

# **INTERIM REPORT**

Period from January 2015 to September 2015

Peptonic Medical AB (publ) org nr 556776-3064 (www.aktietorget.se ticker: PMED)

### 2015 THIRD QUARTER (Jul-Sep)

- Operating loss KSEK -2,683 (-2,713)
- Loss per share SEK -0.28 (-0.34)

# FIRST NINE MONTHS 2015 (Jan-Sep)

- Derating loss KSEK -9,190 (-6,467)
- Loss per share SEK -0.97 (-0.81)

# IMPORTANT EVENTS DURING THE PERIOD

- 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.

# IMPORTANT EVENTS AFTER THE END OF THE PERIOD

- The Board announces that the investigation has 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 has called for an extraordinary general meeting on November 19, 2015, to seek shareholder approval for a rights issue of approximately MSEK 22.7 (the "Offer") in order to finance the proposed phase IIb study.



# From the CEO

Vaginal atrophy is a condition affecting approximately one out of two women during or post menopause. The symptoms e.g. vaginal dryness and pain during intercourse, markedly reduce quality of life and negatively impact the life in a partnership of those affected. There is a great need for safe and effective treatments. This we have noticed, for example, during the recruitment of patients to our clinical studies with oxytocin (Vagitocin<sup>®</sup>). Many are seeking relief, but do not want to or cannot use estrogen based products due to the many serious side effects associated with their use.

Clinical studies with oxytocin up until 2013 showed good effects and safety. The objectives of the latest study during 2014-2015 were to make a leap towards phase 3 clinical development and to show good efficacy of a commercially viable product. This was done by changing the previously used glass syringe and storage in refrigerator to an aluminium tube with a disposable applicator and storage in room temperature. Despite good stability data for oxytocin when stored in the aluminium tube, the results of the clinical study were disappointing. Oxytocin treatment did not result in an improvement compared with placebo for any of the primary endpoints.

During the course of the study, a few patients reported that they felt that the gel was runny. This triggered a suspicion that the viscosity of the gel was lower now than in previous studies. We decided to issue a recommendation to the patients still to be treated to store the gel tubes in a refrigerator during the course of the treatment period. Analysis of the results generated after the issuance of this recommendation showed a significant reduction of the Most Bothersome Symptoms. Further investigations have confirmed our suspicion that the viscosity of the gel was too low. This lead to an insufficient adherence to the vaginal mucosa and daily oxytocin dose.

We are now planning for a repeat clinical study using both a glass syringe and a new type of tube. This tube has shown to preserve gel viscosity as well as glass syringes. We are confident that the clinical endpoints can be obtained and that we can take the next important step towards phase 3 and a subsequent commercial launch. This study is to be concluded during 2016 and carried out as cost-effectively and professionally as the previous one. The physicians at the clinical sites have long experience from both conducting clinical studies and from oxytocin. This is a guarantee that both patients and data collection are in good hands.

The vaginal atrophy market is estimated to USD 2 billion annually. Based on its unique properties we believe that Vagitocin<sup>®</sup> will capture a significant share of this market and make it grow. We are able to offer a safe and effective treatment for everyone – both to those that do not want to use estrogens, but also to those that must not use estrogens.

Peptonic Medical is not only focusing on Vagitocin<sup>®</sup>. There are patents owned by the company covering many therapeutic areas of great commercial potential such as pain, wound healing and cancer. Patent applications for additional indications have been submitted, and more are under development. In addition, new oxytocin formulations have been developed for use in either existing or new indication areas.

There are many potential medical applications for oxytocin not yet developed. It is the aim of Peptonic Medical to develop products based on oxytocin for indications with a pronounced need for new treatments and great market potential.

Stockholm November 11, 2015 Johan Inborr CEO, Peptonic Medical AB



## **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 third quarter were KSEK -2,683 (-2,722). Costs for the first nine months were KSEK -9,190 (-6,476).

**Result** – Loss before tax for the third quarter was KSEK -2,683 (-2,714). Loss before tax for the first nine months was KSEK -9,175 (-6,469).

**Financial position and liquidity** – Liquid assets was KSEK 10,537 (15,212) as of September 30, 2015. During the first six months the company received KSEK 14,522 in a private placement.

**Equity** – PEPTONIC medical AB's equity amounted to KSEK 46,257 (44,119) as of September 30, 2015, resulting in a solidity of 81 (97) percent.

**Organization** – The average number of employees during the period was 2 (1). At the end of the period the number of employees was 2 (2).

