

## Promore Pharma AB (publ)

# Interim report January - June 2020

## April to June

- Net sales amounted to MSEK 0 (0.7).
- The operating loss for the period was 6.7 (-7.4) MSEK
- Net loss was 6.5 (-7.3) MSEK, corresponding to earnings per share of SEK -0.18 (-0.36)
- Cash flow from operating activities amounted to -6.0 (-6.9) MSEK
- Cash and cash equivalents amounted to 39.9 (19.7) MSEK

## Significant events during the period January - June

## January to June

- Net sales amounted to MSEK 0 (1.2).
- The operating loss for the period was 14.0 (-12.9) MSEK
- Net loss was 13.6 (-12.8) MSEK, corresponding to earnings per share of SEK -0.37 (-0.63)
- Cash flow from operating activities amounted to 21.0 (11.3) MSEK
- The targeted number of 120 patients completing treatment in the HEAL LL-37 Phase IIb clinical trial with ropocamptide was reached
- The company CFO leaves in 2020
- A performance-based stock savings program approved by the AGM
- Erik Magnusson appointed CFO

## Significant events after the reporting period

• Patent granted for ropocamptide in the US

" We have made our most important progress in our project with ropocamptide. It is very gratifying to note that the recruitment- and treatment period for the subjects in our clinical trial (HEAL LL-37) regarding ropocamptide is now completed , despite the ongoing COVID-19 pandemic, and earlier this year, we achieved the goal to to have approximately 120 patients complete the treatment period in accordance with the study protocol. All data in our study database is now controlled and verified; we were therefore able to declare clean file in July, which means that we have now started processing the data. This is very extensive analysis work that will allow us to compare tolerability, safety and efficacy between different treatment groups. We expect to be able to present final data from the study during the fourth quarter of this year. So far, we note that the technical quality of the project, in terms of compliance with the study protocol, is very high"

Jonas Ekblom, President and CEO Promore Pharma

## **Financial overview for the Company**

Amounts in MSEK	1 April -	30 June	1 January - 30 June	
	2020	2019	2020	2019
Net sales	0,0	0,7	0,0	1,2
Operating loss	-6,7	-7,4	-14,0	-12,9
Profit/Loss for the period	-6,5	-7,3	-13,6	-12,8
Earnings per share, before/after dilution, SEK	-0,18	-0,36	-0,37	-0,63
Cash flow from operating activities	-6,0	-6,9	-21,0	-11,3
Cash and cash equivalents at the end of the period	39,9	19,7	39,9	19,7

#### 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 half of 2020 has been filled with activities that, fortunately, have not been significantly affected by the ongoing COVID-19 pandemic. In contrast to many companies in our sector that have experienced disruptions in their clinical programs, we have had the privilege of being able to follow our business plan.

We have made our most important progress in our project with ropocamptide, involving a new treatment of venous leg ulcers, the most common type of chronic leg wounds. It is very gratifying to note that the recruitment- and treatment period for the subjects in our clinical trial (HEAL LL-37) regarding ropocamptide is now completed , despite the ongoing COVID-19 pandemic and earlier this year, we achieved the goal to to have approximately 120 patients complete the treatment period in accordance with the study protocol. All data in our study database is now controlled and verified; we were therefore able to declare clean file in July, which means that we have now started processing the data. This is very extensive analysis work that will allow us to compare tolerability, safety and efficacy between different treatment groups. We expect to be able to present final data from the study during the fourth quarter of this year. So far, we note that the technical quality of the project, in terms of compliance with the study protocol, is very high.

If the analysis of data from the ongoing clinical study shows a clear treatment effect of ropocamptide versus placebo, we assess that we should have very good opportunities to create great value for our shareholders, as we address a great medical need, and a huge market. Estimates show that healthcare costs for treating a single chronic wound often exceed USD10,000. In the United States alone, the aggregated healthcare costs for patients with chronic wounds are estimated to exceed USD 25 billion annually. In Scandinavia, chronic wounds are estimated to account for up to four percent of the total societal cost of healthcare. Our goal is to develop the ropocamptide project towards a treatment that can contribute to both improved treatment results and future economic benefits for the healthcare system.

In the ensereptide project, the planning work continues, to allow us to start enrolment into our Phase III study, PHSU03, as soon as the financing of the entire study is secured. Ensereptide is a therapeutic peptide that aims to prevent the occurrence of undesirable post-surgical adhesions, primarily in conjunction with repair of damaged tendons in the hand.

