

YEAR END REPORT

Period from January to December 2015

Peptonic Medical AB (publ) org nr 556776-3064

(<u>www.aktietorget.se</u>, ticker: PMED)

2015 FOURTH QUARTER (Oct-Dec)

- Operating loss KSEK -4,793 (-3,648)
- Loss per share SEK -0.25 (-0.46)

FULL YEAR 2015 (Jan-Dec)

- Operating loss KSEK -13,983 (-10,115)
- Loss per share SEK -0.73 (-1.27)



IMPORTANT EVENTS DURING THE PERIOD

- In March, the US patent office informed Peptonic Medical that the formulation patent will be approved in the USA. Patent expiry is in 2032.
- Peptonic Medical and Swetox entered a research collaboration on the mechanisms of action of oxytocin. The project will add new safety data to Vagitocin[®].
- In March the company raised SEK 14.4 million in a private placement at a share price equal to the average trading price during the three preceding months.
- Patient recruitment to Peptonic Medical's ongoing phase 2b study was completed by the end of March.
- At the AGM in April, Mr. Anders Wiklund and Prof. Emeritus Andris
 Kreicbergs were elected as new members to the Board. At the same
 time, Mr. Christer Sjögren and Mr. Ingvar Wiberger resigned from the
 Board.
- In April, Johan Inborr, CEO, subscribed for 160,000 warrants as authorized by the AGM as part of an adopted incentives scheme.
- Last patient's last visit in the Phase IIb study occurred in July.
- In September the results of the Phase IIb study were announced. Primary endpoints were not met. The Board decided to launch a thorough investigation in to all aspects of the study before publishing the results in more detail.
- The Board announced that the investigation had been concluded. The investigation found that the most probable cause of this unsatisfactory result was that the aluminium tube used to deliver the daily oxytocin dose, reacted with the oxytocin gel to cause a reduction in viscosity, especially when the product was stored at room temperature. This in turn resulted in less adherence of the oxytocin gel to the vaginal mucosal epithelium and therefore an inadequate daily dose of the active compound was delivered to the tissue. Clinical observation and patient reports of leakage of the gel prompted storage of the tubes in refrigerator temperature instead of room temperature to preserve gel viscosity for the last 76 of 224 patients in the trial. Analysis of this subgroup, after the trial results were known, showed a significant reduction of the most bothersome symptom (one of three primary endpoints) compared with placebo further supporting the notion that decreased gel viscosity was the reason for the unexpected outcome of this study.
- The Board of Peptonic Medical called for an extraordinary general meeting on November 19, 2015, and got shareholder approval for a rights issue of approximately MSEK 22.7 in order to finance the proposed phase IIb study. The rights issue was fully underwritten through subscription undertakings, subscriptions without preferential rights from existing shareholders (19.7 MSEK) and underwriting commitments (3 MSEK).
- In November Mr Anders Wiklund resigned from the Board. After Anders Wiklund's resignation, the Board consists of four members.
- In December the Company completed a directed rights issue (private placement) in accordance with the authorisation of the Annual General Meeting. The issue was directed to Humle Kapitalförvaltning, resulting in net proceeds of SEK 5,000,000 to the Company. Subscription price was SEK 3.05 per share, which corresponded to the price of the recently closed rights issue plus 0.25 SEK. The Board considered this to be a well-founded market price for a large investor.

IMPORTANT EVENTS AFTER THE END OF THE PERIOD

- A total of 9 732 452 new shares have been registered per 2016-01-12 with Bolagsverket (the Swedish Companies Registration Office) and the total number of shares in Peptonic Medical after the rights issue amounts to 19 174 412 shares and the share capital amounts to SEK 1 917 441.20.
- In January, an application for a new phase IIB study has been filed for approval by Läkemedelsverket (MPA). According to the protocol, 200 patients will be included in the double-blind randomized placebo controlled study, with the aim to show efficacy of Vagitocin® (400 IU oxytocin) compared with placebo. The gel, both placebo and active, will be pre-filled into glass syringes. This to minimize the risk of a decrease in viscosity. The last 40 patients included in the study will get gel filled into laminate tubes. Tubes that have been tested for stability of the API, the preservative and viscosity. Approval by the MPA is expected in March, and the plan is to start screening patients in April with first treatment in May. Last patient in the head study expect to leave the study in December.



