



PledPharma AB (publ)

Year-end report 2015

February 29, 2016

2015 – a year with key milestones achieved

Significant events during the quarter

- Interim data from PLIANT study –PledOx[®] shown to reduce long-lasting chemotherapy-induced peripheral neuropathy by up to 75 percent
- Constructive End of phase II/pre phase III-meeting with the U.S. Food and Drug Administration (U.S. FDA)
- PledPharma's key patent application for the active pharmaceutical ingredient of the drug candidates PledOx[®] and Aladote[®] approved in the US
- Transition to financial reporting according to IFRS standards. The transition has no effect on reported numbers

Quarter and full year summary

- Net result for the quarter amounted to SEK -8 794 (-17 687) k and to -43 836 (-48 420) k for the year
- Cash equivalents at the end of the year amounted to SEK 50 360 (100 304) k
- Cash flow from operating activities for the quarter amounted to SEK -8 953 (-12 573) k and to -51 153 (-41 405) k for the year
- Result per share for the quarter amounted to SEK -0.3 (-0.7) and to -1.5 (-2.1) for the year

Other significant events during 2015

- Top-line results from phase IIb study presented in March - PledOx[®] reduces nerve damage in conjunction with chemotherapy by 43 percent
- Aladote[®] approved as a trademark in the EU and the US
- Results from the Phase IIb study with PledOx[®] presented at the MASCC scientific congress.
- Patent for the anticancer-effect of PLED compounds approved by the European Patent Office and an use patent for PLED compounds granted by authorities in Canada, Russia, Mexico, Japan and Australia.



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CEO comment

In the spring of 2015, we completed the treatment phase of a comprehensive clinical trial, PLIANT, with good results. The study showed that PledOx[®] can prevent the emergence of nerve damage caused by chemotherapy in a clinically significant way in patients with colorectal cancer. Furthermore, it was noted that PledOx[®] does not impair the effect of the chemotherapy and that the safety profile is favorable. Interim data also shows that the preventive effect against nerve damage is more pronounced six months after completion of treatment - the difference in symptom score between the patients treated with the dose PledOx[®] 5 µmol / kg and placebo was 75 per cent. This difference is both clinically relevant and statistically significant ($p < 0.01$). Annually about 1.5 million people are affected by colorectal cancer and up to half of the patients treated with oxaliplatin get long-lasting nerve damage after chemotherapy. Overall, our results indicate that PledOx[®] may be an important treatment for facilitating desired chemotherapy courses and reduce the risk of long-term, sometimes crippling, nerve injury.

In November, we conducted an end of Phase II meeting with the FDA, where we presented follow-up data from the completed PLIANT study and had the opportunity to discuss the further development of PledOx[®]. The FDA gave constructive advice, based on a careful review of the available documentation.

During the year, patent protection for both PledOx[®] and Aladote[®] was strengthened, when the US Patent Office approved our patent covering the active ingredient in these two products. This patent is the most central in our broad portfolio with protection extending to December 2032.

In 2015, we have been preparing for the start of a Phase II study of Aladote[®]. This work has included study design, discussions with key opinion leaders and preparations for the development of an automated production process. Aladote[®] is being developed to provide medical services with an efficient way of treating acetaminophen poisoning irrespective of when treatment is initiated.

During the past year, we have successfully completed the treatment phase of the PLIANT study, strengthened our patent portfolio and conducted a constructive meeting with the FDA. All of this means that the conditions for PledOx[®] to become a valuable drug for cancer patients have been significantly improved, while we have received clarity on the next steps towards market approval.

I am proud of our achievements in 2015, which significantly increase the chances of PledPharma to provide patients and healthcare providers with better treatments for serious conditions caused by oxidative stress, and I look forward to an equally productive 2016.

Jacques Näsström
CEO, PledPharma AB (publ)



PledPharma in brief

PledPharma develops new drugs that protect the body against oxidative stress – a potentially disabling and sometimes life-threatening condition that can be caused by chemotherapy treatment and acetaminophen (paracetamol) poisoning. The company's most advanced project PledOx[®] reduces nerve damage associated with chemotherapy and positive results from the Phase IIb study PLIANT were presented during the spring of 2015. The drug candidate Aladote[®] is being developed to reduce the risk of acute liver failure associated with acetaminophen poisoning. The project PP-099 seeks to limit the damage that occurs to the heart muscle during myocardial infarction.

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

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 transaction of the PledOx[®] project with attractive commercial revenues and to develop Aladote[®] to commercialization together 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 sold, 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 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, EU, China, Hong Kong, Russia, Australia and Japan 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 calmagofodipir, 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. In addition, PledPharma has four in-licensed patents covering therapeutic use of PLED therapeutics.

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

Our projects

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

PledOx[®] (colorectal cancer)

The results from the Phase IIb study PLIANT, where patients with colorectal cancer (colorectal cancer) treated with the chemotherapy combination FOLFOX and PledOx[®] (calmagofodipir), shows that the patients who received PledOx had a lower risk than the placebo group to suffer from nerve damage.



