Promore Pharma AB (publ)

Interim report January – March 2019

- Net sales amounted to MSEK 0.5 (0.1) MSEK
- The operating loss for the period was 5.5 (loss 7.9) MSEK
- Net loss was 5.5 MSEK (loss 7.9) MSEK, corresponding to a loss per share of SEK 0.27 (loss 0.39)
- Cash flow from operating activities amounted to -4.4 (-8.5) MSEK
- Cash and cash equivalents amounted to 26.6 (54.4) MSEK

Significant events during the period January - March

- Phase III trial with PXL01 modified and the number of clinics in the study expanded

"I am content with the ongoing development of the project portfolio during the quarter and that Promore Pharma has continued to make progress in accordance with our business plan. Promore Pharma is well-positioned to continue to drive the projects forward and to launch new potential value-creating partnerships in the long term in accordance with the company's strategy."

Jonas Ekblom, President and CEO Promore Pharma

Financial overview for the Company

	1 January - 31 March		1 January - 31 December	
Amounts in MSEK	2019	2018	2018	2017
Net sales	0,5	0,1	2,4	0,6
Operating loss	-5,5	-7,9	-32,7	-9,6
Profit/Loss for the period	-5,5	-7,9	-32,5	-8,4
Earnings per share, before/after dilution, SEK [1]	-0,27	-0,39	-1,61	-0,51
Cash flow from operating activities	-4,4	-8,5	-32,5	-7,0
Cash and cash equivalents at the end of the period	26,6	54,4	30,9	63,0

Adjusted for share split 15:1

Promore Pharma in brief:
Promore Pharma is a biopharmaceutical company specialized in the development of therapeutic peptides. The company's aim is to develop first-in-category pharmaceuticals for indications where very few efficacious prescription pharmaceuticals are available, thus, addressing high unmet medical needs. Promore Pharma's two projects are in late stage clinical development phase and have a very strong safety profile since they are based on innate substances that are administered locally. The leading project, PXL01, that will be used for prevention of post-surgical adhesions and scars, is being prepared for clinical phase III-studies in patients undergoing tendon repair surgery in the hand. LL-37 has initiated a clinical phase IIb study in patients with venous leg ulcers (VLU). The product candidates can also be deployed for other indications, such as preventing dermal scarring, adhesions after other surgical procedures and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North.

CEO statement

Promore Pharma's most important task is to develop new products aiming to improve the quality of life for patients with difficult-to-treat wounds and various types of scarring, primarily following surgery. We have continued to develop the company's innovative projects within two treatment areas, both having significant medical needs since the treatment options are poor or absent. The projects are proceeding in line with our business plan.

Both our projects are in late clinical phase and the project that has reached the furthest is the PXL01 program. We are preparing a Phase III clinical trial (PHSU03) with PXL01 where we intend to prevent permanent and undesirable adhesions after tendon repair surgery. In November 2018, the clinical study protocol for PHSU03 was approved by the Drug Controller General of India (DGCI). What remains to be done before we can start recruiting patients to PHSU03, is to finalize the production chain for the experimental drug and to apply and obtain approval from the different national authorities of the European countries where the study will also be conducted.

As for our second development initiative, LL-37 for the treatment of venous leg ulcers, the clinical phase IIb study HEAL, which was started in the third quarter of 2018, progresses satisfactorily. We continue to include patients in Sweden and Poland for the study, where we are planning for about 120 patients to complete the clinical study protocol. Final results after completion of the three-month treatment study are expected to be available by 2020. The primary evaluation criterion is the proportion of completely healed wounds, which is what regulatory authorities also request in confirmatory studies for market approval. With a successful study outcome, we hope to out-license LL-37 to a larger pharmaceutical company having the appropriate configuration of conducting phase III trials and supporting the launch of a future product in the global marketplace.

I am content with the ongoing development of the project portfolio during the quarter and that Promore Pharma has continued to make progress in accordance with our business plan. Promore Pharma is well-positioned to continue to drive the projects forward and to launch new potential value-creating partnerships in the long term in accordance with the company's strategy.

In conclusion, I would like to thank everyone who has contributed to a successful quarter and the beginning of the fiscal year 2019.

Solna, 21 May 2019

Jonas Ekblom
President and CEO

Business Overview

Promore Pharma is a biopharmaceutical company that develops peptide-based product candidates aimed for the bioactive wound care market, the segment within the wound care market expected to show the highest growth with a CAGR of 14% per year until 2020[1]. The company was founded in 2002 and has two therapeutic peptides, PXL01 and LL-37, in late stage clinical development. PXL01 is aimed for prevention of post-surgical adhesions and scars and is being prepared for clinical Phase III-studies on patients undergoing tendon repair surgery in the hand. LL-37 is being investigated in an ongoing clinical Phase IIb trial on patients with venous leg ulcers.

