

## Promore Pharma AB (publ)

# Interim report January - September 2020

### July to September

- Net sales amounted to MSEK 0 (1.3)
- The operating loss for the period was MSEK -8.3 (-6.7)
- Net loss was MSEK -8.1 (-6.7), corresponding to earnings per share of SEK -0.22 (-0.33)
- Cash flow from operating activities amounted to MSEK -8.9 (-6.9)
- Cash and cash equivalents amounted to MSEK 31.3 (13.0)

### January to September

- Net sales amounted to MSEK 0 (2.5)
- The operating loss for the period was MSEK -22.2 (-19.6)
- Net loss was MSEK -21.7 (-19.5), corresponding to earnings per share of SEK -0.59 (-0.96)
- Cash flow from operating activities amounted to MSEK -29.9 (-18.2)

### Significant events during the period January - September

- The targeted number of 120 patients completing treatment in the HEAL LL-37 Phase IIb clinical trial with ropocamptide was reached
- A long-term incentive program approved by the AGM
- Erik Magnusson appointed CFO
- Patent granted for ropocamptide in the US

### Significant events after the reporting period

- In November, the company published positive data from HEAL LL-37 showing that patients with larger leg ulcers treated with the lower dose of ropocamptide, reached complete healing three times more often than placebo.

*"We are very pleased with the outcome of our ropocamptide (LL-37) clinical trial. The results show significantly better results for patients with larger VLUs, the patient population most difficult to treat with today's medical devices. When analyzing the primary endpoint, complete wound healing, more than three times more patients with large VLUs reached complete healing compared to placebo."*

Jonas Ekblom, President and CEO Promore Pharma

### Financial overview for the Company

Amounts in MSEK	Jul-Sep		Jan-Sep	
	2020	2019	2020	2019
Net sales	0,0	1,3	0,0	2,5
Operating loss	-8,3	-6,7	-22,2	-19,6
Profit/Loss for the period	-8,1	-6,7	-21,7	-19,5
Earnings per share, SEK	-0,22	-0,33	-0,59	-0,96
Cash flow from operating activities	-8,9	-6,9	-29,9	-18,2
Cash and cash equivalents at the end of the period	31,3	13,0	31,3	13,0

### 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, ensereptide (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. Ropocamptide (LL-37) has recently passed clinical phase IIb study in patients with venous leg ulcers (VLUs). 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 Growth Market.

## Comments from the CEO

During the third quarter, we primarily worked on completing and analyzing data from our Phase IIb trial, HEAL LL-37, with ropocamptide (LL-37) for the treatment of venous leg ulcers. A very important milestone for the company was reached last week when we were able to present positive data from this clinical study. In parallel, we have continued to work on preparing the phase III study with our drug candidate ensereptide (PXL01) for the prevention of adhesions in tendon and nerve repair in the hand, even though that study is not yet fully financed.

We are very pleased with the outcome of our clinical study of ropocamptide. The trial shows a clear-cut treatment effect of ropocamptide for the patients with larger venous leg ulcers (over 10 cm<sup>2</sup>), the patient population that is most difficult to treat today. The study was conducted with 144 patients treated for three months, randomized into three groups: (i) placebo, (ii) low-dose ropocamptide (0.5 mg / ml), and (iii) high-dose ropocamptide (1.6 mg / ml). The study showed that patients with large wounds, treated with 0.5 mg / ml ropocamptide achieved 28.1% complete wound closure; that the group treated with 1.6 mg / ml ropocamptide reached 19.6%, while only 8.1% of the patients in the placebo group showed complete healing.

