PledPharma AB (publ)
Year-end report 2014
17 February 2015

Successful recruitment in the PLIANT-study and strengthened financial position

Significant events during the fourth quarter

- All patients included in the PLIANT study
- The third and last futility analysis in the PLIANT study approved by the DSMB
- The new project PP-100, with the drug candidate Aladote™ against acetaminophen induced poisoning, presented
- A rights issue for the financing of PP-100 raised approximately SEK 72m net.

Quarter and full year summary

- Net result for the quarter amounted to SEK -17 706 (-6 961)k and to -48 420 (-25 549)k for the full year
- Cash and cash equivalents on December 31 amounted to SEK 100 043 (49 302)k
- Cash flow from operating activities amounted to SEK -12 577 (-5 607)k for the quarter and to -41 385 (-28 066)k for the full year
- Result per share amounted to SEK -0.7 (-0.3) for the quarter and to -2.1 (-1.2) for the full year.

Other significant events during 2014

- Positive data from the first part of the PLIANT study
- PledPharma was awarded Nordic Star of the Year at the Nordic Life Science Days 2014.

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CEO comment

2014 has been an eventful year for PledPharma not least as we reached several very important developmental milestones in the colorectal cancer study PLIANT. Among other things, we have received data from the first open part of the study, and included all patients in the randomized part of the study. We have also presented and financed a new and important project for the treatment of acetaminophen (paracetamol) induced poisoning, PP-100 with the drug candidate Aladote™.

An important goal for the PLIANT study has been to show that PledOx® only protects healthy cells and not cancer cells, from the effect of chemotherapy. Three safety analyzes have therefore been performed by the independent expert panel DSMB. The analyses were made on the first 90 patients who underwent four treatments with chemotherapy, and were completed without remarks. This means that the given doses of PledOx did not attenuate the effect chemotherapy has on cancer cells, and that the study was allowed to proceed as planned.

During the summer we also got the results for the five patients from the first open part of the PLIANT study treated with the antibody bevacizumab in combination with FOLFOX. The results showed that the patients tolerated PledOx well.

In addition to our progress with the PLIANT study we have during the year worked on a new project based on the PLED platform which is assessed to have a significant commercial potential. The project PP-100, with the drug candidate Aladote, is focused on reducing or preventing the occurrence of serious liver damage as a result of overdosing of acetaminophen, one of the most common drug poisonings.

Although we are working with external advisors for licensing, we believe that it is also important at this stage to strengthen our internal business development skills and experience. We have therefore at the beginning of 2015 decided to bring in Anders Härfstrand, MD, PhD as responsible for Business Development. Anders, who has extensive experience in licensing, will together with an internal team and our external advisors conduct the company's work around an out-licensing of PledOx. We have also in the beginning of 2015 significantly strengthened our internal resources in senior technical patent skills by Professor James Van Alstine, who is inventor on more than 50 patents.

At the end of the year we secured the development of the project through a rights issue with the goal to take the project through a phase II study and a licensing deal.

Acetaminophen is the most widely used drug in the world in the treatment of pain. Acetaminophen poisoning is also one of the most common poisonings for intentional or unintentional overdosing. Acetaminophen is considered to be one of the gentlest of pain medications and it can be difficult to learn at the onset that acetaminophen has been accidentally overdosed because the difference between normal and toxic dose is small while the symptoms can be quite vague or missing altogether in the first days after overdosing. Acetaminophen poisoning can lead to, among other things, acute liver failure, which in turn may result in the need for liver transplantation and can at worst result in death.

The existing treatment for overdose of acetaminophen, N-acetylcysteine, is effective if the affected seeks medical care within eight hours after ingestion of acetaminophen. For patients with later arrival there is currently no well-functioning treatment despite the high risk of liver damage. The project goal is to extend this treatment window, and preclinical results clearly show that the drug candidate Aladote can normalize the elevation of certain liver enzymes that are indicators of liver failure long after N-acetylcysteine ceased working.

Entering 2015, we stand strengthened both financially and developmentally with a solid foundation in our PLED platform, and with the important development projects for PledOx and Aladote. In the near future, overall performance (top-line data) from PLIANT study is to be presented.

Jacques Näsström
CEO, PledPharma AB (publ)

PledPharma in brief

PledPharma is a Swedish pharmaceutical company that develops new therapies for the treatment of life threatening diseases. PledPharma has the potential to offer patients valuable and unique treatments for serious life-threatening diseases where there also is an opportunity for earlier registration in the US through "breakthrough therapy" designation.

