

## Promore Pharma AB (publ)

# Interim report January – March 2018

- Net sales amounted to MSEK 0.1 (0) MSEK
- The operating loss for the period was 7.9 (loss 3.2) MSEK
- Net loss was 7.9 MSEK (loss 3.3) MSEK, corresponding to a loss per share of SEK 0.39 (loss 0.24)
- Cash flow from operating activities amounted to 8.5 (-2.8) MSEK
- Cash and cash equivalents amounted to 54.4 (3.8) MSEK

#### Significant events during the period January - March

- Cellastra Inc's option to receive a license to commercialize PXL01 in North America expired.
- Promore Pharma Regained PXL01 Manufacturing Rights

### Significant events after the end of the reporting period

• Out-licensing agreement for PXL01 signed with PharmaResearch Products Ltd ("PRP") meaning PRP will finance the development of PXL01 for use to prevent fibrosis after spinal surgery.

"We see multiple potential applications for PXLO1, Promore Pharma has limited resources and we therefore believe that investments in our technology and our products from strategic and competent partners are an attractive opportunity for us to broaden the use of our technology base. In this way, we can bring more products to the market and thereby raise the value of our business. In this context, the out-licensing agreement we recently signed with PharmaResearch Products Ltd (PRP) regarding spinal surgery was particularly gratifying."

Jonas Ekblom, President and CEO Promore Pharma

#### **Financial overview for the Company**

	1 January - 31 March		1 January - 31 December	
Amounts in MSEK	2018	2017	2017	
Net sales	0,1	-	0,6	
Operating loss	-7,9	-3,2	-9,7	
Profit/Loss for the period	-7,9	-3,3	-8,6	
Earnings per share, before/after dilution, SEK <sup>1</sup>	-0,39	-0,24	-0,52	
Cash flow from operating activities	-8,5	-2,8	-6,9	
Cash and cash equivalents at the end of the period	54,4	3,8	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 for the bioactive wound care market. The company's aim is to develop two first-in-category products for indications where very few efficacious prescription pharmaceuticals are available, thus, addressing high unmet medical needs. Promore Pharma's two projects, PXLO1 and LL-37, are in late stage clinical phase. PXLO1, 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 is being prepared for a clinical Phase IIb study in patients with venous leg ulcers. The product candidates can also be deployed for other indications, such as preventing dermal scarring and treatment of diabetic foot ulcers. The company is listed on Nasdaq First North with Redeye AB as Certified Adviser.



#### **CEO** statement

Promore Pharmas project portfolio consists of therapeutic peptides, each with a significant medical value in a wide variety of indications for the bioactive wound care market. We are working to position the company as a pioneer within wound healing and prevention of scars and adhesions, and we estimate that the aggregated market potential of Promore Pharma's product candidates is more than 1 billion USD annually, if opportunities for indication broadening, such as DDD, dermal scarring and post-surgical adhesions from other minimally invasive surgical procedures are included. We see multiple potential applications for PXL01. Promore Pharma has limited resources and we therefore believe that investments in our technology and our products from strategic and competent partners are an attractive opportunity for us to broaden the use of our technology base. In this way, we can bring more products to the market and thereby raise the value of our business. In this context, the out-licensing agreement we recently signed with PharmaResearch Products Ltd (PRP) regarding spinal surgery was particularly gratifying and in line with our strategy. The agreement means that PRP will fully fund the development of PXL01 to prevent fibrosis after degenerative disc disorder (DDD) surgery. The agreement gives Promore Pharma a share of any milestone payments to PRP as well as a double-digit royalty from the global sales of the product. As part of the initial agreement entered between our companies in March 2016, PRP was granted the right to develop and commercialize a medical device product for spinal surgery for certain Asian markets and through the new agreement we expand our strategic alliance.

The first quarter has been characterized by continued preparatory work for our two clinical trials; PHSU03, a phase III study of PXL01 for prevention of adhesions after tendon and nerve repair surgery in the hand, and HEAL LL-37, a Phase II study of LL-37 for treatment of venous leg ulcers. Our goal is to begin the patient enrolment in both of these international clinical studies in the current year. An important focus area has been to execute the detailed planning and implementation of the most important steps in the manufacturing of the investigational medicinal products for both of these clinical trials. The manufacturing of the company's drug products is carried out by a multinational network of external product and service suppliers. Another important focus area has been - and continue to be - the work of identifying clinics across Europe that can optimally help recruit patients to these two clinical trials.