The main conclusion is that treatment with ropocamptide in the lower dose of 0.5 mg / ml provides a significantly improved cure in the difficult-to-treat patient group with large venous leg ulcers. When analyzing the primary endpoint, i.e. the fraction of patients that reached complete wound closure, more than three times as many patients achieved complete wound healing compared with placebo. The difference is statistically significant ( $p < 0.05$ ) for 0.5 mg / ml. When analyzing the proportion of patients who achieved 70% healing of their wounds, a statistically significant advantage could be demonstrated for both dose groups of ropocamptide compared to placebo. The mean reduction in wound size after end of treatment was 33.7% for patients treated with placebo, and 56.3% for patients treated with the most effective dose of ropocamptide (0.5 mg / ml). Regarding safety and tolerability, no serious side effects have been noted that can be considered related to the investigational drug. We are therefore very satisfied to be able to confirm the favorable safety profile that was also noted in the previous clinical trial of ropocamptide.

The fact that we recognize a clear effect of ropocamptide in patients with large venous leg ulcers is compelling. The company will now, in consultation with clinical experts and advisers within the business area, evaluate various strategic alternatives in order to create the greatest possible shareholder value. The next step is to compile the study results for publication in a scientific journal.

Regarding our clinical phase III trial, PHSU03, we have during the past year worked with further process optimization. To initiate this study, the company will need to bring in new financing, which will have a large impact on the timeline. We expect a lead time of approx. three quarters from secured financing to first patient treated. As a company, we have the advantage of having large and financially strong shareholders, which expands our ability to secure capital.

At Promore Pharma, we are now working on the planning for the coming operating year. Overall, our progress, not least the positive outcome of the ropocamptide trial, gives me great hope that we have an exciting time ahead of us.

In conclusion, I would like to thank everyone who has contributed to our efforts to improve the lives of people with chronic wounds and post-surgical complications; patients, doctors, nurses, partners, employees and shareholders. I really appreciate your valuable contributions and great support.

Stockholm, 24 November 2020,

Jonas Ekblom

President & CEO



## Overview of activities

Promore Pharma is a biopharmaceutical company that develops peptide-based product candidates aimed at the bioactive wound care market. Ensereptide (PXL01) is aimed at prevention of post-surgical adhesions and scars and is being prepared for clinical Phase III studies on patients undergoing tendon repair surgery of the hand. Ropocamptide (LL-37) has recently passed clinical Phase IIb trial on patients with venous leg ulcers.

Promore Pharma's product candidates are based on innate peptides, which are a part of the human defense and healing system 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. This is supported by the results from prior clinical studies, where both ensereptide and ropocamptide showed strong 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 candidates 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 ensereptide (PXL01)

Ensereptide is derived from a human anti-bacterial protein (lactoferrin), which is part of the innate immune system. They are aimed for local application and having a paracrine (local) effect, just as endogenous peptides. 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 ensereptide 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 ensereptide 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 ensereptide 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 picking up small objects from a flat surface. A first product is aimed at obtaining a label for tendon-and nerve-repair in the hand, lower arm and foot. The company also anticipates that there are good opportunities for indication broadening, such as preventing dermal scars or adhesions after spinal surgery.

### About ropocamptide (LL-37)

Ropocamptide 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 (VLUs), ropocamptide 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 be combined with the standard wound care treatments and given by a nurse or the patient. The development of ropocamptide is initially focused on venous leg ulcers and the company has recently concluded a clinical Phase IIb study (HEAL LL-37) on patients with VLUs in Europe. VLUs constitute 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 ropocamptide focuses initially on VLUs but the company sees good potential in also developing ropocamptide for diabetic foot ulcers.

## **Significant events during the report period 1 January – 30 September 2020**

### **The company reached the targeted number of patients completing treatment in the HEAL LL-37 Phase IIb clinical trial**

The company announced in March 2020 that the last patient has been dosed in the treatment phase of the company's Phase IIb-study (HEAL LL-37) with ropocamptide, a new candidate drug for treatment of VLUs. The aim of Promore Pharma's Phase IIb study HEAL LL-37 was that 120 patients with VLUs in Sweden and Poland should complete the study protocol. Despite the challenges within the health care systems in Poland and Sweden following the COVID-19 pandemic, the study has been carried out according to plan and 120 patients completed the treatment phase. Results from the study are expected to be available in the fourth quarter 2020.

