

**Promore Pharma AB (publ)**

**Interim report January – March 2020**

- Net sales amounted to MSEK 0.0 (0.5) MSEK
- The operating loss for the period was 7.3 (-5.5) MSEK
- Net loss was 7.0 MSEK (-5.5) MSEK, corresponding to a loss per share of SEK 0.19 (-0.27)
- Cash flow from operating activities amounted to -15.0 (-4.4) MSEK
- Cash and cash equivalents amounted to 45.9 (26.6) MSEK

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

- The targeted number of 120 patients completing treatment in the HEAL LL-37 Phase IIb clinical trial with ropocamptide was reached

**Significant events after the reporting period**

- The company CFO leaves the company in 2020

*“The first months of 2020 have been intense and successful. It is with great satisfaction I am noting that, despite the prevailing situation in the world, Promore Pharma has been able to follow the business plan to date.”*

Jonas Ekblom, President and CEO Promore Pharma

**Financial overview for the Company**

Amounts in MSEK	1 January - 31 March		1 January - 31 December	
	2020	2019	2019	2018
Net sales	0,0	0,5	3,9	2,4
Operating loss	-7,3	-5,5	-29,1	-32,7
Profit/Loss for the period	-7,0	-5,5	-28,9	-32,5
Earnings per share, before/after dilution, SEK	-0,19	-0,27	-1,35	-1,61
Cash flow from operating activities	-15,0	-4,4	-18,5	-32,5
Cash and cash equivalents at the end of the period	45,9	26,6	60,5	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, 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) is being evaluated in 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 Growth Market.

## CEO statement

The first months of 2020 have been intense and successful. It is with great satisfaction I am noting that, despite the prevailing situation in the world, Promore Pharma has been able to follow the business plan to date. Because of the ongoing COVID-19 pandemic, many companies in our sector have experienced disruptions in their clinical programs where many have had to completely suspend ongoing studies or put them on hold for some time.

We have made important progress in our project with ropocamptide (LL-37), where a new treatment for venous leg ulcers, the most common chronic wound, is being developed. It is very satisfying to note that the recruitment and treatment for the subjects in our clinical trial (HEAL LL-37) regarding ropocamptide could be completed during the first quarter. We have achieved the goal of treating approximately 120 patients in accordance with the study protocol. The project has four principal components: (i) an initial period of three weeks when all patients are treated with placebo, (ii) a three-month treatment period with ropocamptide or placebo, (iii) a follow-up period of four months, and finally, (iv) an analysis phase of the study when data is quality assured and analyzed in detail by the company's management and external expert consultants. Our goal is to be able to present final data from the study in the fourth quarter of this year.

If the analysis of data from the ongoing clinical study demonstrates a clear-cut treatment effect of ropocamptide, we believe that we have very good opportunities to create great corporate value since we address a major medical need, and a huge marketplace. Our goal is that the ropocamptide project should be developed towards a treatment of venous leg ulcers that in the future can contribute to both improved treatment outcomes and health-economic benefits.

In the ensereptide project (PXL01), the planning work continues in order to enable the Phase III trial, PHSU03. Ensereptide is a therapeutic peptide intended to prevent the occurrence of unfavorable adhesions with initial focus on surgical repair of injured tendons in the hand. As previously announced, PHSU03 will not commence patient enrolment before additional financing is secured.

The company has not been affected by any significant direct effects of the ongoing COVID-19 pandemic. Opinions on the trajectory of this crisis vary, but one thing experts in various functions seems to agree on is that it will take a long time to reach a normalization. As a result, a large number of uncertainties arise in virtually all sectors of society. For us as a company, this may for example involve delayed interactions with authorities, restrictions in our contacts with health care institutions, capacity constraints of subcontractors, changed priorities in other companies regarding propensity and interest in entering into license agreements and strategic alliances, and uncertainties on the capital markets with potential implications for future fundraising. At present, our overall plans have not been significantly affected, but we are of course constantly working to understand how the COVID-19 pandemic may affect our situation. At the same time, we are reviewing how we can reduce our variable costs to allow for an extension of the time horizon of our current cash holdings, beyond what we had originally planned for.

All in all, our progress in the company's research program gives me great hope for an exciting time ahead of us. We are now primarily awaiting results from our clinical trial of ropocamptide, HEAL LL-37, where we expect to have results by the end of the year. My colleagues and I are convinced that our clinical results in the future will benefit all our stakeholders, not least the patients.