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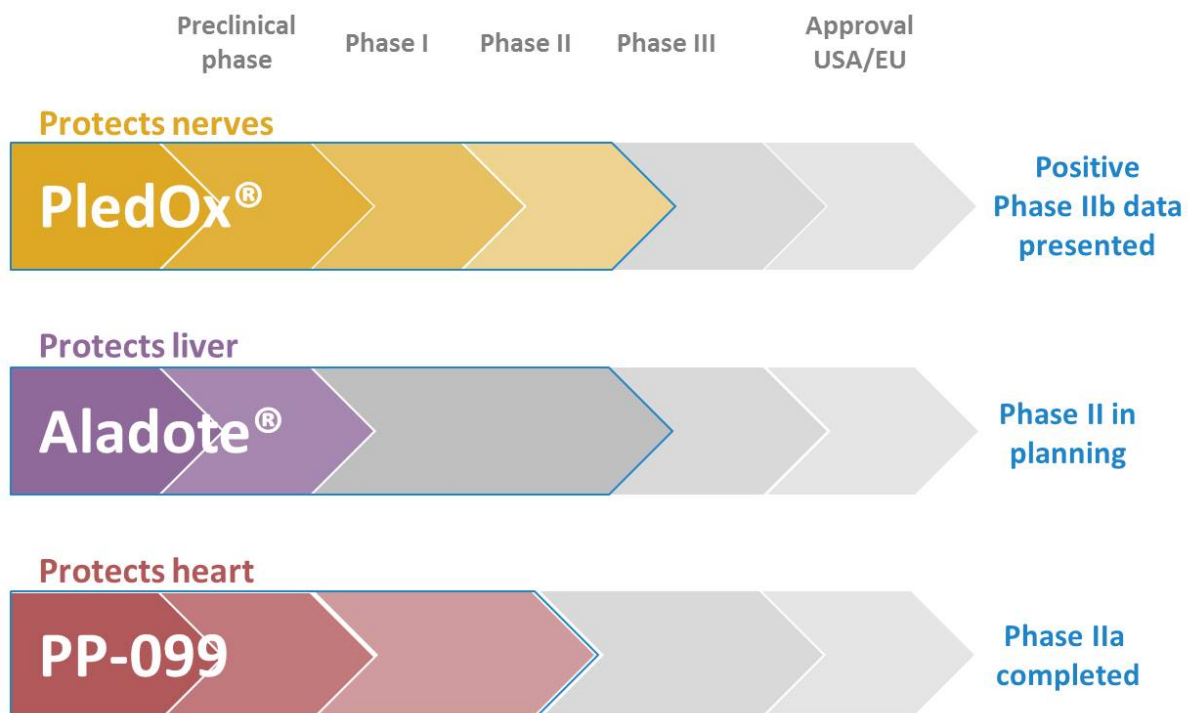
Aladote[®] (hepatic/ALF)

Aladote[®] is a new formulation based on calmagafodipir 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 under preparation.

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 ongoing projects





Financial summary - Group Fourth quarter 2015

Financial performance

Revenue Oct - Dec

Revenue amounted to SEK 58 (56) k during the quarter and consisted of rental revenues and foreign exchange gains. Interest income amounted to SEK 38 (4) k for the period.

Revenue Jan- Dec

Revenue amounted to SEK 378 (233) k for the year and consisted of rental revenues and foreign exchange gains. Interest income amounted to 203 (312) k for the period.

Expenses Oct-Dec

Operating expenses amounted to SEK 8 890 (17 747) k for the quarter. Of these, planned project costs, mainly related to the ongoing clinical study in PledOx project, amounted to SEK 3 993 (13 577) k. Employee costs amounted to SEK 1 820 (1 898) k for the quarter. Other operating costs amounted to SEK 3 039 (2 223) k for the quarter. Depreciation amounted to SEK 1 (1) k.

Expenses Jan-Dec

Operating expenses amounted to SEK 44 406 (48 964) k for the year. Of these, planned project costs, mainly related to the ongoing clinical study in PledOx project, amounted to SEK 26 093 (29 459) k for the period.

Employee costs amounted to SEK 6 909 (6 271) k for the year. Other operating costs amounted to SEK 11 274 (13 086) k. Depreciation amounted to SEK 2 (2) k for the period.

Results Oct-Dec

Operating result amounted to SEK -8 832 (-17 691) k for the quarter. Result after financial items amounted to SEK -8 794 (-17 687) k. No income tax was recorded for the quarter (-) Result per average share amounted to SEK -0.3 (-0.7).

Results Jan-Dec

Operating result amounted to SEK -44 028 (-48 731) k for the year. Result after financial items amounted to SEK -43 836 (-48 420) k. No income tax was recorded for the period (-). Result per average share amounted to SEK -1.5 (-2.1).

