PledPharma

PledPharma AB (publ)
Year end report January – December 2016
February 24, 2017

Preparations for the Phase III program with PledOx®

January – December summary

- Net result for the year amounted to KSEK -38 223 (-43 836)
- Cash equivalents at the end of the period amounted to KSEK 393 998 (50 360)
- Cash flow from operating activities amounted to KSEK -36 115 (-51 153)
- Result per share amounted to SEK -1.3 (-1.5)

Fourth quarter summary

- Net result for the quarter amounted to KSEK -11 462 (-8 794)
- Cash equivalents at the end of the quarter amounted to KSEK 393 998 (50 360)
- Cash flow from operating activities amounted to KSEK -9 344 (-8 953)
- Result per share amounted to SEK -0.3 (-0.3)

Significant events during the year

- PledPharma completed a guaranteed rights issue of SEK 406 million in order to take PledOx® into phase III
- PledPharma conducted a constructive meeting with the European Medicines Agency (EMA)
- Follow-up data indicates that PledOx® does not negatively interfere with the anti-cancer effect of chemotherapy
- PledPharma presented the Phase IIb PLIANT study data at the American Society of Clinical Oncology (ASCO) cancer meeting

Significant events after the end of the period

- Gunilla Osswald and Elisabeth Svanberg were elected to the Board of Directors. Håkan Åström and Sten Nilsson will remain on the board.

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CEO comment

In 2016 we decided to develop our main product, PledOx®, towards an application for market registration. This means that we will start pivotal clinical trials, i.e. phase III trials in patients with colorectal cancer during this year. The results from these studies will form the basis for a new drug application (NDA) to the Food and Drug Administration ("FDA") in the US and for a marketing authorization application (MAA) to the European Medicines Agency ("EMA") in Europe and as a base for discussions with potential partners. To finance the phase III studies up to top-line results we conducted a new rights issue during the fall.

The results from the Phase IIb study PLIANT has been met with great interest by both clinicians and potential partners. The results were presented in June at the American Society of Clinical Oncology (ASCO), by the study's lead investigator Professor Bengt Glimelius. The follow-up data presented during the year confirms that PledOx® provides a clinically meaningful reduction of neuropathy compared with the placebo group. Long-term follow-up also showed that PledOx® has no apparent negative impact on the anti-cancer effect of the chemotherapy.

During the year, we also had a constructive discussion with EMA regarding the continued clinical development of PledOx® where we received confirmation that the next development stage for PledOx® is Phase III. Several potential partners have, however, expressed a wish for additional studies, with patient-reported neuropathy as the primary endpoint, before they are ready for further business discussions. PledPharma has therefore decided to move forward into clinical development by ourselves and thereby create added value in the company.

Since last autumn, there are a series of ongoing activities in preparation for the start of the Phase III studies – that among other things include design of the studies, regulatory preparations and manufacturing.

The previous studies with PledOx® were performed in patients with metastatic colorectal cancer but as we move into Phase III we will, in addition to metastatic colorectal cancer patients, also include patients treated adjuvantly for colorectal cancer. These patients have great potential to be cured from their cancer. PledOx® aims to prevent these patients from receiving chronic and debilitating chemotherapy induced nerve injury.

In February this year Gunilla Osswald and Elisabeth Svanberg were elected as new board members to strengthen the expertise in phase III clinical development. Gunilla (PhD in Biopharmaceutics and Pharmacokinetics) has extensive experience in preclinical and clinical drug development, in big pharma and smaller biotech companies and is the CEO at BioArctic AB. Elisabeth (MD, PhD and associate professor of surgery) has extensive experience from leading positions at e.g. Bristol-Myers Squibb and Janssen Pharmaceuticals and is the Chief Development Officer at Ixaltis SA.

In 2016, we furthermore worked on the preparations for the start of a proof of principle study with Aladote® - a drug candidate with the potential to prevent liver damage in connection with overdosing of paracetamol/acetaminophen. The study aims to identify the possibility to add Aladote® to the existing treatment for acetaminophen poisoning.

In 2017, when PledPharma moves into Phase III with PledOx® and furthermore takes Aladote® into a proof of principle study, this means that PledPharma will have two potential first-in-class drugs in clinical development. We are confident that this will create significant value for our shareholders.