Share – Total numbers of shares in the company amounted to 9,441,960 as of September 30, 2015.



#### **INCOME STATMENT**

KSEK	Note	3 months Jul-Sep 2015	3 months Jul-Sep 2014	9 months Jan-Sep 2015	9 months Jan-Sep 2014	12 months Jan-Dec 2014
Operating income						
Other operating income		0	9	0	9	10
Total operating income	_	0	9	0	9	10
Operating expenses						
Other external expenses	1	-1,648	-2,232	-5,682	-4,957	-7,410
Personnel costs		-1,032	-490	-3,499	-1,519	-2,713
Depreciation		-3	-	-9	-	-2
Total operating expensses	_	-2,683	-2,722	-9,190	-6,476	-10,125
Operating loss		-2,683	-2,713	-9,190	-6,467	-10,115
Net financial income/expense		-	-1	15	-2	18
Loss before taxes		-2,683	-2,714	-9,175	-6,469	-10,097
Taxes		-	-	-	-	-
Net loss for the period		-2,683	-2,714	-9,175	-6,469	-10,097

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#### **BALANCE SHEET**

		Sep 30	Sep 30	Dec 31
KSEK	Note	2015	2014	2014
Assets				
Non-Current assets				
Intangeble assets	2	45,023	29,301	34,606
Tangeble assets	2	43,023	- 20,301	35
Financial assets		-	-	-
Total non-current assets		45,049	29,301	34,641
Current assets				
Raw materials and consumables		_	11	_
Other receivbles		1,049	825	456
Tax receivable		-	92	-
Prepaid expenses and accrued income		135	117	207
Liquid assets		10,537	15,212	10,528
Total current assets		11,721	16,257	11,191
Total assets		56,770	45,558	45,832
Equity and liabilites				
Equity				
Restricted equity				
Share capital		944	797	797
Ongoing right issues		-	-	-
Non- restricted equity				
Share premiun reserv non-restricted		86,953	72,159	72,578
Profit or loss brought forward		-32,465	-22,368	-22,368
Net loss for the period		-9,175	-6,469	-10,097
Total equity	3	46,257	44,119	40,910
Current liabilites				
Trade payables		7,217	1,078	1,330
Other payables		472	154	183
Prepaid income and accrued expenses		2,824	207	3,409
Total current liabilites		10,513	1,439	4,922
Total equity and liabilities		56,770	45,558	45,832



## 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 period companies represented by members of the Board of Directors were contracted as consultants. Total compensation for consultancy services amounted to KSEK 1,625 (1,472) and is 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 and took place during the period.

	2015	2014	2014
KSEK	Jan-Sep	Jan-Sep	Jan-Dec
Consulting fees Board of Directors	1,625	1,472	1,957
Total	1,625	1,472	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.

	Sep 30	Sep 30	Dec 31
Capitalized development costs	2015	2014	2014
Accumulated acquisition value			
Opening balance	28,274	20,132	20,132
Capitalizations during the period	9,288	3,208	8,142
	37,562	23,340	28,274
No depreciation has been made as no income has been acquired	-	-	-
Net booked amount at end of period	37,562	23,340	28,274
Patents och licenses			
Accumulated acquisition value			
Opening balance	6,332	5,236	5,236
Capitalizations during the period	1,129	725	-
Reclassifications do to exchange of shares to patent rights		_	1,096
	7,461	5,961	6,332
No depreciation has been made as no income has been acquired	-	-	-
Net booked amount at end of period	7,461	5,961	6,332
Total intangible assets	45,023	29,301	34,606

# Note 3 – Equity and liabilites

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



KEY FIGURES	9 months Jan-Sep 2015	9 months Jan-Sep 2014	12 months Jan-Dec 2014
Operating loss, KSEK	-9,190	-6,467	-10,115
Return on equity, %	-28.1	-23.0	-28.1
Solidity, %	81	97	89
Earnings per share, SEK	-1.0	-0.8	-1.3
Liquid assets per share, SEK	1.1	1.9	1.3
Shareholders' equity per share , SEK	4.9	5.5	5.1
Share price per closing, SEK	4.98	10.25	8.90
Share price/Shareholders' equity per share,			
SEK	1.0	1.9	1.7
Number of share per closing	9,441,960	7,971,054	7,971,094



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

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

FINANCIAL CALENDER Year-end report	February 26, 2016
Stockholm, November 11 <sup>th</sup> , 2015	
Ron Long, Chairmen of the Board	Kerstin Uvnäs Moberg, Board member
Anders Wiklund, 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.