Financial position

Cash

Cash at 31 December 2015 amounted to SEK 50 360 (100 304) k.

Cash flow Oct-Dec

Cash flow from operating activities amounted to SEK -8 953 (-12 573) k for the quarter.

Cash flow, affected by a share issue in the comparative period, amounted to SEK -8 953 (59 372) k for the quarter.

Cash flow Jan-Dec

Cash flow from operating activities amounted to SEK -51 153 (-41 405) k for the year.

Cash flow, affected by a share issue in the comparative period, amounted to SEK -49 943 (50 720) k for the period.

Equity and equity ratio

Shareholders' equity amounted to SEK 48 032 (90 658) k. The company's equity ratio was 92 (88) %.

Debts

No long-term debts were outstanding (-), current liabilities amounted to SEK 4 329 (12 810) k and shareholders' equity per share amounted to SEK 1.7 (3.2), at the end of the period.

Investments, tangible and intangible assets

PledPharma will capitalize the costs for development projects after the projects have completed phase III trials and been market launched. 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.

Share

The number of shares at December 31, 2015, after the subscription of shares in the Options Program, were 28 388 883. PledPharma's shares were listed on NASDAQ Stockholm First North on 7 April 2011.



Parent Company

Expenses Oct-Dec 2015

The parent company's expenses for the period amounted to SEK 8 890 (17 747) k.

Expenses Jan-Dec 2015

The parent company's expenses for the year amounted to SEK 44 390 (48 945) k.

Results Oct-Dec 2015

The parent company's result after financial items amounted to SEK -8 811 (-17 706) k for the period.

Results Jan-Dec 2015

The parent company's result after financial items amounted to SEK -43 836 (-48 420) k for the year.

Consolidated statement of comprehensive income

SEKk	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Revenue				
Other operating income	58	56	378	233
	58	56	378	233
Operating expenses				
Project costs	-3 993	-13 577	-26 093	-29 459
Other external costs	-3 039	-2 223	-11 274	-13 086
Employee benefit costs	-1 820	-1 898	-6 909	-6 271
Depreciation and impairment, fixed assets	-1	-1	-2	-2
Other operating expenses	-37	-49	-128	-146
Operating result	-8 832	-17 691	-44 028	-48 731
Net financial items				
Interest income	38	4	203	312
Interest expense and similar items	(0)	(0)	(10)	(1)
Result after financial net	-8 794	-17 687	-43 836	-48 420
Result before tax	-8 794	-17 687	-43 836	-48 420
Tax	-	-	-	-
Result after tax	-8 794	-17 687	-43 836	-48 420

Statement of comprehensive income

Other comprehensive income	-	-	-	-
Comprehensive income for the period	-8 794	-17 687	-43 836	-48 420

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

Share Data

Number of shares at the end of period	28 388 883	28 346 883	28 388 883	28 346 883
Average number of shares during period	28 388 883	23 766 462	28 373 133	22 649 770
Result per share before dilution (SEK)	-0,3	-0,7	-1,5	-2,1
Result per share after dilution (SEK)	-0,3	-0,7	-1,5	-2,1
Equity per share (SEK)	1,7	3,2	1,7	3,2
Equity per share after dilution (SEK)	1,7	3,2	1,7	3,2

Consolidated statement of financial position

SEKk	2015-12-31	2014-12-31	2013-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	0	2	5
Total fixed assets	0	2	5
Current assets			
<i>Current receivables</i>			
Other receivables	788	2 732	995
Prepaid expenses and accrued income	1 213	430	428
	2 001	3 162	1 423
Cash and bank balances	50 360	100 304	49 584
Total current assets	52 361	103 466	51 007
Total assets	52 361	103 468	51 012
EQUITY AND LIABILITIES			
Equity			
Share capital	1 494	1 492	1 154
Other capital contributions	90 374	137 586	71 347
Accumulated loss including net loss	-43 836	-48 420	-25 549
Total equity	48 032	90 658	46 953
Short term liabilities			
Accounts payable	1 766	9 967	1 280
Other liabilities	177	292	539
Accrued expenses and deferred income	2 386	2 551	2 240
Total short term liabilities	4 329	12 810	4 059
Total equity and liabilities	52 361	103 468	51 012

Consolidated statement of cash flows

SEKk	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
OPERATING ACTIVITIES				
Result after financial net	-8 794	-17 687	-43 836	-48 420
Adjustments for non-cash items	1	1	2	2
Tax paid	-	-	-	-
Cash flow from operating activities before changes in working capital	-8 794	-17 687	-43 833	-48 418
Changes in short term liabilities	1 163	114	1 161	-1 739
Changes in account payables	-715	5 185	-8 201	8 688
Changes in operating liabilities	-607	-185	-280	64
Cash flow from operating activities	-8 953	-12 573	-51 153	-41 405
INVESTING ACTIVITIES				
Cash flow from investing activities	-	-	-	-
FINANCING ACTIVITIES				
New share issue	-	75 592	1 210	95 839
Cost new share issue	-	(3 647)	-	(3 714)
Cash flow from financing activities	-	71 945	1 210	92 125
Cash flow for the period				
Balance at beginning of period	59 313	40 957	100 304	49 584
Change in cash	-8 953	59 372	-49 943	50 720
CASH BALANCE AT THE END OF THE PERIOD	50 360	100 328	50 360	100 304