Jacques Näsström, CEO, PledPharma AB (publ)

PledPharma in brief

PledPharma develops new drugs that protect the body against oxidative stress – a potentially debilitating and sometimes life-threatening condition that can be caused by chemotherapy treatment and following acetaminophen (paracetamol) overdose. The company's most advanced project PledOx® reduces nerve damage associated with chemotherapy. A phase IIb study has been conducted and will serve as the basis for the continued phase III development. The drug candidate Aladote® is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning.

PledPharma (STO: PLED) is listed on Nasdaq First North. Erik Penser Bank is the company's Certified Adviser (tel +46 8 463 80 00). For more information, see www.pledpharma.se

Vision
PledPharma is a leading pharmaceutical company, developing new, unique therapies for debilitating and life-threatening conditions.

Business idea
PledPharma develops therapies to improve the treatment of debilitating and life-threatening conditions based on the company's patented and clinically proven technology, PLED (PyridoxyL EtylDiamin based compounds).

Goals
PledPharma's goal is to create value for patients, society and the shareholders by developing effective new treatments for debilitating and life-threatening conditions. PledPharma's primary business objective is:

- To successfully develop PledOx® to market registration
- To successfully develop Aladote® to clinical "proof of concept"

Business model and strategy
PledPharma uses its patented and clinically proven technology, PLED, to develop treatments for debilitating and life-threatening conditions caused by oxidative stress. The company focuses on a few key projects. The projects are selected based on several criteria, the most important are the medical need, scientific rational and development path. That the potential treatments are in areas with limited competition is considered to be beneficial.

With a small number of projects in development PledPharma can give each project the attention and resources necessary for successful development. The company has an entrepreneurial approach and manage their projects in a resource efficient manner. The business is run by its own expert organization with expertise in preclinical and clinical development collaborating with partners, including conducting studies. PledPharma also intends to work with partners to manufacture, sale and distribute future approved products. Until profitable, the organization will mainly be financed through equity and licensing of projects to commercial partners.

Patents and trademarks
PledPharma has four patents/patent applications in a large number of countries, aiming to get an exclusive market protection and broad commercial rights for the manufacture and use of PLED therapeutics.

PledPharma portfolio of patents expands with new applications and approvals as applications are processed and new innovations are made, for example, regarding formulations and new application areas.

PledPharmas patent applications are approved in 16 countries. The first is so far approved in the US, EU, China, Hong Kong, Russia, Australia, Japan, South Korea and Israel with patent protection until 2028. The second is approved in Australia, Japan, Canada, Mexico, Russia and South Africa with patent protection until 2030. For the third and most important, the compound patent for calmangafodipir, for the active ingredient of the drug candidates PledOx® and Aladote® is approved in the US with patent protection until December 2032. The fourth application has entered the national phase and is expected to provide patent protection until October 2033.

PledPharma has trademark protection for PledOx® since 2010 and since 2015 for Aladote®.

Our projects

PledPharma develops therapeutics based on PLED technology and currently has two projects in or about to enter the clinical development.

PledOx®

PledOx® (chemotherapy induced peripheral neuropathy)

PledOx® is developed to provide patients, that are treated adjuvantly or for metastatic colorectal cancer, protection against the nerve damage that can occur in conjunction with chemotherapy treatment. The side-effects of chemotherapy can lead to a reduction of the planned dose or in worst case, treatment discontinuation. Unfortunately, the chemotherapy can induce permanent nerve damage. Patients may, for example, experience discomfort and numbness in the hands and feet, difficulty with balance with risk of falling and problems with sensation that can last for the rest of their lives. PledOx® is a "first-in-class" treatment and there is a large medical need as there are currently no preventive or curative treatment for nerve damage from chemotherapy.

The results from the Phase IIb study PLIANT, where patients with metastatic colorectal cancer (colorectal cancer) treated with the chemotherapy combination FOLFOX and PledOx® (calmangafodipir), indicates that the patients who received PledOx® had a lower risk than the placebo group to suffer from nerve damage during the chemotherapy. Patients also showed a reduction in chronic symptoms of nerve damage up to 6 months after treatment. This is the first time where one has succeeded in preventing chemotherapy caused nerve damage in a clinically significant manner in a controlled clinical trial and also without interfering with the cancer treatment. Currently, preparations are in progress for a Phase III program with PledOx®.