#### **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<sup>1</sup>. 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 prepared for a clinical Phase IIb study 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**

PXLO1 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 EU countries, 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 500-600 patients with flexor tendon injuries in the hand where a single administration event of PXLO1 at two different doses will be compared with placebo. A similar clinical Phase III study is planned 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 future indication broadening, such a preventing 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 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

<sup>&</sup>lt;sup>1</sup> 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 is currently preparing for a clinical Phase IIb study 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 2018

#### Adjusted plans in North America

According to the co-development agreement signed with Cellastra in March 2017, Cellastra received an option to participate in the financing of the Phase III clinical trial for patients undergoing tendon repair surgery. If Cellastra solely had funded the clinical trial, Cellastra would have obtained a license to commercialize PXL01 on the North American market. The option expired by 31 December 2017, since Cellastra did not reach its fundraising objectives before the shift of the year. Promore Pharma intended to use parts of the proceeds from the share issue conducted in conjunction with the listing on Nasdaq First North to finance the Phase III clinical trial in North America if Cellastra did not do so. The share issue brought less capital than anticipated, however, and the company will primarily focus its resources on the EU, which represents the main market opportunity for PXL01. In parallel, the company continues its discussions with Cellastra, but will also consider new and complementary avenues for financing a US-based initiative.

Promore Pharma still prepares for a dialogue with the US Food and Drug Administration FDA in the first half of 2018 in the path towards IND approval.

#### **Promore Pharma Regained PXL01 Manufacturing Rights**

In February 2018 the company agreed with PharmaResearch Products Ltd ("PRP") that Promore Pharma will assume responsibility for the manufacturing of investigational medicinal product for the PXL01 phase III trial in EU and Asia. At the same time, Promore Pharma regains the global manufacturing rights for the commercial product.

In March 2016, Promore Pharma entered into an agreement with PRP regarding development collaboration on PXL01, complemented by a manufacturing agreement in January 2017. In accordance with the agreements, PRP has contributed to the financing of the Phase III clinical trial on PXL01 through milestone payments as well as manufacturing of investigational medicinal product for the trial. In cooperation with Promore Pharma, PRP has been working intensively to prepare the manufacturing. Since the clinical trial will be conducted primarily in Europe, the parties agreed that Promore Pharma will assume responsibility for the manufacturing of investigational medicinal product to facilitate control of manufacturing and product supply for the trial. At the same time, Promore Pharma regains the global manufacturing rights for the commercial product.

## Significant events after the reporting period

# Out-licensing agreement for PXL01 where PRP will finance the development of PXL01 for use to prevent fibrosis after spinal surgery

In May 2018 the company announced that PRP will fully finance the development of PXL01 to prevent fibrosis after spinal surgery used in the treatment of degenerative disc disorder ("DDD"). Promore Pharma will participate in the upside through participation in any milestone payments to PRP and a double-digit royalty from worldwide sales of the product. As part of the original agreement between the two companies from March 2016, PRP received the rights to develop and commercialize a medical device for spinal surgery and only in certain Asian markets. The new agreement means an expansion of this strategic collaboration to include a license to develop also a pharmaceutical product world-wide.

#### Other events

#### Patent granted for PXL01 in the United States

The company was granted a patent for PXL01 in combination with high molecular weight hyaluronic acid in January 2018, through its wholly owned subsidiary Pergamum. The patent is valid until January 12, 2030. Patents within the same patent family have previously been granted in several countries in Europe, South Africa and Australia.



#### **Financial information**

#### Net sales and result for the first quarter 2018

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 2018, the company's net sales amounted to 57,259 SEK, which is primarily attributable to the re-invoicing of consulting costs to the company's partners. Other operating income. Other income during the period is exchange rate profits

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 2018 these costs increased to 5.5 MSEK (1.2 MSEK) due to preparatory work for the two clinical studies such as consultancy fees as well as milestone payments to the company's partner Technomark Group USA LLC.

Other external costs decreased in the first quarter 2018 to 1.2 MSEK (1.6 MSEK), mainly due to higher costs for the IPO in 2017

Personnel expenses increased in the first quarter 2018 to 1.1 MSEK (0.1 MSEK) due to the employment of the company CEO from 1 May 2017.

Net loss in 2017 amounted to 7.9 MSEK (loss 3.3) MSEK, corresponding to a loss per share of 0.39 SEK (loss 0.24 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 38.981 SEK (0 SEK) is attributable to an additional consideration payment.

The company's cash and cash equivalents amounted to 54.4 MSEK per 31 March 2018, as compared to 3.8 MSEK per 31 March 2017.

# **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 was 20,235,090 (13,564,245). The main owners Rosetta Capital IV S.a.r.L., Midroc New Technology AB and PharmaResearch Products Ltd. own over 87 percent of shares in the company.

Promore Pharma issued in connection with the listing on Nasdaq First North 6,523,560 warrants. The warrants were listed on Nasdaq First North at the same time as the share with ticker PROMO TO1 and ISIN code SE0009997158. 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 correspond to a dilution 8.6%.

#### Holding of shares in Herantis Pharma Oyi

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 57,262 per 31 March 2018. The board of directors of the company has decided that this holding shall be divested in a stepwise 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 December 2017, the company had one employee. There have been no changes in the reporting period.



## **Transactions with related parties**

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

## Principles for the preparation of the year-end report

This year-end report has been prepared in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 (K3).