Consolidates statement of changes in equity

	Share capital	Other capital contributions	Accumulated loss incl. net result for the period	Total equity
kSEK				
Opening balance 20140101	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
Issue costs	-	(3 713)	-	(3 713)
Comprehensive income 2014	-	-	(48 420)	(48 420)
Closing balance 20141231	1 492	137 586	(48 420)	90 658
Opening balance 20150101	1 492	137 586	(48 420)	90 658
Loss allocation according AGM resolution	-	(48 420)	48 420	-
New share issue	2	1 208	-	1 210
Comprehensive income 2015	-	-	(43 836)	(43 836)
Closing balance 20151231	1 494	90 374	(43 836)	48 032

Consolidated key ratios

SEK	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Operating result (EBIT)	-8 831 871	-17 690 977	-44 027 901	-48 731 189
Operating margin %	neg.	neg.	neg.	neg.
Result for the period	-8 794 101	-17 687 470	-43 835 609	-48 420 026
Cash flow from operating activities	-8 952 616	-12 573 175	-51 152 940	-41 404 764
Total assets	52 361 472	103 467 691	52 361 472	103 467 691
Equity	48 032 222	90 657 830	48 032 222	90 657 830
Equity ratio %	92%	88%	92%	88%
Return on equity %	neg.	neg.	neg.	neg.
Number of shares at the end of the period	28 388 883	28 346 883	28 388 883	28 346 883
Number of shares at the end of the period after dilution	28 388 883	28 746 883	28 388 883	28 746 883
Average number of shares under the period	28 388 883	23 776 462	28 373 133	22 649 770
Average number of shares under the period after dilution	28 388 883	24 176 462	28 373 133	23 049 770
Share Data				
Result per share	-0,3	-0,7	-1,5	-2,1
Result per average share	-0,3	-0,7	-1,5	-2,1
Cash flow from operating activities	-0,3	-0,5	-1,8	-1,8
Equity per share	1,7	3,2	1,7	3,2
Equity per share after dilution	1,7	3,2	1,7	3,2
Dividend	-	-	-	-
Number of employees	4	4	4	4

Parent company - Income statement

SEKk	2015 Oct-Dec	2014 Oct-Dec	2015 Jan-Dec	2014 Jan-Dec
Revenue				
Other operating income	57	56	378	233
	57	56	378	233
Operating expenses				
Project costs	-3 993	-13 577	-26 093	-29 459
Other external costs	-3 039	-2 223	-11 258	-13 067
Employee benefit costs	-1 820	-1 898	-6 909	-6 271
Depreciation and impairment, fixed assets	-1	-1	-2	-2
Other operating expenses	-37	-49	-128	0
Operating result	-8 832	-17 691	-44 012	-48 712
Net financial items				
Depreciation of investment in subsidiaries	(16)	(19)	(16)	-19
Interest income	38	3	203	312
Interest expense and similar items	(0)	(0)	(10)	-1
Result after financial net	-8 811	-17 706	-43 836	-48 420
Result before tax	-8 811	-17 706	-43 836	-48 420
Tax	-	-	-	-
Result after tax	-8 811	-17 706	-43 836	-48 420

Parent company - Balance sheet

SEkk	2015-12-31	2014-12-31	2013-12-31
ASSETS			
Fixed assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	0	2	5
<i>Financial assets</i>			
Shares and participations in group companies	50	50	50
Total fixed assets	50	52	55
Current assets			
<i>Current receivables</i>			
Receivables group companies	-	216	234
Other receivables	787	2 727	991
Prepaid expenses and accrued income	1 213	430	428
	2 001	3 373	1 653
<i>Cash and bank balances</i>			
	50 360	100 043	49 302
Total current assets	52 361	103 416	50 956
Total assets	52 411	103 468	51 011
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	1 494	1 492	1 154
<i>Non-restricted equity</i>			
Share premium reserve	90 374	137 586	71 348
Result for the period	-43 836	-48 420	-25 549
Total equity	48 032	90 658	46 954
Liabilities			
Debt to group company	51		
Accounts payable	1 766	9 967	1 278
Other liabilities	176	292	539
Accrued expenses and deferred income	2 386	2 551	2 240
Total short term liabilities	4 379	12 810	4 057
Total equity and liabilities	52 411	103 468	51 011



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Notes

NOTE 1 - Accounting principles

PledPharma applies International Financial Reporting Standards (IFRS) as adopted by the EU. This report is the first financial report that is prepared in accordance with IFRS, for more information on the transition, see Note 6. 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.