Aladote®

Aladote® (Acetaminophen overdose)

The Aladote® project is based on calmangafodipir, that has been evaluated and tested pre-clinically with promising results. A clinical trial for the prevention of acetaminophen induced acute liver failure (ALF) in patients that have overdosed acetaminophen is under preparation. Aladote® is a "first-in-class" treatment and there is a large medical need as there are currently no adequate treatment for patients arriving late to the hospital.

Status in PledPharma´s ongoing projects

PledOx® – protects the nerves

Pre clinic	Phase I	Phase II	Phase III	Approval (USA/EU)

▶ Preparation for phase III study

Aladote® – protects the liver

Pre clinical	Phase I	Phase II	Phase III	Approval (US/EU)

▶ Preparation for phase II study

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Financial summary - Group
January - December 2016

Revenue
Revenue amounted to KSEK 41 (58) during the quarter and to KSEK 1 026 (378) for the year. The revenue consisted of rental revenues, foreign exchange gains and a retroactive price adjustment in the PLIANT study. Interest income amounted to KSEK 33 (38) for the quarter and to KSEK 140 (203) for the year.

Expenses
Operating expenses amounted to KSEK 11 537 (8 890) for the quarter and to KSEK 39 389 (44 406) for the year. Of these, planned project costs amounted to KSEK 6 371 (3 993) for the quarter and to KSEK 19 513 (26 093) for the year. The increase of costs during the quarter was associated with the production of PledOx for the Phase III program. Over the year, the project costs decreased primarily due to reduced activity in PLIANT study.

Employee costs amounted to KSEK 1 727 (1 820) for the quarter and to KSEK 6 357 (6 909) for the year. Other operating costs amounted to KSEK 3 370 (3 039) for the quarter and to KSEK 13 162 (11 274) for the year. The increase is partly due to increased licensing fees due to the development in the USD/SEK and partly because of increased costs for consultants. Depreciation amounted to KSEK 0 (1) for the quarter and to KSEK 0 (2) for the year.

Results
Operating result amounted to KSEK -11 495 (-8 832) for the quarter and to KSEK -38 363 (-44 028) for the year. Result after financial items amounted to KSEK -11 462 (-8 794) for the quarter and to KSEK -38 223 (-43 836) for the year.

No income tax was recorded for the quarter (-) or for the year. Result per average share amounted to SEK -0.3 (-0.3) for the quarter and to SEK -1.3 (-1.5) for the year.

Financial position

Cash
Cash at 31 December 2016 amounted to KSEK 393 998 (50 360).

Cash flow
Cash flow from operating activities amounted to KSEK -9 344 (-8 953) for the quarter and to KSEK -36 115 (-51 153) for the year. The cash flow from financing activities amounted to KSEK 379 753 (0) for the quarter and to KSEK 379 753 (1 210) due to a new share issue. Cash flow amounted to KSEK -370 408 (-8 953) for the quarter and to KSEK 343 638 (-49 943) for the year.

Equity and equity ratio
At December 31 2016 shareholders' equity amounted to KSEK 389 562 (48 032). The company's equity ratio was 98 (92) %. Shareholders' equity per share amounted to SEK 8.0 (1.7), at the end of the period.

Debts
No long-term debts were outstanding (-), current liabilities amounted to KSEK 6 874 (4 329).

Investments, tangible and intangible assets
During the period, investments in tangible fixed assets corresponding to 0 (0) SEK.

Employees
Average number of employees during the period was four (four) persons, 3 women and 1 man.

Share
The number of shares at December 31 2016 were 48 666 656. PledPharma´s shares were listed on NASDAQ Stockholm First North on 7 April 2011.

Parent Company
The parent company's expenses for the quarter amounted to KSEK 11 537 (8 890) and to KSEK 39 389 (44 390) for the year.

The parent company's result after financial items amounted to KSEK -11 462 (-8 811) for the quarter and to KSEK -38 223 (-43 836) for the year.