In project PP-095, PledOx® is developed to reduce severe side-effects associated with chemotherapy. In project PP-100, the ability of Aladote™ in reducing or preventing acute liver failure due to acetaminophen (paracetamol) overdose is investigated. Project PP-099 is based on limiting reperfusion injuries in patients with acute myocardial infarction undergoing percutaneous coronary intervention.

PledPharma (STO:PLED) is since April 2011 listed on NASDAQ Stockholm First North. Erik Penser Bankaktiebolag is the Certified Adviser. For further information, please visit www.pledpharma.se

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Vision

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

Business idea, goals and strategy

PledPharma develops therapeutics to improve the treatment of life-threatening diseases based on the company's patented and clinically proven technology, PLED.
The primary goal is a successful out-licensing of the PledOx project with attractive commercial revenues and to develop Aladote to commercialization toghether with a partner.
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 typical compensation is anticipated to be received in the form of signing fees, milestone payments and royalties.

Patents and trademarks

PledPharma has four in-licensed patents covering therapeutic use of PLED therapeutics. In addition, PledPharma has four applications for a large number of countries aiming to get an exclusive market protection and broad commercial rights for the manufacture and use of PLED therapeutics. The first is so far approved in the US, China, Hong Kong, Russia, Australia and Japan with patent protection until 2028. The second was approved in 2013 in South Africa as the first country with patent protection until 2030.

PledPharma has trademark protection for PledOx® and has recently applied for trademark protection for Aladote™.

Our projects

PledPharma develops therapeutcs based on PLED therapeutics and currently has three projects in or about to enter the clinical phase.

PledOx® (colorectal cancer)

PledOx® (calmangafodipir) is tested in an international phase IIb study in patients with colorectal cancer treated with the chemotherapy combination FOLFOX. The study goes according to plan and the first results are expected by the end of the first quarter of 2015.

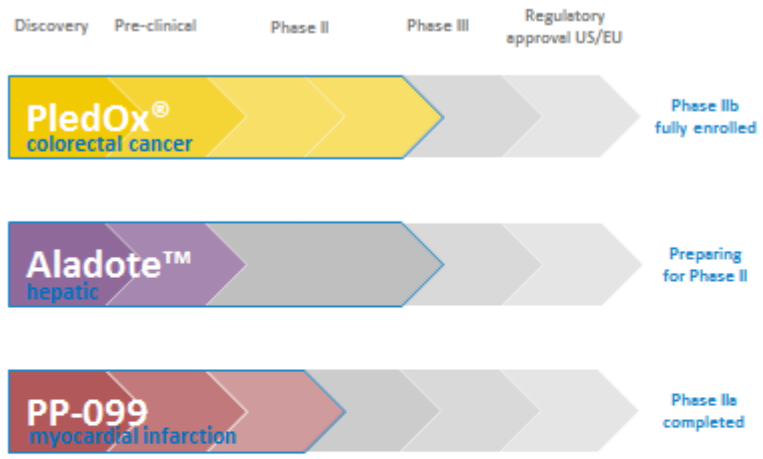
Aladote™ (hepatic/ALF)

Aladote™ is a new formulation based on calmangafodipir evaluated and tested pre-clinically with promising results. A clinical trial for the prevention of acute liver failure (ALF) in patients with acetaminophen induced poisoning is planned.

Project PP-099 (myocardial infarction)

The PLED substance mangafodipir has been tested in a smaller national phase IIa study in heart attack patients undergoing angioplasty. The study indicated that PLED therapeutics can reduce reperfusion damage after acute myocardial infarction. No additional studies will be carried out without a partner.

Status in PledPharma´s onging projects



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Financial summary
Fourth quarter and full year 2014

Revenue
Revenue amounted to SEK 56 (159)k during the quarter and to SEK 233 (287)k for the full year, and consisted of foreign exchange gains and rental revenues. Interest income amounted to SEK 3 (142)k for the quarter and to SEK 312 (568)k for the full year.

Expenses
Operating expenses amounted to SEK 17 698 (7 221)k for the quarter and to SEK 48 799 (26 371)k for the full year.
Of these, project costs mainly related to the ongoing clinical study in PP95 project amounted to SEK 13 577 (2 981)k for the quarter and to SEK 29 459 (10 558)k for the full year.
Employee costs amounted to SEK 1 898 (1 488)k for the quarter and to SEK 6 271 (6 025)k for the full year.
Depreciation amounted to SEK 1 (1)k for the quarter and to 2 (2)k for the full year.