NOTE 2 - Important estimates and assumptions for accounting purposes

The Group makes estimates and assumptions concerning the future. The estimates for accounting purposes that result from these will, by definition, seldom equal the related actual results. No estimates and assumptions that have a significant risk of material adjustments to the carrying values of assets are deemed to exist. The Group has unused taxes loss that have not been assigned any value in the balance sheet since they are not expected to be utilized within the time period applicable to the accounting valuation.

NOTE 3 - Financial risk management

The Group seeks to minimize potential adverse effects of the unpredictability of the financial markets in which the Group operates. Risk is managed by the Group's administrative department in accordance with policies established by the Board. The Group's main financial risks include foreign exchange risk, liquidity risk, credit risk and interest rate risk. Except as outlined below regarding current foreign currency, no other significant financial risks exist in the current situation. The Group has not used any financial hedging instruments in 2015 or 2014.

Foreign currency risk

Risks in foreign currency arises when business transactions are conducted in a currency different from the Group's functional currency. The Group operates internationally and has certain purchases mainly in USD. The exposure is currently limited and a reasonable change in the US dollar against SEK will not materially affect the Group's results. A change in the exchange rate by 10% for the USD would affect costs by approximately SEK 1 million. As of December 31, 2015, there was no significant assets or liabilities denominated in foreign currencies.

Liquidity Risk

Liquidity risk management is based on maintaining sufficient cash. Liquidity risk is managed through regular liquidity planning. Company's current business plan and business orientation is deemed to be fully funded based on the current financial status.

Credit risk

Only investment in fixed income securities with low credit risk and high liquidity are permitted. The group works mainly with established and creditworthy counterparties and regularly evaluates claims to ensure a low exposure related to bad debts.

Interest rate risk

Interest rate risk refers to the Group's exposure to changes in interest rates related to bank deposits and loans. As the Group's interest-bearing assets mainly relates to bank balances the consolidated operating cash flow is substantially independent of changes in market interest rates. The group currently lacks interest-bearing liabilities.

NOTE 4 - Segment Reporting

PledPharma ongoing development projects are based on the company's proprietary technology platform, therefore the company's operations are monitored in its entirety. Internal reporting within PledPharma is designed accordingly. The company's potential customers are located in many different countries, but all product development efforts are conducted from Sweden. Based on the above, there is currently no accounting of operations in different segments. Should the situation change, segment reporting will be established.

NOTE 5- Related parties transactions

No transactions with related parties have occurred during the period.



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NOTE 6- Transition to financial reporting in accordance with IFRS.

Consolidated financial statements in this annual report are the first prepared in accordance with IFRS. The formal date of transition to IFRS was set at 1 January 2014. During the transition, IFRS 1 has been applied. In previous annual reports, PledPharma AB (publ) has not prepared and presented consolidated financial statements with reference to the Annual Accounts Act Chapter 7, § 5, when the subsidiary is considered to be of little importance. The transition to financial reporting in accordance with IFRS has not generated any effect on the reported values. The transition to IFRS has not had any effect on the Group's cash flows. The transition to IFRS has resulted in certain adjustments to the format of the consolidated income statements and balance sheets. No optional exemptions have been relevant to apply during the transition. The following describes the Group's accounting principles as applied in the transition to IFRS.

Basis of accounting

PledPharma consolidated financial statements are based on historical cost. All amounts are in KSEK unless otherwise stated.

New standards, amendments and interpretations to existing standards that are not yet effective and have not been early adopted.

IFRS 9 Financial Instruments

IFRS 9 Financial Instruments addresses the classification, measurement and recognition of financial assets and liabilities. The full version of IFRS 9 was issued in July 2014. IFRS 9 Financial Instruments comes into effect on January 1, 2018 replacing IAS 39 Financial Instruments: Recognition and Measurement. The new standard has been redrafted into different sections – one section relates to the recognition and measurement of financial assets and financial liabilities. IFRS 9 classifies financial assets into three different categories. Classification is determined at initial recognition based on the characteristics of the asset and the company's business model. The second section relates to hedge accounting. To a large extent, the new policies provide better conditions for accounting that gives a fair picture of a company's financial risk management through financial instruments. Finally, new policies have been introduced that relate to the impairment of financial assets, whereby the model is based on expected losses. The purpose of the new impairment model is, for instance, for provisions for credit losses to be made at an earlier stage. The EU has not yet approved the standard, therefore IFRS 9 in the current form does not apply to early retirement.