From the CEO

Last year was a roller coaster ride for Peptonic. Early in the year, the phase 2b study progressed according to plan with a steady in-flow of study subjects and a high proportion of them completing the treatment and attending all follow-up visits. The results of the study, however, were a disappointment to all concerned. When the data was decoded in September, treatment with oxytocin did not show any improvement compared to placebo.

A thorough investigation in to the materials, processes and management before, during and after the study revealed that the most probable cause for the lack of effect on the primary endpoints was related to the viscosity of the oxytocin gel.

During the course of the study, a few subjects reported that the gel felt runny, which triggered a suspicion that the viscosity of the gel was lower than in previous studies. It was concluded that the combination of the aluminium tube used and storage in room temperature was the cause. At the time of the initial reports from the study subjects, a recommendation was issued to the remaining subjects to store the tubes refrigerated. Analysis of this sub-group, after the trial results were known, showed a significant reduction of the most bothersome symptom compared with placebo. Additional investigations also pointed at low viscosity being the culprit. This in turn resulted in too weak adhesion of the gel to the vaginal wall and an insufficient oxytocin dose.

These encouraging results and a strong belief that the causes of the low viscosity can be eliminated prompted the board to decide to repeat the study, provided of course, that financing could be secured. So it happened. In December a rights issue and a follow-on private placement brought SEK 27.7 m to the company (before issues costs). This was a clear sign by our shareholders of the strong confidence in the competence resting in the company.

The preparations for the new study are now well under way. In the main study (160 subjects), the gel will be stored in a glass syringe, whereas a new tube (laminated) will be used in the pilot part of the study (40 subjects). In stability studies the glass syringe and the laminate tube have shown to preserve gel viscosity equally well. In this double-blinded study subjects will be treated with a daily dose of either 400 IU oxytocin or placebo.

We plan to start randomising subjects in to the study in May and to present initial results before the end of the year. This, of course, provided that plans and deadlines are met, and nothing unexpected occurs. We feel very comfortable by the choice of clinics, suppliers and service providers, and we have a strong belief that the study will be successful.

The contacts with potential partners will now be re-activated with the aim to have the partner candidates ready to move forward when the results of the new study are published.

I want to take this opportunity to thank our shareholders, the board members, suppliers and service providers for their support, assistance and confidence, and my closest colleagues for the courage and fighting spirit they have shown during the challenging times during last year.

Stockholm, 26th of February 2016

Johan Inborr, CEO



COMPANY BRIEF

Peptonic Medical AB is an innovative Swedish pharmaceutical company developing oxytocin based products e.g. for the treatment of menopausal symptoms, such as vaginal atrophy. Oxytocin has a long history of safe and effective medical use and offers an alternative to estrogen and estrogen-like acting compounds for menopausal and postmenopausal women. Peptonic Medical AB's mission is to develop safe and effective drugs based on the known beneficial properties of oxytocin.



FINANCIAL INFORMATION

Net sales – Currently the company has no net sale.

Costs – Costs for the fourth quarter were KSEK -4,793 (-3,649). Costs for the full year were KSEK -13,983 (-10,115).

Result – Loss before tax for the fourth quarter was KSEK -4,785 (-3,628). Loss before tax for the full year was KSEK -13,960 (-10,097).

Financial position and liquidity – Liquid assets was KSEK 28,431 (10,528) as of December 31, 2015. During the full year the company received KSEK 40,564 (20,099) in new share issues.

Equity – PEPTONIC medical AB's equity amounted to KSEK 67,514 (40,910) as of December 31, 2014, resulting in a solidity of 91 (89) percent.

Organization – The average number of employees during the period was 2 (2). At the end of the year the number of employees was 2 (2).

Share – Total numbers of shares in the company amounted to 19,174,412 as of December 31, 2015. That inclusive paid shares that havn't been registerd at Bolagsverket until the 12th of January 2016. But all of there paid before New Year.