Consolidated statement of comprehensive income

KSEK	2016 Oct-Dec	2015 Oct-Dec	2016 Jan-Dec	2015 Jan-Dec
Revenue				
Other operating income	41	58	1 026	378
	41	**58**	**1 026**	**378**
Operating expenses				
Project costs	-6 371	-3 993	-19 513	-26 093
Employee benefit costs	-1 727	-1 820	-6 357	-6 909
Depreciation and impairment, fixed assets	0	-1	0	-2
Other operating expenses	-69	-37	-356	-128
Operating result	**-11 495**	**-8 832**	**-38 363**	**-44 028**
Net financial items				
Interest income	33	38	140	203
Interest expense and similar items	-	-	-	(10)
Result after financial net	**-11 462**	**-8 794**	**-38 223**	**-43 836**
Result before tax	**-11 462**	**-8 794**	**-38 223**	**-43 836**
Tax	-	-	-	-
Result after tax	**-11 462**	**-8 794**	**-38 223**	**-43 836**

Statement of comprehensive income

Other comprehensive income				
Comprehensive income for the period	**-11 462**	**-8 794**	**-38 223**	**-43 836**

Net earnings and comprehensive income is entirely attributable to parent company shareholders

Share Data				
Number of shares at the end of period	48 666 656	28 388 883	48 666 656	28 388 883
Average number of shares during period	33 678 737	28 388 883	29 675 504	28 373 133
Result per share before and after dilution (SEK)	-0,3	-0,3	-1,3	-1,5
Result per average share (SEK)	-0,3	-0,3	-1,3	-1,5
Equity per share (SEK)	8	1,7	8	1,7

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Consolidated statement of financial position

KSEK	2016-12-31	2015-12-31
ASSETS		
Fixed assets		
Property, plant and equipment		
Equipment, tools, fixtures and fittings	0	0
Total fixed assets	0	0
Current assets		
Current receivables		
Other receivables	1 344	788
Prepaid expenses and accrued income	1 093	1 213
	2 437	2 001
Cash and bank balances	393 998	50 360
Total current assets	**396 435**	**52 361**
Total assets	**396 435**	**52 361**
EQUITY AND LIABILITIES		
Equity		
Share capital	2 561	1 494
Other capital contributions	425 224	90 374
Accumulated loss including net loss	-38 223	-43 836
Total equity	**389 562**	**48 032**
Short term liabilities		
Accounts payable	4 678	1 766
Other liabilities	213	177
Accrued expenses and deferred income	1 983	2 386
Total short term liabilities	**6 873**	**4 329**
Total equity and liabilities	**396 435**	**52 361**

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Consolidated statement of cash flows

KSEK	2016 Oct-Dec	2015 Oct-Dec	2016 Jan-Dec	2015 Jan-Dec
OPERATING ACTIVITIES				
Result after financial net	-11 462	-8 794	-38 223	-43 836
Adjustments for non-cash items	0	1	0	2
Tax paid	0	0	0	0
Cash flow from operating activities before changes in working capital	**-11 462**	**-8 794**	**-38 223**	**-43 833**
Changes in short term liabilities	13	1 163	-436	1 161
Changes in account payables	2 407	-715	2 912	-8 201
Changes in operating liabilities	-302	-607	-367	-280
Cash flow from operating activities	**-9 344**	**-8 953**	**-36 115**	**-51 153**
INVESTING ACTIVITIES				
Cash flow from investing activities	**0**	**0**	**0**	**0**
FINANCING ACTIVITIES				
New share issue	405 555	0	405 555	1 210
Cost new share issue	-25 803	0	-25 803	0
Cash flow from financing activities	**379 753**	**0**	**379 753**	**1 210**
Cash flow for the period				
Balance at beginning of period	23 590	59 313	50 360	100 304
Change in cash	370 408	-8 953	343 638	-49 943
CASH BALANCE AT THE END OF THE PERIOD	393 998	50 360	393 998	50 360

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Consolidates statement of changes in equity