### **Patent granted for ropocamptide in the United States**

The company announced in July 2020 that a patent was granted in the US for the product candidate ropocamptide (LL-37). The company filed a continuation application with the U.S. Patent Office (USPTO) in May 2020 for a previously granted patent, which protects important elements in the formulation of ropocamptide. The patent has now been formally granted, and it is valid until at least 2034.

### **A long-term incentive program ("LTI 2020") approved by the AGM**

It was resolved at the Annual General Meeting in May 2020, as proposed by the board, to adopt a performance-based stock savings program for certain employees and contractors in Promore Pharma AB. The duration of the program is about three years and will be offered to three current employees and contractors in, and newly hired persons by, the company.

A maximum of 1,400,000 Performance Share Rights may be allotted under LTI 2020, corresponding to approximately 3.7 percent of the shares in the company. In accordance with the Board's proposal, the meeting resolved on a directed issue of 1,800,000 warrants with the right to subscribe for new shares in the company to implement LTI 2020. For those who are offered to join LTI 2020 and previously participated in the company's old bonus program, the old bonus agreements will be terminated without any awards.

### **Erik Magnusson appointed CFO**

The company announced in May 2020 the appointment of Erik Magnusson to CFO. Erik has extensive professional experience from the financial markets and the life science sector. He joins from Coop Online, where he has had the role Financial Manager/Business Controller since 2016. Erik assumed the position in August 2020 and thereby replaces the company's previous CFO, Jenni Björnulfson.

## **Other events after the reporting period**

### **Publication of Phase IIb data**

In late November, the company presented data from the recently finalized HEAL LL-37 study. The main conclusion is that treatment with ropocamptide in the lower dose of 0.5 mg / ml provides a significantly improved cure in the difficult-to-treat patient group with large venous leg ulcers. When analyzing the primary endpoint, i.e. the fraction of patients that reached complete wound closure, more than three times as many patients achieved complete wound healing compared with placebo. The difference is statistically significant ( $p < 0.05$ ) for 0.5 mg / ml. When analyzing the proportion of patients who achieved 70% healing of their wounds, a statistically significant advantage could be demonstrated for both dose groups of ropocamptide compared to placebo. The mean reduction in wound size after 13 weeks of treatment was 33.7% for patients treated with placebo, and 56.3% for patients treated with the most effective dose of ropocamptide (0.5 mg / ml).

## Financial information

### Net sales and result third quarter 2020

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 third quarter 2020 company sales were MSEK 0.0 (1.3). The sales reported in the third quarter 2019 were re-invoiced manufacturing and consulting costs. The net loss for the period was MSEK -8.1 (-6.7), corresponding to SEK -0.22 (-0.33) per share.

### Net sales and result first nine months 2020

In the first nine months of 2020, the company's net sales amounted to MSEK 0.0. In the first nine months of 2019, the reported net sales amounted to MSEK 2.5, which primarily was attributable to the re-invoicing of manufacturing and 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 nine months of 2020 these costs increased to MSEK -13.9 (-11.7) since costs for HEAL LL-37 increased compared to the same period 2019.

Other external costs decreased in the first nine months of 2020 to MSEK -4.5 (-6.3), mainly due to lower consultancy and travelling costs compared to the same period 2019.

Personnel expenses costs were MSEK -3.2 for the first nine months of 2020 compared to MSEK -3.1 for the first nine months of 2019.

Net loss for the first nine months of 2020 amounted to MSEK -21.7 (-19.5), corresponding to earnings per share of SEK -0.59 (-0.96).

### Liquidity and financing

The cash flow from operating activities during the first nine months of 2020 amounted to MSEK -29.9 (-18.2) mainly explained by higher working capital. The cash-flow from investments during the period amounted to 0.7 MSEK (0.2). Both in 2020 and 2019, the company divested shares in Herantis Pharma Oyj.

The cash flow from financing activities was MSEK 0.0 (0.0) during the period.