IFRS 15 Revenue from Contracts with Customers

IFRS 15 Revenue from Contracts with Customers comes into effect on January 1, 2017 and replaces all previously issued standards and interpretations relating to revenues (i.e. IAS 11 Construction Contracts, IAS 18 Revenue, and related IFRIC and SIC). IFRS 15 contains a comprehensive model for revenue recognition with regard to customer contracts. The idea behind the standard is that everything begins in an agreement between two parties for the sale of a product or service. Initially, a customer agreement will be identified, which generates an asset for the vendor (rights, the promise of receiving remuneration) and a liability (commitment, a promise of transfer of goods/services). According to the model, revenue should then be recognized, thus demonstrating that the commitment to supply goods or services to the customer has been fulfilled. The EU has not yet approved the standard. IFRS 15 is scheduled to enter into force on 1 January 2018 and earlier application is permitted. The standard is not yet approved by the EU. As the Group has not yet reported any income, no evaluation has been performed of the impact of the application of the standard.

IFRS 16 Leases

In January 2016 the IASB published the new standard for lease accounting, IFRS 16 Leases. The standard brings changes especially for lessees while accounting for the lessor essentially remains unchanged. For the lessee the concepts of financial and operational leasing disappears under IFRS 16. Instead, all leases are handled in the same manner as finance leases in accordance with IAS 17. The accounting is based on the view that the lessee has a right to use an asset for a specific period of time and at the same time an obligation to pay for that right, which is why the lessee should recognize a "right-of-use asset" and a lease liability in its balance sheet. Exceptions are contracts with maturities of less than 12 months and contracts relating to assets amounting to lesser amounts. IFRS 16 clarifies that a lessee should distinguish between lease components and service components of a contract, and that the reporting requirements apply only to lease components. The new guidance on what constitutes a lease, can also affect the lessor, for example agreements containing services. The standard is applicable for fiscal years beginning January 1, 2019 or later. IFRS 16 is not yet adopted by the EU. The Group has not evaluated the effects of the application of the standard. None of the other IFRS or IFRIC interpretations that have not yet entered into force, are expected to have a material impact on the Group.

Consolidated

Consolidated financial statements include the parent company and subsidiaries in which the parent company has a controlling influence. Controlling interest exists if the parent company has influence over the investee, is exposed, or has rights to variable returns from its involvement and to use its influence over the investment to affect yields. In assessing whether control exists, potential voting shares and 'de facto control' are considered. Subsidiaries acquired are reported in the consolidated financial statements using the purchase method. This applies to businesses acquired directly. The purchase price of a subsidiary is the fair value of transferred assets, liabilities incurred by the Group to the former owners of the acquired company and the shares issued by the Group. The purchase price also includes the fair value of all assets or liabilities that are a result of an agreement on contingent consideration. The identifiable assets acquired and liabilities assumed in a business combination are measured initially at fair value at the acquisition date. Acquisition-related costs are expensed as incurred. If the amount of the total purchase price and fair value of non-controlling interests exceeds the fair value of identifiable assets acquired and liabilities assumed it is recorded as goodwill. All intercompany receivables and liabilities, income and expenses, gains or losses arising from transactions between companies included in the consolidated accounts are eliminated in full.

Translation of receivables and liabilities in foreign currency

Functional and reporting currency

Items included in the financial statements for the various units in the Group are valued in the currency used in the economic environment in which the entity operates (its functional currency). The parent company's functional currency and reporting currency is Swedish Kronor. The Group's reporting currency is Swedish Kronor.

Transactions in foreign currencies

Foreign currency transactions are translated into the functional currency at the exchange rate prevailing on the transaction date. On the closing date, monetary assets and liabilities denominated in foreign currencies at the exchange rate prevailing at closing date. All differences are the result. Exchange differences from operating items are recorded in operating income as other operating income and other operating expenses, while exchange differences on financial assets and liabilities are recorded as financial income or financial expense.

Income

Revenue is reported at the fair value of the financial compensation to be received. The following specific criteria must also be met for revenue to be recognized:

Licenses and signing fees

Revenues from technology licenses are recognized as revenue over the license period. Signing fees and other payments received in connection with signing the contract revenue is recognized when the conditions for obtaining them are met.

Milestone payments

Milestone payments are recognized as revenue when the related milestones are met.

Services related to research and development collaborations

Received remuneration for research services are recognized over the period to which they relate. If no such relationship exist, revenue is recognized based on the degree of completion of the respective projects / contracts. Degree of completion is determined on the basis of time spent in relation to the estimated total time for the project / contract, or based on the clauses in the contract with the customer.

Public funding

Public funding and other grants are recognized when the Company meets the conditions attached to the grant and that it can be conclusively established that the grants will be received. Grants received are recognized in the balance sheet as deferred income and are recognized in the period in which the cost of the subsidy is intended, is reported. In the income statement, government support is reported as other income.

Tangible fixed assets

Tangible fixed assets are stated at acquisition cost less accumulated depreciation and any impairment. The cost consists of the purchase price and costs directly attributable to bringing the asset into use. The cost less estimated residual value at the end of useful life are depreciated over their useful lives. Fixed assets book value is tested for impairment when events or changes in circumstances indicate that the carrying amount



over the recoverable amount. Fixed assets value and useful lives are evaluated and adjusted if appropriate, at each year-end.