Promore Pharma's product candidates are based on peptides, possessing multiple biological functions and properties. These molecules are derived from sequences of human innate defence system. They are aimed for local application and have a strong safety profile since they are quickly degraded in the blood stream and are therefore unlikely to contribute to severe systemic adverse events. The results from prior clinical studies are very promising for both PXL01 and LL-37 when it comes to tolerability and safety as well as efficacy. The product candidates are protected by several international patent families offering protection until 2030 and longer. The patents provide protection in several dimensions, such as therapeutic use, formulation and dosage ranges.

Promore Pharma's product candidate represent first-in-category therapeutics for several patient groups, segments where patients experience pain, reduced mobility, and lowered quality-of-life. If Promore Pharma's product candidates in clinical development receive market authorization and are established as treatment for chronic wounds and for preventing adhesions and scars, it would mean shorter treatment times for patients and lower costs for society.

Promore Pharma is a small and cost-effective company without its own laboratories or research facilities, using a network of high-quality contract research organizations and contract manufacturing organizations. The company has experienced advisors in all critical aspects of the strategic planning process, including product development, regulatory affairs, design and execution of clinical trials.

Promore Pharma's overall strategy is to take the product candidates through clinical development to market authorization or to a point when a license agreement, alternatively a commercial deal with a larger pharmaceutical company with global presence can be realized. Such transactions may include out-partnering/licensing, strategic partnerships, joint ventures or asset sales.

About PXL01

PXL01 is derived from a human anti-bacterial protein (lactoferrin), which is part of the innate immune system. This protein and its fragments have several modes of action, including immunomodulation and enhancement of fibrinolytic activity. It is well established that inflammation and fibrin formation after surgery are two pivotal mechanisms that strongly contribute to scar formation. The development of PXL01 is initially aiming at preventing postsurgical adhesions after tendon repair surgery. In a Phase-II clinical study that has been completed by the company in several countries of the European Union (EU), it has been demonstrated that PXL01 is efficacious and safe. Promore Pharma is preparing for a clinical Phase III study in EU and India. The trial is planned as a randomized, double-blinded study including some 600 patients with flexor tendon injuries in the hand where a single administration event of PXL01 at two different doses will be compared with placebo. It is the company's ambition to conduct a similar clinical Phase III study in the USA, to form the basis for market authorization in North America. The first indication that the company is focusing on is preventing post-surgical adhesions after tendon repair surgery. Postoperative adhesions constitute a substantial clinical problem after most surgical procedures, but in particular hand surgery. Flexor tendon injury and surgical repair result in adhesion formation around the tendon, which restricts the gliding function of the tendon, leading to decreased digit mobility and impaired hand recovery. Small decreases in mobility greatly impact the quality of life due to difficulties in performing easy tasks, such as closing buttons or using a key board. A first product is aimed at obtaining a label for tendon-and nerve-repair in the hand, lower arm and foot. Additionally, it is anticipated that there are good opportunities for indication broadening, such a preventing fibrosis after spine surgery, dermal scars and adhesions after total knee arthroplasty.

About LL-37

LL-37 is based on a human antimicrobial peptide, which stimulates several processes in wound healing. In a clinical Phase IIa study conducted by the company in patients with venous leg ulcers (VLU), LL-37 showed, in the most effective dose, an increase in healing rate of relative wound area reduction of close to 70% after one month's treatment, suggesting a significantly higher efficacy than what has been reported for any other treatment in chronic wounds. No serious adverse events that were deemed to be caused by the investigational product occurred in the trial. The product candidate can easily

[1] Technavio "Global bioactive wound care market 2016-2020"

be combined with the standard wound care treatments. The development of LL-37 is initially focused on venous leg ulcers and the company has initiated a clinical Phase IIb study (HEAL) on patients with VLU in Europe. VLU constitutes the largest category of all chronic, or hard-to-heal, ulcers and represent significant challenges to patients and healthcare systems since they are frequent, costly to manage, recurring, and may persist for months or years. There are an estimated 13-18 million patients in the traditional pharmaceutical markets. Standard treatment consists of compression bandaging and there are no approved pharmaceutical products for VLUs. In the US alone, the costs for VLUs are estimated at a minimum of USD 14 billion annually. The development of LL-37 focuses initially on VLU but the company sees good potential in developing LL-37 for also diabetic foot ulcers.