The company's cash and cash equivalents amounted to MSEK 31.3 per 30 September 2020, MSEK 39.9 per 30 June 2020, MSEK 60.5 at the beginning of the year, and MSEK 13.0 MSEK per 30 September 2019.

## Auxiliary information

### Number of shares

Promore Pharma's share is listed on Nasdaq First North (now Nasdaq First North Growth Market) in Stockholm since 6 July 2017 with the ticker PROMO and ISIN code SE0009947740. The number of shares as of 30 September 2020 were 36,428,362 (20,235,090). The average number of shares in the third quarter 2020 was 36,428,362 (20,235,090) and for the first nine months 2020 it was 36,428,362 (20,235,090). The main owners Midroc New Technology and PharmaResearch Products Ltd. own approximately 58 percent of shares in the company.

There are 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 ensereptide and these outstanding warrants correspond to a potential dilution 5.0%.

It was resolved at the Annual General Meeting in 2020 to adopt a performance-based stock savings program (LTI 2020) for certain employees and contractors in Promore Pharma. A maximum of 1,400,000 Performance Share Rights may be allotted under LTI 2020, corresponding to approximately 3.7 percent of the shares in the company. In accordance with the Board's proposal, the meeting resolved on a directed issue of 1,800,000 warrants with the right to subscribe for new shares in the company to implement LTI 2020. For those who are offered to join LTI 2020 and previously participated in the company's old bonus program, the old bonus agreements will be terminated without any awards.

## 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 36,573 per 30 September 2020. 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 30 September 2020, the company consequently had one employee.

## Transactions with related parties

The company had in the first nine months 2020 transactions with related parties as shown below.

Cavastor AB (Kerstin Valinder Strinnholm)	SEK 40,000
MDA Management AB (Marianne Dicander Alexandersson)	SEK 44,000
<b>Total</b>	<b>SEK 84,000</b>

## 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

Year-end Report 2020	23 February 2021
Annual General Meeting	27 May 2021
Interim report January – March 2021	27 May 2021
Interim report January – July 2021	24 August 2021
Interim report January – September 2021	23 November 2021

## Review by auditor

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

Solna 24 November 2020

Göran Pettersson

Chairman

Marianne Dicander Alexandersson

Torsten Goesch

Satyendra Kumar

Göran Linder

Kerstin Valinder Strinnholm

## Consolidated income statement

<i>Amounts in kSEK</i>	Jul-Sep		Jan-Sep		Jan-Dec
	2020	2019	2020	2019	2019
<b>Operating income</b>					
Net sales	3	1 284	3	2 465	3 928
Other operating income	8	11	19	5	-7
<b>Operating expenses</b>					
Commodities and supplies	-5 914	-4 439	-13 901	-11 704	-20 298
Other external expenses	-1 383	-2 272	-4 500	-6 279	-7 205
Personnel costs	-1 000	-973	-3 224	-3 145	-4 200
Depreciation and impairments on fixed assets	0	-304	-609	-913	-1 217
Other operating expenses	-1	-21	-29	-67	-70
<b>Operating loss (EBIT)</b>	<b>-8 287</b>	<b>-6 713</b>	<b>-22 241</b>	<b>-19 636</b>	<b>-29 069</b>
<b>Financial items</b>					
Net financial items	145	28	587	145	204
<b>Profit/loss after financial items</b>	<b>-8 142</b>	<b>-6 685</b>	<b>-21 654</b>	<b>-19 492</b>	<b>-28 865</b>
<b>Profit/loss before tax</b>	<b>-8 142</b>	<b>-6 685</b>	<b>-21 654</b>	<b>-19 492</b>	<b>-28 865</b>
Tax	-	-	-	-	-
<b>Profit/Loss for the period</b>	<b>-8 142</b>	<b>-6 685</b>	<b>-21 654</b>	<b>-19 492</b>	<b>-28 865</b>