KSEK	Share capital	Other	Net income	Total equity
Opening balance 2015-01-01	**1 492**	**137 586**	**-48 420**	**90 658**
Loss allocation according AGM resolution	0	-48 420	48 420	0
New share issue	2	1 208	0	1 210
Net result for the period	0	0	-43 836	-43 836
Closing balance 2015-12-31	**1 494**	**90 374**	**-43 836**	**48 032**
Opening balance 2016-01-01	**1 494**	**90 374**	**-43 836**	**48 032**
Loss allocation according AGM resolution	0	-43 836	43 836	0
New share issue	1 067	404 488	0	405 555
Issue costs	0	-25 803	0	-25 803
Net result for the period	0	0	-38 223	-38 223
Closing balance 2016-12-31	**2 561**	**425 224**	**-38 223**	**389 562**

Consolidated key ratios

KSEK	2016 Oct-Dec	2015 Oct-Dec	2016 Jan-Dec	2015 Jan-Dec
Equity	389 562	48 032	389 562	48 032
Equity ratio %	98%	92%	98%	92%
Return on equity %	neg.	neg.	neg.	neg.
Number of shares at the end of the period	48 666 656	28 388 883	48 666 656	28 388 883
Number of shares at the end of the period after dilution	48 666 656	28 388 883	48 666 656	28 388 883
Average number of shares under the period	33 678 737	28 388 883	29 722 216	28 373 133
Average number of shares under the period after dilution	33 678 737	28 388 883	29 722 216	28 373 133
Share Data (SEK)				
Result per share	-0,3	-0,3	-1,3	-1,5
Cash flow from operating activities	-0,3	-0,3	-1,2	-1,8
Equity per share	8,0	1,7	8,0	1,7
Dividend	-	-	-	-
Number of employees	4	4	4	4

Key Ratios definitions

Ratios that have been calculated according to IFRS

Earnings per share
Net income divided by average number of shares before dilution

Number of shares at end of period
The number of outstanding shares before dilution at the end of the period

Number of shares after dilution
The number of issued shares after dilution effect of potential shares at end of period

Average number of shares during the period
Average number of outstanding shares before dilution for the period

Average number of shares during the period after dilution
Average number of issued shares after dilution effect of potential shares

Number of employees (average)
The number of employees at the end of each period

Ratios that have not been calculated in accordance with IFRS

Equity ratio, %
The company defines the ratio as follows; The period's closing equity divided by the period's closing balance sheet. The company uses the alternate ratio Equity as it shows the proportion of total assets represented by shareholders' equity and has been included to allow investors to assess the company's capital structure.

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Return on equity, %
The company defines the ratio as follows; Net income divided by shareholders' equity. The company uses the alternate key figure Return on equity, % because the company believes that the key ratio gives investors a better understanding of the return generated on the total capital that the shareholders have invested in the Company.

Cash flow from operations per share
The company defines the ratio as follows; Cash flow from operating activities divided by the number of shares outstanding at the end of the period. The company uses the alternate key figure Cash flow from operations per share because the Company believes that the key ratio gives investors a better understanding of the company's cash flow in relation to its number of shares adjusted for changes in the number of shares outstanding during the period.

Equity per share
The company defines the ratio as follows; Equity divided by number of shares outstanding at the end of the period. The company uses the alternate key ratio equity per share because the Company believes that the key ratio gives investors a better understanding of the historical return per share adjusted for changes in the number of shares outstanding during the period.

Parent company - Income statement

KSEK	2016 Oct-Dec	2015 Oct-Dec	2016 Jan-Dec	2015 Jan-Dec
Revenue				
Other operating income	41	57	1 026	378
	41	**57**	**1 026**	**378**
Operating expenses				
Project costs	-6 371	-3 993	-19 513	-26 093
Employee benefit costs	-1 727	-1 820	-6 357	-6 909
Depreciation and impairment, fixed assets	0	-1	0	-2
Other operating expenses	-69	-37	-356	-128
Operating result	**-11 495**	**-8 832**	**-38 363**	**-44 012**
Net financial items				
Depreciation of investment in subsidiaries	-	-16	-	-16
Interest income	33	38	140	203
Interest expense and similar items	-	0	-	-10
Result after financial net	**-11 462**	**-8 811**	**-38 223**	**-43 836**
Result before tax	**-11 462**	**-8 811**	**-38 223**	**-43 836**
Tax	-	-	-	-
Result after tax	**-11 462**	**-8 811**	**-38 223**	**-43 836**

