

**Promore Pharma AB (publ)**

**Interim report January - June 2019**

**April to June**

- Net sales amounted to 0.7 (0) MSEK.
- The operating loss for the period was 7.4 (-10.8) MSEK
- Net loss was 7.3 (- 9.8) MSEK, corresponding to earnings per share of SEK -0.36 (-0.48)
- Cash flow from operating activities amounted to -6.9 (-8.6) MSEK
- Cash and cash equivalents amounted to 19.7 (46.0) MSEK

**January to June**

- Net sales amounted to 1.2 (0.1) MSEK.
- The operating loss for the period was 12.9 (-18.7) MSEK
- Net loss was 12.8 (-17.7) MSEK, corresponding to earnings per share of SEK 0.63 (-0.88)
- Cash flow from operating activities amounted to -11.3 (-17.1) MSEK

**Significant events during the period January - June**

- Phase III trial with PXL01 modified and the number of clinics in the study expanded
- Kerstin Valinder Strinnholm elected member of the Board of Directors
- Half of the patients have been recruited in HEAL LL-37

**Events after the reporting period**

- Patent granted for LL-37 in Japan

*“ The first half of the year has been characterized by continued work to develop the company's innovative projects in two treatment areas, both of which have significant medical needs because the current treatment options are poor or non-existent. HEAL LL-37 is progressing fully in line with our business plan and we have made progress in our continued efforts to improve the manufacturing and supply network for PXL01.”*

Jonas Ekblom, President and CEO Promore Pharma

**Financial overview for the Company**

Amounts in MSEK	1 April - 30 June		1 January - 30 June		1 January - 31 December	
	2019	2018	2019	2018	2019	2018
Net sales	0,7	0,0	1,2	0,1	2,4	
Operating loss	-7,4	-10,8	-12,9	-18,7	-32,7	
Profit/Loss for the period	-7,3	-9,8	-12,8	-17,7	-32,5	
Earnings per share, before/after dilution, SEK	-0,36	-0,48	-0,63	-0,88	-1,61	
Cash flow from operating activities	-6,9	-8,6	-11,3	-17,1	-32,5	
Cash and cash equivalents at the end of the period	19,7	46,0	19,7	46,0	30,9	

**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

The first half of the year has been characterized by continued work to develop the company's innovative projects in two treatment areas, both of which have significant medical needs because the current treatment options are less effective or non-existent. The clinical trial HEAL LL-37 is progressing fully in line with our business plan and we have made progress in our continued efforts to secure the manufacturing of PXL01.

Both of our projects, LL-37 and PXL01, are in the late clinical phase and the project that has advanced the furthest is the PXL01 program where we are preparing a Phase III clinical trial (PHSU03). We intend to prevent permanent adhesions, after tendon repair surgery. In November 2018, the clinical trial protocol for PHSU03 was approved by the Indian medical authority (Drug Controller General of India, DGCI). What remains to be done before we can start recruiting patients for PHSU03 is to complete the supply chain for investigational medicinal product and to apply for and obtain approval from the national authorities of the countries in the European Union where the study also will be conducted. We are very satisfied with the outcome of the meeting we held together with one of our suppliers at the Swedish Medical Products Agency in May, in a so-called *industrial dialogue*. As a result of this meeting, several uncertainties have been eliminated and we are convinced that we will be able to carry out the production of investigational product in accordance with a more definite timetable, which aims to start patient recruitment to PHSU03 in the first half of 2020.

With respect to our second project, LL-37 for the treatment of venous leg ulcers, the Phase IIb clinical trial HEAL, which was started during the third quarter of 2018, is progressing according to plan. We continue to include patients in Sweden and Poland. The aim is that approximately 120 patients should complete the clinical study protocol. In June, we completed enrolment of approximately half of the patients. If the current recruitment rate is sustained, all patients should be included and randomized in early 2020 and we anticipate having final results from the study concluded later in 2020.

During the second quarter we also had our annual general meeting. It is gratifying that the former board was re-elected and also that Kerstin Valinder Strinnholm was added as an independent board member. Kerstin Valinder has more than 30 years of experience in strategic planning and business development from the pharmaceutical industry. This gives us further breadth and experience as we gradually approach opportunities to enter into strategic partnerships and out-licensing deals. The Board of Promore Pharma continuously evaluates alternatives to secure the company's long-term financing. To this end, and to investigate several different strategic options, the company has engaged ABG Sundal Collier as financial advisor.

I feel that the current Board of Directors and the company's management have evolved into a strong and dynamic team with the ambition to positioning the company as a pioneer in the treatment of wounds and the prevention of scars and adhesions. Finally, I want to say that I am confident that the company has appropriate strategic goals to continue to build value that result in financial rewards for its shareholders.

Solna 28 August 2019

Jonas Ekblom  
President and CEO



## Overview of activities

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

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 approximately 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. 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 indication broadening, such as 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

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<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 during the report period 1 January – 30 June 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 PSHU03 study by also including a number of hospitals in Italy, thereby minimizing the overall delay by accelerating the recruitment of patients.