We announced earlier this year that we have not been affected by any significant direct effects of the ongoing COVID-19 pandemic and that perception remains. It is still difficult to assess the consequences of the crisis, but one thing experts in various functions seem to agree on is that it will take a long time to reach normalization. This creates a large number of uncertainties in almost all sectors of society. For us as a company, this can mean, for example, delayed interactions with

authorities, limitations in our contacts with healthcare institutions, capacity limitations of subcontractors, changed priorities at other companies with potential interest in concluding license agreements and strategic alliances, and uncertainties in the capital markets that may have implications for future capital raising. Our overall plans have not been significantly affected, but we will of course continuously work to understand how our situation may be affected. I also want to stress, that we are constantly reviewing how we can reduce our costs to enable us to extend the runway for our current cash, in addition to what we originally planned for. In this way, we hope to create increased flexibility for future financing.

I would also like to take this opportunity to welcome our new CFO, Erik Magnusson, who is joining the company this month. Erik has extensive experience from the capital markets and the life science sector and I am very much looking forward to our future collaboration. I would also like to take this opportunity to direct my heartfelt thanks to Jenni Björnulfson who is leaving us, for all her important contributions in recent years in our management team. I want to wish her the best of luck in her upcoming new professional endeavors.

With excitement, I am now I looking forward to the results of our clinical trial HEAL LL-37, which we hope to be able to publish at the end of the year. My coworkers and I are convinced that our future outcome will benefit both shareholders and patients.

Solna 25 August 2020

Jonas Ekblom President and 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 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 nerverepair in the hand, lower arm and foot. The company also anticipates that there are good opportunities for indication broadening, such a 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 during the report period 1 January – 30 June 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.

## 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.

## A performance-based stock savings 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 Magnusson assumes the position in August 2020 and thereby replaces the company's current CFO Jenni Björnulfson, who is available for the company until the end of September to facilitate a smooth transition.

## Other events after the reporting period

## 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 at least until 2034.



## **Financial information**

## Net sales and result second 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 second quarter 2020 company sales were 0 MSEK (0.7 MSEK). The sales reported in the second quarter 2019 were re-invoiced manufacturing and consulting costs. The net loss for the period was 6.7 (-7.3) MSEK, which was explained by lower consultancy and travelling costs and lower costs for the company's clinical trials, compared with the second quarter 2019.

## Net sales and result first six months 2020

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 2020, the company's net sales amounted to 0 SEK. In the first six months 2019, the reported net sales amounted to 1.2 MSEK, 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 six months 2020 these costs increased to 8.0 MSEK (7.3 MSEK) since costs for HEAL LL-37 increased compared to the first six months 2019.

Other external costs decreased the first six months 2020 to 3.2 MSEK (4.0 MSEK), mainly due to lower consultancy and travelling costs compared to the first six months 2019.

Personnel expenses costs were 2.2 MSEK for the first six months 2020 compared to 2.2 MSEK for the first six months 2019.

Net loss for the first six months 2020 amounted to 13.6 MSEK (-12.8 MSEK), corresponding to earnings per share of SEK -0.37 (SEK -0.63).

## Liquidity and financing

The cash flow from operating activities during the first six months 2020 amounted to 21.0 MSEK (-11.3 MSEK) mainly explained by higher working capital. The cash-flow from investments during the period amounted to 0.5 MSEK (0.1 MSEK). Both in 2020 and 2019 the company has divested shares in Herantis Pharma Oyj.

The cash flow from financing activities was 0.03 MSEK (0 MSEK) during the period.

The company's cash and cash equivalents amounted to 39.9 MSEK per 30 June 2020, as compared to 19.7 MSEK per 30 June 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 June 2020 were 36,428,362 (20,235,090). The average number of shares in the first six months 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%.

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 40,118 per 30 June 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 June 2020, the company consequently had one employee.

## **Transactions with related parties**

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

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## 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 2020