Intangible assets

Acquired intangible assets are reported as assets in the balance sheet. Acquired intangible assets are initially measured at cost. Intangible assets' acquisition value in connection with acquisitions, the fair value at the acquisition date. After initial recognition, intangible assets are at acquisition cost less any amortization and impairment losses. Intangible assets with finite lives are amortized over their useful lives. Assessment of impairment occurs when there is an indication that an impairment exists. The useful lives and depreciation periods for intangible assets are evaluated at least annually in conjunction with the annual financial statements. Any changes in useful lives are handled by changing the depreciation periods.

Research and development expenses

Research costs are expensed in the period they occur. Intangible assets relate to development costs or a separate development project is recognized only when the Group can demonstrate the technical possibilities available to implement the project, the asset is expected to give rise to future economic benefits and the cost can be measured reliably. PledPharma intends to capitalize costs for development projects after the projects have completed Phase III studies, to be launched on the market and when the conditions for activation are otherwise met. So far, the Group has expensed all development costs since the above criteria for capitalization has not been met.

Depreciation

Throughout the year it is assessed if there are indications that assets may be impaired. If such an indication exists, the asset's recoverable amount is calculated. Goodwill and other intangible assets with indefinite useful life and for intangible assets not yet ready for use is calculated annually. If it is not possible to establish essentially independent cash flows for an individual asset, when testing for impairment, assets are grouped at the lowest level it is possible to identify significant independent cash flows (cash-generating unit). An impairment loss is recognized when an asset's or cash-generating unit's carrying amount exceeds the recoverable amount. Impairment is charged to earnings. Impairment of assets attributable to a cash-generating unit is first allocated to goodwill. Thereafter, a proportional impairment of other assets included in the unit is carried out.

Calculation of recoverable value

The recovery value is the higher of the asset's net realizable value and value in use. Value in use is the present value of future cash flows discounted at a rate that is based on risk-free interest adjusted for the risk associated with the specific asset. For an asset that does not generate cash flows, the recoverable amount of the cash-generating unit to which the asset belongs, is estimated.

Reversal of impairment

Impairment losses are reversed if a subsequent increase in recoverable amount can be related objectively to an event occurring after the impairment loss was recognized. Impairment of goodwill is not reversed. An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that the asset would have had if no impairment had been recognized.

Financial instruments

A financial instrument is reported in the balance sheet on the date the Group under contract takes part of the contractual rights to the cash flow of the instrument. A financial asset is derecognized when the contractual rights to the cash flow ceases. A financial liability is derecognized only when it is extinguished. Financial instruments recognized in the balance sheet assets include trade receivables and cash. Financial liabilities consist of borrowings and payables. Financial instruments are classified into different categories, depending on the purpose of the financial instrument. The classification is determined at the time of acquisition. When a financial asset or liability is reported for the first time it is measured at fair value plus, in the case of a financial asset or financial liability that does not belong to the category of financial assets or liabilities at fair value through profit or loss, transaction costs that are directly attributable to the acquisition or issue of the financial asset or liability. Subsequent measurement is determined by how the instrument has been classified.

Loans and receivables

Loans and receivables are financial assets with fixed payments or payments that can be determined to the amount. Receivables are associated with the group's deliveries of goods and services. If payment is expected within one year or receivable are classified as current assets while loans with a maturity longer than one year are recognized as fixed assets. Loans and receivables are initially recognized at fair value and



subsequently at amortized cost using the effective interest method, less any provisions for impairment, which are assessed individually.

Other financial liabilities

In this category, interest-bearing and noninterest-bearing financial liabilities not held for trading purpose are reported. Valuation is carried at amortized cost. Long-term liabilities have a maturity exceeding one year, while liabilities with shorter maturities are reported as current. Accounts payable are classified as current liabilities if they fall due within one year or earlier. Trade payables with maturity exceeding one year are recognized as non-current liabilities. Accounts payable, interest-bearing liabilities and other financial liabilities not held for trading purposes are recognized initially at fair value and subsequently at amortized cost using the effective interest method.

Provisions

Provisions are recognized when the Group has a present obligation (legal or constructive) due to a past event and it is probable that an outflow of resources associated with economic benefits will be required to settle the obligation and the amount can be reliably estimated. If the Group expects to receive compensation corresponding to a provision made, for example through an insurance contract, the reimbursement is reported as an asset when it is virtually certain that reimbursement will be received. If the effect of the time value of the future payment is considered significant, the provision is determined by the value of the expected future payments discounted to present value using a discount rate before tax that reflects the current market valuation of the time value and any risks that are attributed to the obligation. The gradual increase in the amount of provision calculation is recognized as an expense in the results.

Employee Benefits

Short-term benefits

Short-term employee benefits such as salary, paid holidays, paid sick leave, bonuses, etc. are calculated without discounting and are expensed in the period when the related services are performed. A provision for bonus payments is reported when the Group has a legal or constructive obligation to make such payments as a result of the services in question have been received from the employees and the provision can be reliably measured.