### **The Board of Directors strengthened by the election of Kerstin Valinder Strinnholm**

At the Annual General Meeting in May 2019, Kerstin Valinder Strinnholm was elected as new member of the Board of Directors. Kerstin Valinder Strinnholm has long experience from the pharmaceutical industry and has among others been responsible for business development and strategy at Nycomed (now Takeda) and previously had leading positions within marketing and business development at Astra and AstraZeneca. She has a degree from the School of Journalism at the University of Gothenburg.

### **Half of the patients recruited in HEAL LL-37**

The company announced in June 2019 that half of the patients have been enrolled and started the treatment in the company's Phase II-study (HEAL) with the company's product candidate LL-37 for treatment of venous leg ulcers. With the same pace in recruitment all patients should be included and randomized in the beginning of 2020.

## **Events after the reporting period**

### **Patent granted for LL-37 in Japan**

In August 2019 the company announced that The Japanese patent authority formally granted the patent "New Treatment of Chronic Ulcers" with LL-37. The patent is valid until 19 November 2034. Patents within the same patent family have previously been granted in the USA.

## Financial information

### Net sales and result second 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 second quarter 2019 company net sales amounted to 0.7 (0.7) MSEK, primarily attributable to the re-invoicing of consulting costs. The net loss for the period was 7.3 (-9.8) MSEK, which was explained by lower costs for company's clinical program compared with the second quarter 2018, when Investigational Medicinal Product was manufactured for HEAL LL-37 and a number of preparations were done before the start of the study.

### Net sales and result first six months 2019

Promore Pharma is an innovation company and its product candidates are still undergoing clinical development. Consequently, the company has no revenues from product sales during the reporting period. In the first six months 2019, the company's net sales amounted to 1.2 MSEK, which is primarily attributable to the re-invoicing of consulting costs.

The company's costs for raw materials and consumables are mainly related to development costs, such as costs for patents, products for the clinical trials and consultants working with the development of the company's candidate drugs. During the first six months 2019 these costs decreased to 7.3 (13.5) MSEK. In the first half of 2018 Investigational Medicinal Product was manufactured for HEAL LL-37 and the company also made a milestone payment related to PXL01 in the first six months in 2018.

Other external costs increased the first six months 2019 to 4.0 (3.1) MSEK, mainly due to higher consultancy fees in 2019.

Personnel expenses increased the first six months 2019 to 2.2 (2.1) MSEK, explained by higher social security costs in 2019 when remuneration to the members of the Board were paid as salary.

Net loss for the first six months 2019 amounted to 12.8 (-17.8) MSEK, corresponding to a loss per share of SEK 0.63 (loss per share of 0.88).

## Liquidity and financing

The cash flow from operating activities during the first six months 2019 amounted to -11.3 (-17.1) MSEK, explained by an improved operating result. The cash-flow from investments during the period amounted to 0.1 (0.2) MSEK. Both in 2019 and 2018 the company has divested shares in Herantis Pharma Oyj.

The cash flow from financing activities was 0 (-0.04) MSEK. during the period. In the first six months in 2018 the company made a loan installment.

The company's cash and cash equivalents amounted to 19.7 MSEK per 30 June 2019, as compared to 46.0 MSEK per 30 June 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 30 June was 20,235,090 (20,235,090). The main owners the Midroc Group, 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 48,011 per 30 June 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 30 June 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**

Interim report January – September 2019	29 November 2019
Year-end Report 2019	18 February 2020

### **Review by auditor**

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

Solna 28 August 2019

Göran Pettersson

Chairman

Marianne Dicander Alexandersson

Torsten Goesch

Satyendra Kumar

Göran Linder

Kerstin Valinder Strinnholm

## Consolidated income statement

Amounts in SEK	1 April - 30 June		1 January - 30 June	1 January - 31 December	
	2019	2018	2019	2018	2018
<b>Operating income</b>					
Net sales	719 415	3	1 181 044	57 262	2 446 785
Other operating income	-9 499	672 903	-5 300	686 176	683 892
<b>Operating expenses</b>					
Commodities and supplies	-4 325 251	-8 018 916	-7 264 760	-13 482 320	-24 452 267
Other external expenses	-2 259 285	-1 963 071	-4 006 996	-3 123 691	-5 841 185
Personnel costs	-1 167 766	-1 086 718	-2 172 394	-2 138 297	-4 189 945
Depreciation and impairments on fixed assets	-304 285	-304 285	-608 571	-608 571	-1 217 143
Other operating expenses	-32 951	-53 863	-46 076	-85 421	-106 367
<b>Operating loss (EBIT)</b>	<b>-7 379 622</b>	<b>-10 753 947</b>	<b>-12 923 053</b>	<b>-18 694 862</b>	<b>-32 676 230</b>
<b>Financial items</b>		0			0
Net financial items	44 683	972 239	116 620	972 096	193 147
<b>Profit/loss after financial items</b>	<b>-7 334 939</b>	<b>-9 781 708</b>	<b>-12 806 433</b>	<b>-17 722 766</b>	<b>-32 483 083</b>
<b>Profit/loss before tax</b>	<b>-7 334 939</b>	<b>-9 781 708</b>	<b>-12 806 433</b>	<b>-17 722 766</b>	<b>-32 483 083</b>
Tax	-	-	-	-	-
<b>Profit/Loss for the period</b>	<b>-7 334 939</b>	<b>-9 781 708</b>	<b>-12 806 433</b>	<b>-17 722 766</b>	<b>-32 483 083</b>