Solna 26 May 2020

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. Ensereptide (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. Ropocamptide (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 innate peptides, which are a part of the human defence 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 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 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 (VLU), 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 is performing a clinical Phase IIb study (HEAL LL-37) 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 ropocamptide focuses initially on VLU but the company sees good potential in also developing ropocamptide for diabetic foot ulcers.

## Significant events 1 January – 31 March 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 last patient has been dosed in the treatment phase of the company's Phase IIb-study (HEAL LL-37) with ropocamtide, 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.

## Significant events after the reporting period

### The company CFO leaves the company in 2020

The company CFO, Jenni Björnulfson, announced in April 2020 that she has decided to leave her role in the company for a position in another company. Jenni Björnulfson will remain in her current role during her notice period of six months.

## Financial information

### Net sales and result for the first 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 first quarter 2020, the company's net sales amounted to 0 SEK.

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 2020 these costs increased to 4.1 (2.9) MSEK.

Other external costs were unchanged in the first quarter 2020 compared to the first quarter 2019 at 1.7 MSEK. External costs are mainly consultancy costs and different administrative services such as IT systems and insurances.

Personnel expenses in the first quarter 2020 were 1.2 MSEK compared to 1.0 MSEK in the first quarter 2019. The increase is explained by a different periodisation in the first quarter 2019 and salaries and personnel costs remain at the same level.

Net loss in the first quarter 2020 amounted to 7.0 MSEK (loss 5.5 MSEK), corresponding to a loss per share of 0.19 SEK (loss 0.27 SEK).

### Liquidity and financing

The cash flow from operating activities amounted in the first quarter 2020 to -15.0 MSEK (-4.4 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 0.3 MSEK (0.1 MSEK). In both the first quarter 2020 and 2019 shares in Herantis Pharma Oyj were divested.

The company's cash and cash equivalents amounted to 46.9 MSEK per 31 March 2020, as compared to 26.6 MSEK per 31 March 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 31 March 2020 were 36,428,362 (20,235,090). The average number of shares in the first quarter 2020 was 36,428,362 (20 235 090). The main owners Midroc New Technology, PharmaResearch Products Ltd. and Rosetta Capital IV S.a.r.L. own approximately 75 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 PXL01 and these outstanding warrants correspond to a potential dilution 5.0%.

### **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 41,518 per 31 March 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 31 March 2020, the company consequently had one employee.

### **Transactions with related parties**

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

Cavastor AB (Kerstin Valinder Strinnholm)	40,000
<b>Total</b>	<b>40,000</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").

### **Review by auditor**

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

### **Financial calendar**

Interim report January – June 2020	25 August 2020
Interim report January – September 2020	24 November 2020

Solna 26 May 2020

Göran Pettersson

Chairman

Marianne Dicander Alexandersson

Torsten Goesch

Satyendra Kumar

Göran Linder

Kerstin Valinder Strinnholm

## Consolidated income statement

Amounts in SEK	1 January - 31 March		1 January - 31 December
	2020	2019	2019
<b>Operating income</b>			
Net sales	0	461 629	3 927 800
Other operating income	22 106	4 199	-7 249
<b>Operating expenses</b>			
Commodities and supplies	-4 141 888	-2 939 509	-20 298 050
Other external expenses	-1 744 533	-1 747 711	-7 204 699
Personnel costs	-1 155 820	-1 004 628	-4 200 280
Depreciation and impairments on fixed assets	-304 286	-304 286	-1 217 142
Other operating expenses	-21 788	-13 125	-69 734
<b>Operating loss (EBIT)</b>	<b>-7 346 209</b>	<b>-5 543 431</b>	<b>-29 069 354</b>
	0		
<b>Financial items</b>		0	0
Net financial items	332 172	71 937	203 948
<b>Profit/loss after financial items</b>	<b>-7 014 037</b>	<b>-5 471 494</b>	<b>-28 865 406</b>
			0
<b>Profit/loss before tax</b>	<b>-7 014 037</b>	<b>-5 471 494</b>	<b>-28 865 406</b>
Tax	-	-	-
<b>Profit/Loss for the period</b>	<b>-7 014 037</b>	<b>-5 471 494</b>	<b>-28 865 406</b>