Significant events 1 January – 31 March 2019

Phase III trial with PXL01 modified and the number of clinics in the study expanded

The company announced in February 2019 that it is making adjustments to the manufacturing chain of the investigational medicinal product for the company's clinical phase III study, PSHU03, with PXL01 for prevention of adhesions following tendon repair surgery. The product consists of a kit with several components and is supplied through contract manufacturing where service providers in both the USA and Europe are engaged. One of these service providers has not succeeded in renewing all of the manufacturing permits required, which affects the coordination of the manufacturing chain, and it consequently cannot be implemented according to the original plan. In order to reduce the likelihood of time losses on the way to market approval, the company plans to increase the number of clinics in the PHSU03 study by also including a number of hospitals in Italy, thereby minimizing the overall delay by accelerating the recruitment of patients.

Financial information

Net sales and result for the first quarter 2019

Promore Pharma is an innovation company and its product candidates are still undergoing clinical development. Consequently, the company has no revenues from products sales during the reporting period. In the first quarter 2019, the company's net sales amounted to 461,629 SEK, which is primarily attributable to the re-invoicing of consulting costs to the company's partners.

The company's costs for raw materials and consumables are mainly related to development costs, such as costs for patents and consultants working with the development of the company's candidate drugs. In the first quarter 2019 these costs decreased to 2.9 MSEK (5.5 MSEK) due to milestone payment to the company's partner Technomark Group USA LLC paid in the first quarter of 2018.

Other external costs increased in the first quarter 2019 to 1.7 MSEK (1.2 MSEK), mainly due to higher consultancy costs for the first quarter 2019.

Personnel expenses in the first quarter 2019 were 1.1 MSEK (1.0 MSEK).

Net loss in the first quarter 2019 amounted to 5.5 MSEK (loss 7.9 MSEK), corresponding to a loss per share of 0.27 SEK (loss 0.39 SEK).

Liquidity and financing

The cash flow from operating activities amounted in the first quarter 2018 to -8.5 MSEK (-2.8 MSEK) which is explained by a larger operating loss as well as increased working capital requirement. The cash-flow from investments during the period amounted to 0 SEK (0.1 MSEK). In the first quarter 2017 shares Herantis Pharma Oyj was divested.

The cash flow from financing activities was 0 SEK (38.981 SEK) is attributable to an additional consideration payment.

The company's cash and cash equivalents amounted to 26.6 MSEK per 31 March 2019, as compared to 54.4 MSEK per 31 March 2018.

Auxiliary information

Number of shares

Promore Pharma's share is listed on Nasdaq First North in Stockholm since 6 July 2017 with the ticker PROMO and ISIN code SE0009947740. The number of shares as of 31 March 2018 was 20,235,090 (20,235,090). The average number of shares in the first quarter 2019 was 20,235,090 (20 235 090). The main owners Midroc New Technology, Rosetta Capital IV S.a.r.L., and PharmaResearch Products Ltd. own over 88 percent of shares in the company.

Promore Pharma issued in connection with the listing on Nasdaq First North 6,523,560 warrants. The subscription price was determined according to the terms and conditions for the warrants to 23.30 SEK per share on 31 January 2018. The subscription period ended on 22 February 2019. There are additional outstanding warrants, which entitle to subscription of 1,910,310 shares. These warrants are held by PharmaResearch Products Ltd., Technomark Group USA LLC and Kentron Biotechnology Pvt. Ltd., all partners to the company for the development of PXL01 and these outstanding warrants correspond to a potential dilution 8.6%.

Holding of shares in Herantis Pharma Oyj

The company holds shares in the Finnish biotech company Herantis Pharma Oyj. This is a consequence of a passive historic holding in the Finnish company Biocis Oy since the formation of Pergamum AB in 2010. Biocis has since then undergone a number of corporate mergers and ownership restructurings which has resulted in a holding of shares in Herantis Pharma Oyj, a company that executed an IPO in 2015. Promore Pharma's holding of shares in Herantis Pharma Oyj amounted to 48,882 per 31 March 2019. The board of directors of the company has decided that this holding shall be divested in a step-wise fashion.

Personnel

Promore Pharma has a small and cost-effective organization that primarily is focused on business development, project coordination as well as management of intellectual property and core development documentation. All personnel except the CEO operate on a consultancy basis. Per 31 March 2019, the company consequently had one employee.

Transactions with related parties

The company has not been part of any transactions involving related parties during the reporting period.

Accounting principles

The report has been drawn up in accordance with the Swedish Annual Accounts Act (1995:1554) and the Swedish Accounting Standards Board's (BFNAR) General Recommendation 2012:1: Annual Report and Consolidated Accounts ("K3").