## **Review by auditor**

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

Solna 25 August 2020

Göran Pettersson

24 November 2020

Chairman

Marianne Dicander Alexandersson

Satyendra Kumar

Kerstin Valinder Strinnholm

Torsten Goesch

Göran Linder



# **Consolidated income statement**

	1	April - 30 June	1J	anuary - 30 June	1 January - 31 December
Amounts in SEK	2020	2019	2020	2019	2019
Operating income					
Net sales	-11 132	719 415	10 974	1 181 044	3 927 800
Other operating income	0	-9 499	0	-5 300	-7 249
Operating expenses					
Commodities and supplies	-3 845 208	-4 325 251	-7 987 096	-7 264 760	-20 298 050
Other external expenses	-1 415 703	-2 259 285	-3 160 236	-4 006 996	-7 204 699
Personnel costs	-1 068 313	-1 167 766	-2 224 133	-2 172 394	-4 200 280
Depreciation and impairments on fixed assets	-304 285	-304 285	-608 571	-608 571	-1 217 142
Other operating expenses	-6 788	-32 951	-28 576	-46 076	-69 734
Operating loss (EBIT)	-6 651 429	-7 379 622	-13 997 638	-12 923 053	-29 069 354
	0				
Financial items		0			0
Net financial items	109 805	44 683	441 977	116 620	203 948
Profit/loss after finanical items	-6 541 624	-7 334 939	-13 555 661	-12 806 433	-28 865 406
					0
Profit/oss before tax	-6 541 624	-7 334 939	-13 555 661	-12 806 433	-28 865 406
Tax	-	-	-	-	-
Profit/Loss for the period	-6 541 624	-7 334 939	-13 555 661	-12 806 433	-28 865 406



# **Consolidated balance sheet**

Amounts in SEK	30 June 2020	30 June 2019	31 December 2019
ASSETS			
FIXED ASSETS			
Intangible fixed assets	0	1 217 143	608 572
Tangible fixed assets	0	0	0
Financial fixed assets	2 815 665	2 809 597	2 809 597
Total fixed assets	2 815 665	4 026 740	3 418 169
CURRENT ASSETS			
Short term receivables	1 195 415	2 149 283	4 773 253
Cash at bank and in hand	39 944 229	19 725 319	60 543 047
Total current assets	41 139 644	21 874 602	65 316 300
TOTAL ASSETS	43 955 310	25 901 342	68 734 469
EQUITY AND LIABILITIES			
EQUITY			
Share capital	1 457 135	809 404	1 457 135
Other equity including the result for the period	37 181 076	19 631 274	50 736 737
Total equity	38 638 211	20 440 678	52 193 872
LONG-TERM LIABILITIES			
Other liabilities to credit institutions	714 038	714 038	714 038
Other liabilities	341 264	288 413	370 486
Total long-term liabilities	1 055 302	1 002 451	1 084 524
CURRENT LIABILITIES			
Accounts payable	2 390 787	2 636 205	12 224 595
Other current liabilities	1 871 010	1 822 008	3 231 478
Total current liabilities	4 261 797	4 458 213	15 456 073
TOTAL EQUITY AND LIABILITIES	43 955 310	25 901 342	68 734 469



# Consolidated cash flow analysis

	1 April - 30 June		1 J;	anuary - 30 June	1 January - 31 December	
Amounts in SEK	2020	2019	2020	2019	2019	
OPERATING ACTIVITIES						
Operating profit	-6 651 429	-7 379 622	-13 997 638	-12 923 053	-29 069 354	
Adjustments for items not included in cash flow	301 563	298 644	596 963	602 930	1 210 943	
Tax paid	0	0	0	0	0	
Cash flow from operating activities before changes in working						
capital	-6 349 866	-7 080 978	-13 400 675	-12 320 123	-27 858 411	
Increase/decrease other current receivables	91 974	-10 216	3 577 838	-67 120	-2 691 090	
Increase/decrease other current liabilities	235 121	157 885	-11 194 276	1 100 320	12 098 180	
Cash flow from operating activities	-6 022 771	-6 933 309	-21 017 113	-11 286 923	-18 451 321	
Cash flow from investing activities	112 527	50 324	447 517	129 814	299 773	
Cash flow from financing activities	-29 222	0	-29 222	0	47 812 167	
Cash flaw facable merical	E 030 466	C 003 005	-20 598 818	44 457 400	20.000.000	
Cash flow for the period	-5 939 466	-6 882 985		-11 157 109	29 660 619	
Cash and cash equivalents at the beginning of the period	45 883 695	26 608 304	60 543 047	30 882 428	30 882 428	
Exchange rate difference cash and cash equivalents		0	0	0	0	
Cash and cash equivalents at the end of the period	39 944 229	19 725 319	39 944 229	19 725 319	60 543 047	

# Changes in equity for the group

	Share capital	Other equity	Total equity
Amount at the beginning of the period (1 January 2020)	1 457 134	50 736 738	52 193 872
Profit for the period		-13 555 661	-13 555 661
Amount at the end of the period (30 June 2020)	1 457 134	37 181 077	38 638 211
	Share capital	Other equity	Total equity
Amount at the beginning of the period (1 January 2019)	809 404	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



## For additional information, please contact

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