Results and financial position
Operating result amounted to SEK -17 642 (-7 062)k for the quarter and to -SEK 48 566 (-26 084)k for the full year.

Result after financial items amounted to SEK -17 706 (-6 961)k for the quarter and for the full year to SEK -48 420 (-25 549)k for the quarter. No income tax was recorded for the quarter (-) or for the full year period (-).

Cash flow from operating activities amounted to SEK -12 577 (-5 607)k for the quarter and to SEK -41 385 (-28 066)k for the full year.
Cash flow from financing activities amounted to SEK 71 945 (-)k for the quarter and to SEK 92 125 (18 560)k for the full year and was a consequence of performed new issues of shares. Cash flow amounted to SEK 59 368 (-5 607)k for the quarter and to SEK 50 740 (-9 506)k for the full year.

Cash per 31 December 2014 amounted to SEK 100 043 (49 302)k.

Shareholders' equity per 31 December 2014 amounted to SEK 90 658 (46 954)k and the company's equity ratio was 88 (92) %. Shareholders' equity per share amounted to SEK 3.2 (2.1). No long-term debts were outstanding (-). Current liabilities at the end of the year amounted to SEK 12 810 (4 057)k.

Employees
Average number of employees during the quarter and the full year period was 4 (5) persons.

Options Program
As of December 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 December 31, 2014 were 28 346 883. After full dilution, the number of shares will be 28 746 883. PledPharma´s shares were listed on NASDAQ Stockholm First North on 7 April 2011.

Seasonal variations
PledPharma´s activity is not subject to seasonal variations.

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Income statement

SEKk	2014 Oct-Dec	2013 Oct-Dec	2014 Jan-Dec	2013 Jan-Dec
Revenue				
Other operating income	56	159	233	287
	56	**159**	**233**	**287**
Operating expenses				
Project costs	-13 577	-2 981	-29 459	-10 558
Employee benefit costs	-1 898	-1 488	-6 271	-6 025
Other operating costs	-2 223	-2 751	-13 067	-9 785
Depreciation and impairment, fixed assets	-1	-1	-2	-2
Operating result	**-17 642**	**-7 062**	**-48 566**	**-26 084**
Net financial items				
Depreciation of investment in subsidiaries	-19	-32	-19	-32
Interest income	3	142	312	568
Interest expense and similar items	-49	-9	-147	-1
Result after financial net	**-17 706**	**-6 961**	**-48 420**	**-25 549**
Result before tax	**-17 706**	**-6 961**	**-48 420**	**-25 549**
Tax	-	-	-	-
Result after tax	**-17 706**	**-6 961**	**-48 420**	**-25 549**
Share Data				
Number of shares at the end of period	28 346 883	21 935 089	28 346 883	21 935 089
Avarage number of shares during period	23 776 462	21 935 089	22 649 770	21 190 579
Result per share beforeand after dilution (SEK)	-0,6	-0,4	-1,7	-1,2
Result per average share (SEK)	-0,7	-0,3	-2,1	-1,2
Equity per share (SEK)	3,2	2,7	2,7	2,1
Equity per share after dilution (SEK)	3,2	2,6	2,6	2,1

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Balance sheet

SEKk	2014-12-31	2013-12-31
ASSETS		
Fixed assets		
Property, plant and equipment		
Equipment, tools, fixtures and fittings	3	5
Financial assets		
Shares and participations in group companie	50	50
Total fixed assets	**53**	**55**
Current assets		
Current receivables		
Receivables group companies	216	234
Other receivables	2 727	991
Prepaid expenses and accrued income	430	428
	3 373	1 653
Cash and bank balances	100 043	49 302
Total current assets	**103 415**	**50 956**
Total assets	**103 468**	**51 011**

SEKk	2014-12-31	2013-12-31
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	1 492	1 154
Non-restricted equity		
Share premium reserve	137 586	71 348
Result for the period	-48 420	-25 549
	89 166	45 799
Total equity	**90 658**	**46 954**
Accounts payable	9 967	1 278
Current tax liabilities	-	-
Other liabilities	292	539
Accrued expenses and deferred income	2 551	2 240
Total short term liabilities	**12 810**	**4 057**
Total equity and liabilities	**103 468**	**51 011**