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Annual General Meeting 2018 16 May 2018

Interim report January – June 2018 20 August 2018

Interim report January – September 2018 23 November 2018

#### **Review by auditor**

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

Solna 16 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	2018	2017	2017	
Operating income				
Net sales	57 259	-	632 126	
Other operating income	13 273	12 450	14 957 600	
Operating expenses				
Commodities and supplies	-5 463 404	-1 203 770	-10 937 929	
Other external expenses	-1 160 620	-1 569 627	-9 350 533	
Personnel costs	-1 051 579	-123 912	-3 734 264	
Depreciation and impairments on fixed assets	-304 286	-304 286	-1 217 144	
Other operating expenses	-31 558	-48 804	-69 052	
Operating loss (EBIT)	-7 940 915	-3 237 949	-9 719 196	
Financial items				
Net financial items	-143	-186 979	1 151 140	
Profit/loss after finanical items	-7 941 058	-3 299 341	-8 568 056	
Profit/oss before tax	-7 941 058	-3 299 341	-8 568 056	
Tax Profit/Loss for the period	-7 941 058	-3 299 341	-8 568 056	
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# **Consolidated balance sheet**

Amounts in SEK	31 March 2018	31 March 2017	31 December 2017
ASSETS			
FIXED ASSETS			
Intangible fixed assets	2 738 570	3 955 711	3 042 853
Financial fixed assets	3 035 393	1 859 162	3 035 393
Total fixed assets	5 773 963	5 814 873	6 078 246
CURRENT ASSETS			
Short term receivables	1 767 731	459 365	2 200 133
Cash at bank and in hand	54 425 897	3 814 157	62 972 202
Total current assets	56 193 628	4 273 522	65 172 335
TOTAL ASSETS	61 967 591	10 088 395	71 250 581
EQUITY AND LIABILITIES			
EQUITY			
Restricted equity			
Share capital	809 404	54 257	809 404
Other equity including result for the period	56 979 732	100 056	64 920 790
Equity attributable to parent company shareholders	57 789 136	154 313	65 730 194
LONG-TERM LIABILITIES			
Other liabilities to credit institutions	714 038	714 038	714 038
Other liabilities	291 888	7 364 000	330 869
Total long-term liabilities	1 005 926	8 078 038	1 044 907
CURRENT LIABILITIES			
Accounts payable	1 875 695	742 070	3 409 044
Other current liabilities	1 296 834	1 113 974	1 202 510
Total current liabilities	3 172 529	1 856 044	4 611 554
TOTAL EQUITY AND LIABILITIES	61 967 591	10 088 395	71 386 655



# Consolidated cash flow analysis

	1 October - 31 December		1 January - 31 December	
Amounts in SEK	2017	2016	2017	
OPERATING ACTIVITIES				
Operating loss	-7 940 915	-3 237 949	-9 719 196	
Depreciation	304 286	304 286	1 217 144	
Exchange rate difference cash and cash equivalents		0		
Interest received	0	0	0	
Interest paid	-143	-4	-12 050	
Tax paid	0	-	0	
Cash flow from operating activities before changes in working capital	-7 636 772	-2 933 667	-8 514 102	
Increase/decrease other current receivables	529 442	90 386	-1 678 891	
Increase/decrease other current liabilities	-1 399 994	40 608	3 282 106	
Cash flow from operating activities	-8 507 324	-2 802 673	-6 910 887	
Cash flow from investing activities	0	125 586	294 767	
Cash flow from financing activities	-38 981	0	63 097 078	
Cash flow for the period	-8 546 305	-2 677 087	56 480 958	
Cash and cash equivalents at the beginning of the				
period	62 972 202	6 491 244	6 491 244	
Cash and cash equivalents at the end of the period	54 425 897	3 814 157	62 972 202	

# Changes in equity for the group

<b>EQUITY</b>
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	Share capital	Other paid-in capital	Other equity	Total equity
Opening balance (1 January 2018)	809 404	0	64 920 790	65 730 194
Profit for the period			-7 941 058	-7 941 058
Closing balance (31 March 2018)	809 404		56 979 732	57 789 136
	Share capital	Other paid-in capital	Other equity	Total equity
Opening balance (1 January 2018)	54 257	0	3 399 397	3 453 654
Profit for the period			-2 579 551	-2 579 551
Closing balance (31 March 2018)	54 257		819 846	874 103
	Share capital	Other paid-in capital	Other equity	Total equity
Opening balance (1 January 2017)	54 257	0	3 399 397	3 453 654
Bonus issue	488 313		0	488 313
New share issue	266 834		69 953 375	70 220 209
Profit for the period			-8 568 056	-8 568 056
Closing balance (31 December 2017)	809 404		64 784 716	65 594 120



# 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 and the Securities Markets Act. The information was submitted for publication, through the agency of the contact persons set out above, at 14:30 CET on 16 May 2018.