

## **INTERIM REPORT**

Period from January 2017 to March 2017

Peptonic Medical AB (publ) org nr 556776-3064

(www.aktietorget.se ticker: PMED)

## 2017 FIRST QUARTER (Jan-Mar)

- Operating loss KSEK -2,681 (-3,551)
- Loss per share SEK -0.13 (-0.18)

## IMPORTANT EVENTS DURING THE PERIOD

- In January, the Company announced that the last study subject of the Company's phase 2b clinical study had been enrolled and started the treatment. This concerned the second (exploratory) part, 40 patients, of the clinical phase 2b study, in which the oxytocin gel is stored in laminated tubes.
- In February the Company announced that all of the randomized subjects of the first part of the ongoing phase 2b study, the main study with 160 patients administrated with a glass syringe, had completed the treatment and exited the study.
- On March 10<sup>th</sup>, the Company announced that the primary efficacy endpoints of the first part of its phase 2b study, in which the Vagitocin<sup>®</sup> gel was investigated for the treatment of vaginal atrophy, were not met. However, further analyses of the study data showed that the gel, both without and with the active ingredient (oxytocin), had a marked and statistically significant alleviating effect on the Most Bothersome Symptoms (MBS) after the twelve week treatment. To enter a clinical phase 3 programme, a new phase 2b study will be required. Hence, the Company has now decided to focus on bringing the oxytocin-free gel to the market as a non-prescription product.

# IMPORTANT EVENTS AFTER THE END OF THE PERIOD

- At the shareholder information meeting held April 11, the CEO, Johan Inborr, announced that the Board intends to submit a proposal for a rights issue, subject to the shareholders' approval at the Annual General Meeting (AGM) on May 18, 2017. The proceeds of the rights issue will be used to finance the development and market launch of the vaginal gel as a non-prescription, CEmarked product.
- On May 4<sup>th</sup> the Company informed about the proposed conditions for the planned issue of rights. The decision will be subject to the shareholders' approval at the Annual General Meeting on May 18<sup>th</sup> 2017.

PEPTONIC medical AB (publ)

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### From the CEO

The first quarter this year has been rather shocking for the management, the Board and the shareholders of Peptonic. The results of the phase 2b study, which were supposed to form the springboard to phase 3, turned out to be disappointing. None of the set efficacy endpoints were met, which appears totally incomprehensible given the results from previous studies, the meticulous preparations and the excellently performed study. This result means that we cannot proceed to phase 3 as planned. A thorough investigation of the results and all available information from the study is still underway. This with the hope of finding an explanation to the unexpected results and to come up with a plan for the continued development of Vagitocin<sup>®</sup>.

If the lack of effect of oxytocin was surprising, so were the positive results of the placebo gel itself. The effect of the gel on the most important clinical endpoints – both objective and subjective – was of a great magnitude and on par with effects reported from studies with pharmaceutical products in the same indication. During the study, the responsible investigators of the participating clinics reported that a significant proportion of the study subjects experienced symptom relief, which was confirmed by the final results. The most surprising, however, was that the proportion of the study subjects experiencing symptom relief was somewhat larger in the placebo arm (8 out of 10 study subjects) than in the active arm (7 out of 10). These results were so conclusive that we have now decided to bring the vaginal gel – without oxytocin - to the market as an OTC/ self-care product.

Before launch, the product needs to be CE –marked and it will be classified as a medical device. The process of CE –marking will take approximately 9 months and after obtaining the CE –mark it can be sold in all of Europe. A corresponding certification (510k) will be obtained for the US market as soon as possible. We have already registered a new trade name for the product - VagiVital<sup>®</sup>.

Initially, VagiVital<sup>®</sup> is planned to be launched in Sweden during 2018 and thereafter in the neighbouring Nordic countries. The Nordic market for products used to the treatment of vaginal atrophy is estimated to approximately SEK 700 million. Pharmacies will be the primary sales channel but other channels may be considered. Marketing and promotion will be supported by the documented efficacy from large clinical studies, which makes VagiVital<sup>®</sup> unique among its competing self-care products.

In parallel with the CE-marking and manufacturing sale-up processes we will be looking for distributors and commercial partners both in the home market (Sweden/Nordics) and abroad. This to give us more alternatives to find the best and most cost-effective ways of launching VagiVital<sup>®</sup>.

Bringing VagiVital<sup>®</sup> to the market is clearly a change of direction of Peptonic. However, it is not a 180 degree turn around. We are still a serious player in the field of women's health, we are still focussing on vaginal atrophy, and our development work is still based on high quality clinical research. The main advantage of bringing VagiVital<sup>®</sup> to the market now is that it will create an income stream in



the company already next year. It also gives us the possibility to complete the investigations relating to the lack of effect of oxytocin and potentially develop a plan for how to go forward with the development of an oxytocin based product.

I am thrilled about the unexpected possibility that has emerged from the phase 2b study. VagiVital<sup>®</sup> is a great opportunity for Peptonic and I hope that all shareholders share the enthusiasm with me and participate in the planned rights issue. The proceeds of which will be used to bring VagiVital<sup>®</sup> to the market.

Stockholm May 16, 2017

Johan Inborr CEO, Peptonic Medical AB



## **COMPANY BRIEF**

Peptonic Medical AB (publ) is an innovative Swedish biopharma company developing products within the field of women's health. The Company was founded in 2009 and its first candidate drug product is Vagitocin<sup>®</sup> – an estrogen-free product for the treatment of vaginal atrophy.