INCOME STATMENT

		3 months Oct-Dec	3 months Oct-Dec	12 months Jan-Dec	12 months Jan-Dec
KSEK	Note	2015	2014	2015	2014
KJEK	11010	2013	2017	2013	2014
Operating income					
Other operating income		-	1	-	10
Total operating income	_	-	1	-	10
Operating expenses					
Other external expenses	1	-3,593	-2,453	-9,274	-7,410
Personnel costs		-1,197	-1,194	-4,696	-2,713
Depreciation		-4	-2	-13	-2
Total operating expensses		-4,793	-3,649	-13,983	-10,125
Operating loss		-4,793	-3,648	-13,983	-10,115
Net financial income/expense		8	20	23	18
Loss before taxes		-4,785	-3,628	-13,960	-10,097
Taxes		-	-	-	-
Net loss for the period		-4,785	-3,628	-13,960	-10,097



BALANCE SHEET

KSEK	Note	Dec 31 2015	Dec 31 2014
Assets			
Non-Current assets			
Intangeble assets	2	45,407	34,606
Tangeble assets		23	35
Financial assets		-	-
Total non-current assets		45,430	34,641
Current assets			
Raw materials and consumables		-	-
Other receivbles		328	456
Tax receivable		-	-
Prepaid expenses and accrued income		160	207
Liquid assets		28,431	10,528
Total current assets		28,919	11,191
Total assets		74,349	45,832
Equity and liabilites			
Equity			
Ristricted equity			
Share capital		944	797
Ongoing right issues		973	-
Non- restrictes equity			
Share premium reserv non-restricted		112,021	72,578
Profit or loss brought forward		-32,465	-22,368
Net loss for the period		-13,960	-10,097
Total equity	3	67,513	40,910
Current liabilites			
Trade payables		1,769	1,330
Other payables		241	183
Prepaid income and accrued expenses		4,826	3,409
Total current liabilites		6,836	4,922
Total equity and liabilities		74,349	45,832



STATMENT OF CASH FLOW

KSEK	Not	12 mån Jan-Dec 2015	12 mån Jan-Dec 2014
CASH FLOW FROM OPERATIONS BEFORE CHANGES IN WORKING CAPITAL			
Operating profit/loss		-13,960	-10,097
Non-cash flow items		12	2
Paid tax NET CASH FLOW FROM OPERATING ACTIVITIES BEFORE CHANGES IN WORKING CAPITAL		-13,948	-10,095
Increase (-) decrease (+) inventory		-	-
Increase (-) decrease (+) receivables		175	-127
Increase (-) decrease (+) liabilities		1,912	2,517
NET CASH FLOW FROM OPERATING ACTIVITIES		-11,861	-7,705
CASH FLOW FROM INVESTING ACTIVITIES			
Investment in immaterial and material assets, net Investment in financial assets Divestment / reduction of financial assets		-10,800 - -	-9,276 - -
NET CASH FLOW FROM INVESTING ACTIVITIES		-10,800	-9,276
CASH FLOW FROM FINANCING ACTIVITIES Rights issue Issue expenses		42,189 -1,624	22,628 -2,529
NET CASH FLOW FROM FINANCING ACTIVITIES		40,564	20,099
TOTAL CASH FLOW FOR THE YEAR Cash and cash equivalents at beginning of period		17,903 10,528	3,118 7,410
CASH AND CASH EQUIVALENTS AT END OF THE YEAR		28,431	10,528



CHANGES IN EQUITY

			Share Premium		Total
	Share	Ongoing	reserve	Accumulate	shareholders
KSEK	Capital	right issue	n-rest	d losses	equity
Opening balance January 1, 2014	274	6,645	46,356	-22,367	30,908
Net loss for the year				-10,097	10,097
Issue bonus shares	297		-297		-
Rights issue	226	-6,645	29,048		22,628
Issue expenses			-2,529		-2,529
Closing balance December 31, 2014	797	0	72,578	-32,465	40,910
Opening balance January 1, 2015	797	0	72,578	-32,465	40,910
Net loss for the year				-13,960	-13,960
Rights issue	147		14,341		14,488
Option scheme			40		40
On-going rights issue		973	26,687		27,660
Issue expenses			-1,625		-1,625
Closing balance December 31, 2015	944	973	112,021	-46,425	67,513



NOTE

Accounting principles

This interim report has been prepared in accordance with the Annual Accounts Act (Chapter 9. Interim Report) and the Swedish Accounting Standards Board's general advice, BFNAR 2012:1 Annual Report and consolidated (K3-rules).