Post-employment benefits

The Group has only defined contribution pension plans. With defined contribution plans, the group pays contributions to a separate legal entity and the host change risks until the funds are paid out falls on the employee. The Group thus has no further obligations once the fees are paid. Pension costs for defined contribution pension plans are charged to earnings as the employees render services. Obligations are calculated without discounting, as payments for all plans due within 12 months.

Termination benefits

Termination benefits are payable when employment is terminated before the normal retirement date or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognizes severance pay when it is demonstrably committed to either terminate employees according to a detailed formal plan without possibility of withdrawal, or to provide compensation upon termination as a result of an offer made to encourage voluntary redundancy.

Leasing

Leases where the risks and benefits associated with ownership do not accrue to the Group are classified as operating leases. Leasing fees for these agreements recognized as an expense in the income statement on a linear basis over the service period. PledPharma classifies all current leases as operating leases.

Loan expenses

Borrowing expenses are expensed in the period to which they relate. Costs incurred in raising loans are distributed over the term of the loan on the basis of the reported liability.

Income tax

Income tax comprises current and deferred tax. Income taxes are recognized in the income statement except when the underlying transaction is recognized in other comprehensive income or directly in equity. Current tax is the tax payable or refundable for the current year using the tax rates enacted or substantially enacted at the balance sheet date. This includes any adjustment of current tax attributable to prior periods. Deferred tax is recognized using the balance sheet method, implying that deferred tax is calculated on all identified temporary differences, i.e. between assets or liabilities for tax purposes and, on the other hand, their carrying values. Deferred tax assets in deductible temporary differences and loss carry-forwards are



only recognized to the extent that it is probable that these will entail lower tax payments in the future. The deferred tax liability is not recognized in the balance sheet for taxable temporary differences relating to goodwill.

Deferred taxes attributable to investments in subsidiaries and associated companies are not reported as a capital loss on the shares since current tax rules are exempt from taxation. Deferred tax assets are recognized only to the extent that it is probable that future taxable profits will be available and against which the temporary differences or unused loss carry forwards can be utilized. The deferred tax assets are tested on each balance sheet date and is reduced to the extent that it is no longer probable that sufficient taxable profit will be available to utilize all or part of the deferred tax assets. Deferred tax assets and liabilities are calculated using the tax rates expected to apply for the period when receivables are realized or the liability is settled, based on tax rates (and tax laws) that exist or in practice on the balance sheet date. Deferred tax assets and liabilities are offset in the balance sheet provided that the tax payment will be made at the net amount.

Cash flow statement

The cash flow statement shows receipts and disbursements. The indirect method has been used for operating activities. Cash and cash equivalents includes cash and bank deposits, short-term liquid investments with an original maturity of less than three months.

Parent company accounting principles

The Parent Company applies the Annual Accounts Act and RFR 2 Accounting for Legal Entities, which essentially means that IFRS is applied. The application of RFR 2 means that the Parent Company in the annual report for the legal entity must apply all EU-approved IFRS statements as far as possible within the framework of the Annual Accounts Act and with regard to the relationship between accounting and taxation. The recommendation specifies which exceptions and additions to IFRS that shall be made. The differences between the parent company and the Group are described below.

Classification and format

The income statement and balance sheet are presented according to the Annual Accounts Act, while the income statement and cash flow statement are based on IAS 1 Presentation of Financial Statements and IAS 7 Statement of Cash Flows. The differences with the Group reports that are evident in the parent company's income statements and balance sheets are carried out mainly by the recognition of equity and provisions as a separate heading. In accordance with RFR 2, the parent company does not apply IAS 39.

Subsidiary

Shares in subsidiaries are recognized in the parent company the acquisition value method.



Other information

Next reports

Interim report Jan-March, 29 April 2016

Interim report April – June, 25 August 2016

Interim report July-Sept, 20 October 2016

The Board plans to hold the Annual General Meeting on 14 April 2016. The Annual Report will be published during the week commencing with 21 March 2016.

PledPharma is required to publish the information in this report under Swedish Securities Market Act. The information was submitted for publication on 29 February, 2016.

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

This report has not been audited.

For further information contact:

Jacques Näsström, CEO cell +46 73 713 09 79

Michaela Gertz, CFO cell: +46 70 926 17 75

Certified Advisor

The company's Certified Advisor is Erik Penser Bankaktiebolag (tel +46 8 463 80 00).

Analysts who follow PledPharma

Erik Penser Bankaktiebolag, through Erik Penser Access

Pareto, Finlay Heppenstall

Redeye, Klas Palin.

PledPharma AB (publ)

Grev Turegatan 11c, 114 46 Stockholm

Phone: +46 8 679 72 10

Org.nr. 556706-6724



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 29, 2016

Håkan Åström
Chairman of the board

Andreas Bunge
Board member

Martin Nicklasson
Board member

Sten Nilsson
Board member

Eva Redhe
Board member