VagiVital<sup>®</sup> is a registered trademark of Peptonic Medical. The product is being developed for the non-prescription use for the treatment of vaginal atrophy.

Find out more at <u>www.peptonicmedical.se</u>



#### **FINANCIAL INFORMATION**

**Net sales** – Currently the company has no net sale.

Costs – Costs for the first quarter were KSEK -2,681 (-3,551).

Result – Loss before tax for the first quarter was KSEK -2,681 (-3,537).

Financial position and liquidity – Liquid assets was KSEK 7,373 (21,650) as of March 31, 2017.

**Equity** – PEPTONIC medical AB's equity amounted to KSEK 58,961 (63,975) as of March 31, 2017, resulting in a solidity of 91 (86) percent.

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

Share – Total numbers of shares in the company amounted to 20,602,984, as of March 31, 2017.



#### **INCOME STATMENT**

		3 months Jan-Mar	3 months Jan-Mar	12 months Jan-Dec
KSEK	Note	2017	2016	2016
Operating income				
Other operating income		0	0	0
Total operating income		0	0	0
Operating expenses				
Other external expenses	1	-1,548	-2,409	-5,709
Personnel costs		-1,130	-1,139	-4,541
Depreciation		-3	-3	-1,070
Total operating expensses		-2,681	-3,551	-11,320
Operating loss		-2,681	-3,551	-11,320
Net financial income/expense		0	14	62
Loss before taxes		-2,681	-3,537	-11,258
Taxes		-	-	-
Net loss for the period		-2,681	-3,537	-11,258

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#### **BALANCE SHEET**

KSEK	Note	Mar 31 2017	Mar 31 2016	Dec 31 2016
Assets				
Non-Current assets				
Intangeble assets	2	57,029	46,401	54,995
Tangeble assets		7	20	10
Financial assets		-	-	
Total non-current assets		57,036	46,421	55,005
Current assets				
Raw materials and consumables		-	_	
Other receivbles		324	227	649
Tax receivable		-	-	
Prepaid expenses and accrued income		95	119	111
Liquid assets		7,373	21,650	12,169
Total current assets		7,792	21,996	12,929
Total assets		64,828	68,417	67,934
Equity and liabilites				
Equity				
Ristricted equity				
Share capital		2,060	1,917	2,060
Ongoing right issues		-	-	(
Development Cost Fund		11,682	0	9,767
Non- restrictes equity				
Share premiun reserv non-restricted		117,265	112,020	117,265
Profit or loss brought forward		-69,365	-46,425	-56,192
Net loss for the period		-2,681	-3,537	-11,258
Total equity	3	58,961	63,975	61,643
Current liabilites				
Trade payables		957	1,016	1,708
Other payables		150	4	434
Prepaid income and accrued expenses		4,760	3,422	4,149
Total current liabilites		5,867	4,442	6,291
Total equity and liabilities		64,828	68,417	67,934



## 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 499 (377) and is mostly 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.

	2017	2016	2016
KSEK	Jan-Mar	Jan-Mar	Jan-Dec
Consulting fees Board of Directors	499	377	1,340
Total	499	377	1,340



#### 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.

	Mar 31	Mar 31	Dec 31
Capitalized development costs	2017	2016	2016
Accumulated acquisition value			
Opening balance	47,659	37,892	37,892
Capitalizations during the period	1,915	777	9,767
	49,574	38,669	47,659
No depreciation has been made as no income has been acquired	-	-	-
Net booked amount at end of period	49,574	38,669	47,659
Patents och licenses			
Accumulated acquisition value			
Opening balance	7,336	7,515	7,515
Capitalizations during the period	119	217	879
Reclassifications do to exchange of shares to patent rights	-	-	-
	7,455	7,732	8,394
Depreciation - closed down of patent families, because of short of time to end of patent	-	-	-1,058
Net booked amount at end of period	7,455	7,732	7,336
Total intangible assets	57,029	46,401	54,995

## Note 3 – Equity and liabilites

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



KEY FIGURES	3 months Jan-Mar 2017	3 months Jan-Mar 2016	12 months Jan-Dec 2016
Operating loss, KSEK	-2,681	-3,551	-11,320
Return on equity, %	-17.8	-21.5	-17.4
Solidity, %	91	94	91
Earnings per share, SEK	-0.1	-0.2	-0.6
Liquid assets per share, SEK	0.4	1.1	0.6
Shareholders' equity per share , SEK	2.9	3.3	2.99
Share price per closing, SEK	1.85	5.80	6.45
Share price/Shareholders' equity per share, SEK	0.65	1.8	2.16
Number of share per closing	20,602,984	19,174,412	20,602,984



## 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	
Quarterly report, 2	August 17 <sup>th</sup> 2017
Quarterly report, 3	November 9 <sup>th</sup> 2017

Stockholm, May 16<sup>th</sup>, 2017

Year end report, 2016

Hans von Celsing, Chairmen of the Board

Kerstin Uvnäs Moberg, Board member

Arne Ferstad, Board member

Johan Inborr, CEO

February 27<sup>th</sup> 2018

### For more information please contact:

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*This information is information that Peptonic Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 16<sup>th</sup> May 2017.* 

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.