## Consolidated balance sheet

Amounts in SEK	30 June 2019	30 June 2018	31 December 2018
<b>ASSETS</b>			
<b>FIXED ASSETS</b>			
Intangible fixed assets	1 217 143	2 434 285	1 825 714
Tangible fixed assets	0	0	0
Financial fixed assets	2 809 597	3 945 420	2 809 597
<b>Total fixed assets</b>	<b>4 026 740</b>	<b>6 379 705</b>	<b>4 635 311</b>
<b>CURRENT ASSETS</b>			
Short term receivables	2 149 283	3 160 196	2 079 807
Cash at bank and in hand	19 725 319	45 965 847	30 882 428
<b>Total current assets</b>	<b>21 874 602</b>	<b>49 126 043</b>	<b>32 962 235</b>
<b>TOTAL ASSETS</b>	<b>25 901 342</b>	<b>55 505 748</b>	<b>37 597 546</b>
<b>EQUITY AND LIABILITIES</b>			
<b>EQUITY</b>			
Share capital	809 404	809 404	809 404
Other equity including the result for the period	19 631 274	47 198 024	32 437 709
<b>Total equity</b>	<b>20 440 678</b>	<b>48 007 428</b>	<b>33 247 113</b>
<b>LONG-TERM LIABILITIES</b>			
Other liabilities to credit institutions	714 038	714 038	714 038
Other liabilities	288 413	394 442	280 860
<b>Total long-term liabilities</b>	<b>1 002 451</b>	<b>1 108 480</b>	<b>994 898</b>
<b>CURRENT LIABILITIES</b>			
Accounts payable	2 636 205	4 797 597	1 312 038
Other current liabilities	1 822 008	1 592 243	2 043 497
<b>Total current liabilities</b>	<b>4 458 213</b>	<b>6 389 840</b>	<b>3 355 535</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>25 901 342</b>	<b>55 505 748</b>	<b>37 597 546</b>

## Consolidated cash flow analysis

Amounts in SEK	1 April - 30 June		1 January - 30 June		1 January - 31 December
	2019	2018	2019	2018	2018
<b>OPERATING ACTIVITIES</b>					
Operating profit	-7 379 622	-10 753 947	-12 923 053	-18 694 862	-32 676 230
Adjustments for items not included in cash flow	298 644	298 681	602 930	602 824	1 153 160
Tax paid	0	0	0	0	0
<b>Cash flow from operating activities before changes in working capital</b>	<b>-7 080 978</b>	<b>-10 455 266</b>	<b>-12 320 123</b>	<b>-18 092 038</b>	<b>-31 523 070</b>
Increase/decrease other current receivables	-10 216	-1 392 465	-67 120	-863 023	217 367
Increase/decrease other current liabilities	157 885	3 217 311	1 100 320	1 817 317	-1 216 988
<b>Cash flow from operating activities</b>	<b>-6 933 309</b>	<b>-8 630 420</b>	<b>-11 286 923</b>	<b>-17 137 744</b>	<b>-32 522 691</b>
Cash flow from investing activities	50 324	170 370	129 814	170 370	471 896
Cash flow from financing activities	0	0	0	-38 981	-38 980
<b>Cash flow for the period</b>	<b>-6 882 985</b>	<b>-8 460 050</b>	<b>-11 157 109</b>	<b>-17 006 355</b>	<b>-32 089 775</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>26 608 304</b>	<b>54 425 897</b>	<b>30 882 428</b>	<b>62 972 202</b>	<b>62 972 202</b>
Exchange rate difference cash and cash equivalents		0	0	0	
<b>Cash and cash equivalents at the end of the period</b>	<b>19 725 319</b>	<b>45 965 847</b>	<b>19 725 319</b>	<b>45 965 847</b>	<b>30 882 428</b>

## 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 April 2019)	809 404	0	26 966 213	27 775 617
Profit for the period			-7 334 939	-7 334 939
Amount at the end of the period (30 June 2019)	809 404		19 631 274	20 440 678
	Share capital	Other paid-in capital	Other equity	Total equity
Amount at the beginning of the period (1 April 2018)	809 404	0	56 979 732	57 789 136
Profit for the period			-9 781 708	-9 781 708
Amount at the end of the period (30 June 2018)	809 404	0	47 198 024	48 007 428
	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			-12 806 433	-12 806 433
Amount at the end of the period (30 June 2019)	809 404		19 631 274	20 440 678
	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			-17 722 766	-17 722 766
Amount at the end of the period (30 June 2018)	809 404		47 198 024	48 007 428

**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 14:00 CET on 28 August 2019.*

*Promore Pharma's Certified Adviser is Redeye AB.*

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