |
| Accounts payable | 434 | 2 766 | 2 331 |
| Current tax liabilities | 163 | 233 | - |
| Other liabilities | 228 | 515 | 403 |
| Accrued expenses and deferred income | 2 190 | 1 922 | 3 782 |
| **Total short term liabilities** | **3 015** | **5 436** | **6 516** |
| | | | |
| **Total equity and liabilities** | **56 928** | **67 501** | **60 457** |

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# Cash flow statement

| SEKk | 2013 July-Sept | 2012 July-Sept | 2013 Jan-Sept | 2012 Jan-Sept | 2012 Jan-Dec |
|---|---|---|---|---|---|
| OPERATING ACTIVITIES | | | | | |
| Result after financial net | -4 509 | -5 642 | -18 588 | -25 467 | -33 857 |
| Adjustments for non-cash items | 1 | 1 | 2 | 3 | 4 |
| Tax paid | 41 | -13 | 113 | -36 | -32 |
| **Cash flow from operating activities before changes in working capital** | -4 467 | -5 654 | -18 474 | -25 501 | -33 885 |
| Changes in short term liabilities | 108 | 1 007 | -645 | -1 089 | -678 |
| Changes in account payables | -375 | 763 | -1 897 | 1 334 | 899 |
| Changes in operating liabilities | 527 | 763 | -1 444 | 245 | 1 708 |
| **Cash flow from operating activities** | -4 207 | -3 121 | -22 459 | -25 010 | -31 956 |
| INVESTING ACTIVITIES | | | | | |
| Investment in intangible assets | - | - | - | - | - |
| Received group contribution | - | - | - | - | 266 |
| Investment in financial assets | - | - | - | (50) | (50) |
| Purchase of property, plant and equipment | - | - | - | - | - |
| **Cash flow from investing activities** | **0** | **0** | **0** | **-50** | **216** |
| FINANCING ACTIVITIES | | | | | |
| New share issue | - | - | 18 560 | - | - |
| Share issue costs | - | - | - | - | - |
| **Cash flow from financing activities** | **0** | **0** | **18 560** | **0** | **0** |
| Cash flow for the period | | | | | |
| Balance at beginning of period | 59 116 | 68 608 | 58 808 | 90 548 | 90 548 |
| Change in cash | -4 207 | -3 121 | -3 898 | -25 060 | -31 740 |
| CASH BALANCE AT THE END OF THE PERIOD | 54 910 | 65 487 | 54 910 | 65 487 | 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 | - |
| Net result for the period | - | - | - | -25 467 | -25 467 |
| **Closing balance 2012-09-30** | **1 066** | - | **86 466** | **-25 467** | **62 064** |

| | | | | | |
|---|---|---|---|---|---|
| **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 | 89 | | 18 472 | | |
| Net result for the period | | | | -18 588 | -18 588 |
| **Closing balance 2013-09-30** | **1 154** | - | **71 347** | **-18 588** | **53 914** |

# Key ratios

| KSEK | 2013 July-Sept | 2012 July-Sept | 2013 Jan-June | 2012 Jan-June | 2012 Jan-Dec |
|---|---|---|---|---|---|
| Operating result (EBIT) | -4 796 | -6 315 | -18 997 | -26 647 | -35 310 |
| Operating margin % | neg. | neg. | neg. | neg. | neg. |
| Result for the period | -4 509 | -5 642 | -18 588 | -25 467 | -33 857 |
| Cash flow from operating activities | -4 207 | -3 121 | -22 459 | -25 010 | -31 956 |
| Total assets | 56 928 | 67 501 | 56 928 | 67 501 | 60 457 |
| Equity | 53 914 | 62 064 | 53 914 | 62 064 | 53 941 |
| Equity ratio % | 95% | 92% | 95% | 92% | 89% |
| Return on equity % | neg. | 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 | 20 247 775 |
| Number of shares at the end of the period after dilution | 22 335 089 | 20 247 775 | 22 335 089 | 20 247 775 | 20 647 775 |
| Average number of shares under the period | 20 637 155 | 20 247 775 | 20 566 997 | 20 247 775 | 20 247 775 |
| Average number of shares under the period after dilution | 21 037 155 | 20 247 775 | 20 966 997 | 20 547 775 | 20 547 775 |
| **Share Data** | | | | | |
| Result per share | -0,2 | -0,3 | -0,8 | -1,3 | -1,7 |
| Result per average share | -0,2 | -0,3 | -0,9 | -1,3 | -1,7 |
| Cash flow from operating activities | -0,2 | -0,2 | -1,0 | -1,2 | -1,6 |
| Equity per share | 2,5 | 3,1 | 2,5 | 3,1 | 2,7 |
| Equity per share after dilution | 2,4 | 3,1 | 2,4 | 3,1 | 2,6 |
| Dividend | - | - | - | - | - |
| Number of employees | 5 | 6 | 6 | 6 | 6 |

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## 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 October 25, 2013

Jacques Näsström
CEO

**For further information contact:**
Jacques Näsström, CEO cell +46 73 713 09 79
Michaela Gertz, CFO cell +46 70 926 17 75

**Next reports**
The interim report for the period January-December 2013 will be published on February 21, 2014.

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

**Analysts who follow PledPharma**
Erik Penser Bankaktiebolag through Erik Penser Access.
Redeye Klas Palin
Aktiespararna (Analysguiden)

PledPharma AB (publ)
Grev Turegatan 11c
114 46 Stockholm
Phone: +46 8 679 72 10
www.pledpharma.se
Org.nr. 556706-6724