Note 1 – Related-party transactions

During the year companies represented by members of the Board of Directors have been contracted as consultants. Total compensation for consultancy services amounted to KSEK 1,706 (1,957) excl. of VAT, and is mainly related to R&D-services. All transactions between related parties are based on market conditions. No other key executives or their immediate family members have been directly or indirectly involved in any business transaction with the Company that is or was unusual in its character or terms and conditions during the year.

	2015	2014
KSEK	Jan-Dec	Jan-Dec
Consulting fees Board of Directors	1,706	1,957
Total	1,706	1,957

Note 2 – Intangible assets

Patents and development costs are capitalized and amortized over five years after the first



income has been acquired. Capitalized patent and development costs are estimated to result in future revenues for the company. Patent and development costs are stated at acquisition value in the balance sheets.

	Dec 31	Dec 31
Capitalized development costs	2015	2014
Accumulated acquisition value		
Opening balance	28,274	20,132
Capitalizations during the period	9,628	8,142
	37,892	28,274
No depreciation has been made as no income has been acquired	-	-
Net booked amount at end of year	37,892	28,274
Patents och licenses		
Accumulated acquisition value		
Opening balance	6,332	5,236
Capitalizations during the period	1,183	-
Reclassifications do to exchange of shares to patent rights		1,096
	7,515	6,332
No depreciation has been made as no income has been acquired	-	-
Net booked amount at end of period	7,515	6,332
Total intangible assets	45,407	34,606

Note 3 – Equity and liabilites

All of the Company's debts are non-interest bearing.

KEY FIGURES 12 months 12 months



		Jan-Dec	Jan-Dec
		2015	2014
Operating loss, KSEK		-13,983	-10,115
Return on equity, %		-25.8	-28.1
Solidity, %		91	89
Earnings per share, SEK		-0.7	-1.3
Liquid assets per share, SEK		1.5	1.3
Shareholders' equity per share , SEK		2.13	5.13
Share price per closing, SEK		6.10	8.90
Share price/Shareholders' equity per share, SEK		2.86	1.73
Number of share per closing	*	19,174,412	7,971,054

^{*}Inclusive shares paid during 2015, but not registered at Bolagsverket until January 2016

Dividend

The Board of Directors proposes that no dividend is paid for the fiscal year 2015.

Annual Report

Complete Annual Report for 2015 can be ordered from the company's office or be downloaded from the webpage from the date of 19th of April 2016. It will be written in Swedish.

Annual General Meeting

The AGM will be held in Stockholm on the 19th of May 2016.



This interim report has not been reviewed by the Company's auditors.

The Board of Directors and the CEO certify that the interim report gives a fair overview of the business, position and profit or loss of the Company.

FINANCIAL CALENDER

Annual report 2015 April 19th 2016

Quarterly report, 1 May 17th 2016

Quarterly report, 2 August 17th 2016

Quarterly report, 3 November 10th 2016

Year end report, 2016 February 27th 2017

Stockholm, February 26th, 2016

Ron Long, Chairmen of the Board Kerstin Uvnäs Moberg, Board member

Andris Kreicbergs, Board member Nadia Whittley, Board member

Johan Inborr, CEO

For more information please contact:

Johan Inborr, CEO PEPTONIC medical AB. Phone: +46 708 853 893

Note: This document has been prepared in both Swedish and English. The Swedish version shall govern in case of differences between the two documents. The document contains certain statements about the Company's operating environment and future performance. These statements should only be regarded as reflective of prevailing interpretations. No guarantees can be made that these statements are free from errors.