## Consolidated balance sheet

<i>Amounts in kSEK</i>	30 Sep.		31 Dec.
	2020	2019	2019
<b>ASSETS</b>			
<b>FIXED ASSETS</b>			
Intangible fixed assets	0	913	609
Tangible fixed assets	0	0	0
Financial fixed assets	2 672	2 810	2 810
<b>Total fixed assets</b>	<b>2 672</b>	<b>3 722</b>	<b>3 418</b>
<b>CURRENT ASSETS</b>			
Current receivables	1 601	2 835	4 773
Cash and cash equivalents	31 348	12 952	60 543
<b>Total current assets</b>	<b>32 949</b>	<b>15 787</b>	<b>65 316</b>
<b>TOTAL ASSETS</b>	<b>35 621</b>	<b>19 509</b>	<b>68 734</b>
<b>EQUITY AND LIABILITIES</b>			
<b>EQUITY</b>			
Share capital	1 457	809	1 457
Other equity including the result for the period	29 083	12 946	50 737
<b>Total equity</b>	<b>30 540</b>	<b>13 756</b>	<b>52 194</b>
<b>LONG-TERM LIABILITIES</b>			
Liabilities to credit institutions	714	714	714
Other liabilities	341	352	370
<b>Total long-term liabilities</b>	<b>1 055</b>	<b>1 066</b>	<b>1 085</b>
<b>CURRENT LIABILITIES</b>			
Accounts payable	2 641	2 187	12 225
Other current liabilities	1 385	2 501	3 231
<b>Total current liabilities</b>	<b>4 026</b>	<b>4 688</b>	<b>15 456</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>35 621</b>	<b>19 509</b>	<b>68 734</b>



## Consolidated cash flow analysis

<i>Amounts in kSEK</i>	Jul-Sep		Jan-Sep		Jan-Dec
	2020	2019	2020	2019	2019
<b>OPERATING ACTIVITIES</b>					
Operating profit	-8 287	-6 713	-22 241	-19 636	-29 069
Adjustments for items not included in cash flow	-3	305	594	908	1 211
Tax paid	0	0	0	0	0
<b>Cash flow from operating activities before changes in working capital</b>	<b>-8 290</b>	<b>-6 409</b>	<b>-21 647</b>	<b>-18 729</b>	<b>-27 858</b>
Increase/decrease other current receivables	-405	-685	3 172	-753	-2 691
Increase/decrease other current liabilities	-192	230	-11 430	1 330	12 098
<b>Cash flow from operating activities</b>	<b>-8 887</b>	<b>-6 864</b>	<b>-29 904</b>	<b>-18 151</b>	<b>-18 451</b>
Cash flow from investing activities	292	91	739	221	300
Cash flow from financing activities	0	0	-29	0	47 812
<b>Cash flow for the period</b>	<b>-8 596</b>	<b>-6 773</b>	<b>-29 195</b>	<b>-17 930</b>	<b>29 661</b>
<b>Cash and cash equiv. at the beginning of the period</b>	<b>39 944</b>	<b>19 725</b>	<b>60 543</b>	<b>30 882</b>	<b>30 882</b>
Exchange rate difference cash and cash equivalents	0	0	0	0	0
<b>Cash and cash equiv. at the end of the period</b>	<b>31 348</b>	<b>12 952</b>	<b>31 348</b>	<b>12 952</b>	<b>60 543</b>

## Change in equity for the group

<i>Amounts in kSEK</i>	Other paid-in			Total equity
	Share capital	capital	Other equity	
Amount at the beginning of the period (1 Jan 2020)	1 457	0	50 737	52 194
Profit for the period			-21 654	-21 654
Amount at the end of the period (30 Sep 2020)	<b>1 457</b>	<b>0</b>	<b>29 083</b>	<b>30 540</b>
Amount at the beginning of the period (1 Jan 2019)	809	0	32 438	33 247
Profit for the period			-19 492	-19 492
Amount at the end of the period (30 Sep 2019)	<b>809</b>	<b>0</b>	<b>12 946</b>	<b>13 756</b>

**For additional information, please contact**

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