## Consolidated balance sheet

Amounts in SEK	31 March 2020	31 March 2019	31 December 2019
<b>ASSETS</b>			
<b>FIXED ASSETS</b>			
Intangible fixed assets	304 286	1 521 428	608 572
Tangible fixed assets	0	0	0
Financial fixed assets	2 815 665	2 809 597	2 809 597
<b>Total fixed assets</b>	<b>3 119 951</b>	<b>4 331 025</b>	<b>3 418 169</b>
<b>CURRENT ASSETS</b>			
Short term receivables	1 287 389	2 139 067	0
Cash at bank and in hand	45 883 695	26 608 304	60 543 047
<b>Total current assets</b>	<b>47 171 084</b>	<b>28 747 371</b>	<b>60 543 047</b>
<b>TOTAL ASSETS</b>	<b>50 291 035</b>	<b>33 078 396</b>	<b>63 961 216</b>
<b>EQUITY AND LIABILITIES</b>			
<b>EQUITY</b>			
Share capital	1 457 135	809 404	1 457 135
Other equity including the result for the period	43 722 700	26 966 213	50 736 737
<b>Total equity</b>	<b>45 179 835</b>	<b>27 775 617</b>	<b>52 193 872</b>
<b>LONG-TERM LIABILITIES</b>			
Other liabilities to credit institutions	714 038	714 038	714 038
Other liabilities	370 486	288 413	280 860
<b>Total long-term liabilities</b>	<b>1 084 524</b>	<b>1 002 451</b>	<b>994 898</b>
<b>CURRENT LIABILITIES</b>			
Accounts payable	1 746 077	3 191 239	1 310 633
Other current liabilities	2 280 599	1 109 089	2 047 260
<b>Total current liabilities</b>	<b>4 026 676</b>	<b>4 300 328</b>	<b>3 357 893</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>50 291 035</b>	<b>33 078 396</b>	<b>56 546 663</b>

## Consolidated cash flow analysis

Amounts in SEK	1 January - 31 March		1 January - 31 December
	2020	2019	2019
<b>OPERATING ACTIVITIES</b>			
Operating profit	-7 346 209	-5 543 431	-32 676 230
Adjustments for items not included in cash flow	295 400	304 286	1 153 159
Tax paid	0	0	0
<b>Cash flow from operating activities before changes in working capital</b>	<b>-7 050 809</b>	<b>-5 239 145</b>	<b>-31 523 071</b>
Increase/decrease other current receivables	3 485 864	-56 904	215 010
Increase/decrease other current liabilities	-11 429 397	942 435	-1 214 628
<b>Cash flow from operating activities</b>	<b>-14 994 342</b>	<b>-4 353 614</b>	<b>-32 522 689</b>
Cash flow from investing activities	334 990	79 490	471 896
Cash flow from financing activities	0	0	-38 981
<b>Cash flow for the period</b>	<b>-14 659 352</b>	<b>-4 274 124</b>	<b>-32 089 774</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>60 543 047</b>	<b>30 882 428</b>	<b>62 972 202</b>
Exchange rate difference cash and cash equivalents		0	
<b>Cash and cash equivalents at the end of the period</b>	<b>45 883 695</b>	<b>26 608 303</b>	<b>30 882 428</b>

## Changes in equity for the group

EQUITY			
	Share capital	Other equity	Total equity
Amount at the beginning of the period (1 January 2020)	809 404	50 736 738	51 546 142
Profit for the period		-7 014 037	-7 014 037
Amount at the end of the period (31 March 2020)	809 404	43 722 701	44 532 105
	Share capital	Other equity	Total equity
Amount at the beginning of the period (1 January 2019)	809 404	32 437 708	33 247 112
Profit for the period		-5 471 494	-5 471 494
Amount at the end of the period (31 March 2019)	809 404	26 966 214	27 775 618

**For additional information, please contact**

Jonas Ekblom, CEO

Phone: [+46] 736 777 540

Email: [jonas.ekblom@promorepharma.com](mailto:jonas.ekblom@promorepharma.com)

Jenni Björnulfson, CFO

Phone: [+46] 708 55 38 05

Email: [jenni.bjornulfson@promorepharma.com](mailto:jenni.bjornulfson@promorepharma.com)

Street address: Fogdevreten 2, 171 65 Solna, Sweden

Website: [www.promorepharma.com](http://www.promorepharma.com)

Corporate registration number: 556639-6809