



## YEAR END REPORT

Period from January to December 2015

Peptonic Medical AB (publ) org nr 556776-3064

([www.aktietorget.se](http://www.aktietorget.se), 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)
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## 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 sub-group, 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 Inbarr, 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 haven't been registered at Bolagsverket until the 12<sup>th</sup> of January 2016. But all of there paid before New Year.

**INCOME STATEMENT**

KSEK	Note	3 months Oct-Dec 2015	3 months Oct-Dec 2014	12 months Jan-Dec 2015	12 months Jan-Dec 2014
<b>Operating income</b>					
Other operating income		-	1	-	10
<b>Total operating income</b>		<b>-</b>	<b>1</b>	<b>-</b>	<b>10</b>
<b>Operating expenses</b>					
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
<b>Total operating expenses</b>		<b>-4,793</b>	<b>-3,649</b>	<b>-13,983</b>	<b>-10,125</b>
<b>Operating loss</b>		<b>-4,793</b>	<b>-3,648</b>	<b>-13,983</b>	<b>-10,115</b>
Net financial income/expense		8	20	23	18
<b>Loss before taxes</b>		<b>-4,785</b>	<b>-3,628</b>	<b>-13,960</b>	<b>-10,097</b>
Taxes		-	-	-	-
<b>Net loss for the period</b>		<b>-4,785</b>	<b>-3,628</b>	<b>-13,960</b>	<b>-10,097</b>

**BALANCE SHEET**

KSEK	Note	Dec 31 2015	Dec 31 2014
<b>Assets</b>			
<b>Non-Current assets</b>			
Intangible assets	2	45,407	34,606
Tangible assets		23	35
Financial assets		-	-
<b>Total non-current assets</b>		<b>45,430</b>	<b>34,641</b>
<b>Current assets</b>			
Raw materials and consumables		-	-
Other receivbles		328	456
Tax receivable		-	-
Prepaid expenses and accrued income		160	207
Liquid assets		28,431	10,528
<b>Total current assets</b>		<b>28,919</b>	<b>11,191</b>
<b>Total assets</b>		<b>74,349</b>	<b>45,832</b>
<b>Equity and liabilites</b>			
<b>Equity</b>			
<b>Ristricted equity</b>			
Share capital		944	797
Ongoing right issues		973	-
<b>Non- restrictes equity</b>			
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
<b>Total equity</b>	3	<b>67,513</b>	<b>40,910</b>
<b>Current liabilites</b>			
Trade payables		1,769	1,330
Other payables		241	183
Prepaid income and accrued expenses		4,826	3,409
<b>Total current liabilites</b>		<b>6,836</b>	<b>4,922</b>
<b>Total equity and liabilities</b>		<b>74,349</b>	<b>45,832</b>

**STATEMENT OF CASH FLOW**

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



**CHANGES IN EQUITY**

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

## 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.

	<b>2015</b>	<b>2014</b>
KSEK	<b>Jan-Dec</b>	<b>Jan-Dec</b>
Consulting fees Board of Directors	<u>1,706</u>	<u>1,957</u>
<b>Total</b>	<b>1,706</b>	<b>1,957</b>

### 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.

	<b>Dec 31</b>	<b>Dec 31</b>
	<b>2015</b>	<b>2014</b>
<b>Capitalized development costs</b>		
Accumulated acquisition value		
Opening balance	28,274	20,132
Capitalizations during the period	9,628	8,142
	<u>37,892</u>	<u>28,274</u>
No depreciation has been made as no income has been acquired	-	-
<b>Net booked amount at end of year</b>	<b>37,892</b>	<b>28,274</b>
<b>Patents och licenses</b>		
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
	<u>7,515</u>	<u>6,332</u>
No depreciation has been made as no income has been acquired	-	-
<b>Net booked amount at end of period</b>	<b>7,515</b>	<b>6,332</b>
<b>Total intangible assets</b>	<b>45,407</b>	<b>34,606</b>

### Note 3 – Equity and liabilities

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

## KEY FIGURES

12 months 12 months

	<b>Jan-Dec 2015</b>	<b>Jan-Dec 2014</b>
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 19 <sup>th</sup> 2016
Quarterly report, 1	May 17 <sup>th</sup> 2016
Quarterly report, 2	August 17 <sup>th</sup> 2016
Quarterly report, 3	November 10 <sup>th</sup> 2016
Year end report, 2016	February 27 <sup>th</sup> 2017

**Stockholm, February 26<sup>th</sup>, 2016**

Ron Long, Chairmen of the Board

Kerstin Uvnäs Moberg, Board member

Andris Kreicbergs, Board member

Nadia Whittley, Board member

Johan Inborr, CEO

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*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.*