Financial calendar

Annual General Meeting	21 May 2019
Interim report January – June 2019	27 August 2019
Interim report January – September 2019	26 November 2019

Review by auditor

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

Solna 21 May 2018

Göran Pettersson

Chairman

Marianne Dicander Alexandersson

Torsten Goesch

Satyendra Kumar

Göran Linder

Consolidated income statement

	1 January - 31 March		1 January - 31 December
Amounts in SEK	2019	2018	2018
Operating income			
Net sales	461 629	57 259	2 446 785
Other operating income	4 199	13 273	683 892
Operating expenses			
Commodities and supplies	-2 939 509	-5 463 404	-24 452 267
Other external expenses	-1 747 711	-1 160 620	-5 841 185
Personnel costs	-1 004 628	-1 051 579	-4 189 945
Depreciation and impairments on fixed assets	-304 286	-304 286	-1 217 143
Other operating expenses	-13 125	-31 558	-106 367
Operating loss (EBIT)	**-5 543 431**	**-7 940 915**	**-32 676 230**
Financial items		0	0
Net financial items	71 937	-143	193 147
Profit/loss after finanical items	**-5 471 494**	**-7 941 058**	**-32 483 083**
			0
Profit/oss before tax	**-5 471 494**	**-7 941 058**	**-32 483 083**
Tax	-	-	-
Profit/Loss for the period	**-5 471 494**	**-7 941 058**	**-32 483 083**

Consolidated balance sheet

Amounts in SEK	31 March 2019	31 March 2018	31 December 2018
ASSETS			
FIXED ASSETS			
Intangible fixed assets	1 521 428	2 738 570	1 825 714
Tangible fixed assets	0	0	0
Financial fixed assets	2 809 597	3 035 393	2 809 597
Total fixed assets	**4 331 025**	**5 773 963**	**4 635 311**
CURRENT ASSETS			
Short term receivables	2 139 067	1 767 731	2 079 807
Cash at bank and in hand	26 608 304	54 425 897	30 882 428
Total current assets	**28 747 371**	**56 193 628**	**32 962 235**
TOTAL ASSETS	**33 078 396**	**61 967 591**	**37 597 546**
EQUITY AND LIABILITIES			
EQUITY			
Share capital	809 404	809 404	809 404
Other equity including the result for the period	26 966 213	56 979 732	32 437 709
Total equity	**27 775 617**	**57 789 136**	**33 247 113**
LONG-TERM LIABILITIES			
Other liabilities to credit institutions	714 038	714 038	714 038
Other liabilities	288 413	291 888	280 860
Total long-term liabilities	**1 002 451**	**1 005 926**	**994 898**
CURRENT LIABILITIES			
Accounts payable	3 191 239	1 875 695	1 312 038
Other current liabilities	1 109 089	1 296 834	2 043 497
Total current liabilities	**4 300 328**	**3 172 529**	**3 355 535**
TOTAL EQUITY AND LIABILITIES	**33 078 396**	**61 967 591**	**37 597 546**

Consolidated cash flow analysis

Amounts in SEK	1 January - 31 March 2019	1 January - 31 March 2018	1 January - 31 December 2018
OPERATING ACTIVITIES			
Operating profit	-5 543 431	-7 940 915	-32 676 230
Adjustments for items not included in cash flow	304 286	304 143	1 153 160
Tax paid	0	0	0
Cash flow from operating activities before changes in working capital	**-5 239 145**	**-7 636 772**	**-31 523 070**
Increase/decrease other current receivables	-56 904	529 442	217 367
Increase/decrease other current liabilities	942 435	-1 399 994	-1 216 988
Cash flow from operating activities	**-4 353 614**	**-8 507 324**	**-32 522 691**
Cash flow from investing activities	79 490	0	471 896
Cash flow from financing activities	0	-38 981	-38 980
Cash flow for the period	**-4 274 124**	**-8 546 305**	**-32 089 775**
Cash and cash equivalents at the beginning of the period	**30 882 428**	**62 972 202**	**62 972 202**
Exchange rate difference cash and cash equivalents		0	
Cash and cash equivalents at the end of the period	**26 608 304**	**54 425 897**	**30 882 428**

Changes in equity for the group

EQUITY

	Share capital	Other paid-in capital	Other equity	Total equity
Amount at the beginning of the period (1 January 2019)	809 404	0	**32 437 707**	**33 247 111**
Profit for the period			-5 471 494	-5 471 494
Amount at the end of the period (31 March 2019)	**809 404**		**26 966 213**	**27 775 617**

	Share capital	Other paid-in capital	Other equity	Total equity
Amount at the beginning of the period (1 January 2018)	**809 404**	**0**	**64 920 790**	**65 730 194**
Profit for the period			-7 941 058	-7 941 058
Amount at the beginning of the period (31 March 2018)	**809 404**		**56 979 732**	**57 789 136**

For additional information, please contact

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This information is information that Promore Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 13:00 CET on 21 May 2019.

Promore Pharma's Certified Adviser is Redeye AB.

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