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Cash flow statement

SEKk	2014 Oct-Dec	2013 Oct-Dec	2014 Jan-Dec	2013 Jan-Dec
OPERATING ACTIVITIES				
Result after financial net	-17 706	-6 961	-48 420	-25 549
Adjustments for non-cash items	19	1	21	2
Tax paid	6	-12	-11	101
Cash flow from operating activities before changes in working capital	**-17 681**	**-6 972**	**-48 410**	**-25 445**
Changes in short term liabilities	-174	483	-1 888	-162
Changes in account payables	5 185	843	8 690	-1 053
Changes in operating liabilities	93	38	224	-1 406
Cash flow from operating activities	**-12 577**	**-5 607**	**-41 385**	**-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	**-**	**-**	**-**	**-**
FINANCING ACTIVITIES				
New share issue	75 592	-	95 839	18 560
Cost new share issue	-3 647	-	-3 714	-
Cash flow from financing activities	**71 945**	**-**	**92 125**	**18 560**
Cash flow for the period				
Balance at beginning of period	40 675	54 910	49 302	58 808
Change in cash	59 368	-5 607	50 740	-9 506
CASH BALANCE AT THE END OF THE PERIOD	100 043	49 302	100 043	49 302

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Change in Equity

SEKk	Share capital	Other emium reserve		Net income	Total equity
Opening balance 2013-01-01	**1 066**	**266**	**86 466**	**-33 857**	**53 941**
Loss allocation according AGM resolutic	-	-266	-33 590	33 857	0
New share issue	89	-	18 472	-	18 560
Net result for the period	-	-	-	-25 549	-25 549
Closing balance 2013-09-30	**1 154**	**-**	**71 347**	**-25 549**	**46 953**

Opening balance 2014-01-01	**1 154**	**-**	**71 347**	**-25 549**	**46 953**
Loss allocation according AGM resolution			-25 549	25 549	
New share issue	89	-	20 159	-	20 248
New share issue	249	-	75 342	-	75 591
Cost new share issue	-	-	-3 714	-	-
Net result for the period				-48 420	-48 420
Closing balance 2014-09-31	**1 492**	**-**	**137 586**	**-48 420**	**90 657**

Key ratios

SEK	2014 Oct-Dec	2013 Oct-Dec	2014 Jan-Dec	2013 Jan-Dec
Operating result (EBIT)	-17 641 590	-7 061 788	-48 566 231	-26 083 801
Operating margin %	neg.	neg.	neg.	neg.
Result for the period	-17 706 301	-6 960 615	-48 420 231	-25 548 985
Cash flow from operating activities	-12 576 876	-5 607 478	-41 384 985	-28 066 021
Total assets	103 467 980	51 010 693	103 467 980	51 010 693
Equity	90 657 830	46 953 951	90 657 830	46 953 951
Equity ratio %	88%	92%	88%	92%
Return on equity %	neg.	neg.	neg.	neg.
Number of shares at the end of the period	28 346 883	21 935 089	28 346 883	21 935 089
Number of shares at the end of the period after dilutio	28 746 883	22 335 089	28 746 883	22 335 089
Average number of shares under the period	23 776 462	21 935 089	22 649 770	21 190 579
Average number of shares under the period after dilu	24 176 462	22 335 089	23 049 770	21 590 579
Share Data			0	
Result per share	-0,6	-0,3	-1,7	-1,2
Result per average share	-0,7	-0,3	-2,1	-1,2
Cash flow from operating activities	-0,4	-0,3	-1,5	-1,3
Equity per share	3,2	2,1	3,2	2,1
Equity per share after dilution	3,2	2,1	3,2	2,1
Dividend	-	-	0,00	-
Number of employees	4	5	4	5

Accounting principles

This report is prepared in accordance with the Annual Accounts Act and the Accounting Standards Board. In preparation of the interim reports the BFNAR 2007: 1 is used and additionally guidance from the Swedish Financial Accounting Standards Council's recommendation RR 20 for Interim Reports. No differences have been identified between the previous rules and K3 which have a bearing on the previous year's balance sheet and profit and thus on the opening balance of equity.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.

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 February 17, 2015

Jacques Näsström
CEO

Next reports

The interim report for the period January-March 2015 will be published on April 21, 2015.
The interim report for the period January-June 2015 will be published on August 18, 2015.
The interim report for the period January-September 2015 will be published on October 20, 2015.

The Annual General Meeting will be held on April 14 at 16.00 in Pareto Securities' premises at Berzelii Park 9 in Stockholm.

Certified Advisor

The company´s Certified Advisor is Erik Penser Bankaktiebolag.

Analysts who follow PledPharma

Aktiespararna, through Birger Jarl Fondkommission
Erik Penser Bankaktiebolag, through Erik Penser Access
Pareto, Yilmaz Mahshid
Redeye, Klas Palin.

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