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Parent company - Balance sheet

KSEK	2016-12-31	2015-12-31
ASSETS		
Fixed assets		
Property, plant and equipment		
Equipment, tools, fixtures and fittings	0	0
Financial assets		
Shares and participations in group companies	50	50
Total fixed assets	50	**50**
Current assets		
Current receivables		
Other receivables	1 344	787
Prepaid expenses and accrued income	1 093	1 213
	2 437	2 001
Cash and bank balances	393 998	50 360
Total current assets	**396 435**	**52 361**
Total assets	**396 485**	**52 411**
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	2 561	1 494
Non-restricted equity		
Share premium reserve	425 224	90 374
Result for the period	-38 223	-43 836
Total equity	**389 562**	**48 032**
Short term liabilities		
Debt to group company	50	51
Accounts payable	4 678	1 766
Other liabilities	213	176
Accrued expenses and deferred income	1 983	2 386
Total short term liabilities	**6 924**	**4 379**
Total equity and liabilities	**396 485**	**52 411**

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Notes

NOTE 1 - Accounting principles

PledPharma applies International Financial Reporting Standards (IFRS) as adopted by the EU. This report is prepared in accordance with IAS 34 Interim Financial Reporting and the Annual Accounts Act. The parent company's interim report is prepared in accordance with the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and the Swedish Annual Accounts Act. Applied accounting principles and calculation methods are the same as in the latest annual report for 2015.

NOTE 2 – Additional information

Other information in accordance with IAS 34.16A are found on pages before the income statement and statement of comprehensive income. Information on earnings, cash flow and financial position, see page 6. For events after the period, see page 1.

NOTE 3 – Financial assets and debts

Group 31 December 2016

The fair value and carrying value are shown in the table below:

KSEK	**Account and loan receivables**	**Financial debts**	**Total carrying amount**	**Fair value**
Accounts receivable	-	-	**-**	**-**
Accrued but not invoiced income	-	-	**-**	**-**
Cash	393 998	-	393 998	393 998
Total assets	**393 998**	**-**	**393 998**	**393 998**
Accounts payable	-	4 678	4 678	4 678
Other liabilities	-	-	**-**	**-**
Total debts	**-**	**4 678**	**4 678**	**4 678**

Group 31 December 2015

The fair value and carrying value are shown in the table below:

	Account and loan receivables	**Financial debts**	**Total carrying amount**	**Fair value**
Accounts receivable	-	-	**-**	**-**
Accrued but not invoiced income	-	-	**-**	**-**
Cash	50 360	-	50 360	50 360
Total assets	**50 360**	**-**	**50 360**	**50 360**
Accounts payable	-	1 766	1 766	1 766
Other liabilities	-	-	**-**	**-**
Total debts	**-**	**1 766**	**1 766**	**1 766**

NOTE 4- Related parties transactions

Consulting agreements existed for 2016 with Board members Håkan Åström, Sten Nilsson and Martin Nicklasson who receives maximum compensation on an annual basis as follows: Håkan Åström KSEK 582, Sten Nilsson KSEK 204 and Martin Nicklasson KSEK 100. During the period the Board member Martin Nicklasson invoiced KSEK 25 and Håkan Åström KSEK 291 in consulting fees.

Other information

Next reports
Interim report Jan – March 2017, April 25 2017
Interim report Jan – June 2017, August 30 2017
Interim report Jan – September 2017, October 20 2017

Annual general meeting
The Board plans to hold the Annual General Meeting April 25, 2017 at. 16:00. The Annual Report will be published on the company website by April 4 2017.

PledPharma is required to publish the information in this report in accordance with Market Abuse Act. and Swedish Securities Market Act. The information was submitted for publication at 8:00 on February 24, 2017.

This report, and further information is available on the website, www.pledpharma.se

This is a translation of the Swedish interim report that has not been reviewed by the company's auditor.

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PledPharma

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.

Stockholm, February 24, 2017

Håkan Åström	Gunilla Osswald	Elisabeth Svanberg
Chairman of the board	*Board member*	*Board member*

Sten Nilsson
Board member