Promore Pharma AB (publ)

Interim report January – September 2019

June – September

- Net sales amounted to 1,3 (1,0) MSEK
- The operating loss for the period was 6,7 (-7,4) MSEK
- Net loss was 6,7 (-7,6) MSEK corresponding to earnings per share of SEK -0,33 (-0,38)
- Cash flow from operating activities amounted to -6,9 (-6,7) MSEK
- Cash and cash equivalents amounted to 13,0 (39,5) MSEK

January – September

- Net sales amounted to 2,5 (1,1) MSEK
- The operating loss for the period was 19,6 (-26,1) MSEK
- Net loss was 19,5 (-25,3) MSEK corresponding to earnings per share of SEK -0,96 (-1,25)
- Cash flow from operating activities amounted to -18,2 (-23,8) MSEK

Significant events during the period January – September

- 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
- Patent granted for LL-37 in Japan

Events after the reporting period

- The Board of Directors resolved on a rights issue of 75 MSEK, guaranteed to 80 percent, where the subscription period is ongoing
- ABG Sundal Collier engaged as liquidity provider

" The Phase IIb clinical trial of the LL-37 project (HEAL LL-37) is proceeding according to plan. The purpose of the clinical trial is to evaluate the medical effect of two doses of LL-37 versus placebo. The aim is that approximately 120 patients shall complete the entire study protocol. During the second quarter of this year, we announced that approximately 50% of patients have been included. We intend to be able to complete the recruitment for the study at the beginning of the coming year."

Jonas Ekblom, President and CEO Promore Pharma

Financial overview for the Company

	1 July - 30 September		1 January - 30 September		1 January - 31 December
Amounts in MSEK	2019	2018	2019	2018	2018
Net sales	1,3	1,0	2,5	1,1	2,4
Operating loss	-6,7	-7,4	-19,6	-26,1	-32,7
Profit/Loss for the period	-6,7	-7,6	-19,5	-25,3	-32,5
Earnings per share, before/after dilution, SEK	-0,33	-0,38	-0,96	-1,25	-1,61
Cash flow from operating activities	-6,9	-6,7	-18,2	-23,8	-32,5
Cash and cash equivalents at the end of the period	13,0	39,5	13,0	39,5	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, 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 Growth Market..

CEO Statement

The first nine months of 2019 have meant significant work in product development, financing and strategic business development, and these initiatives have helped us to further reach our strategic goal; to develop two drugs, the first of their kind, in bioactive wound care, LL-37 and PXL01.

The third quarter of the year was characterized by continued work within our two clinical development programs - HEAL LL-37, which is a phase II study with LL-37 for the treatment of venous leg ulcers, and PHSU03, where we prepare a phase III trial with our drug candidate PXL01 for prevention of adhesions occurring after tendon and nerve repair surgery in the hand.

The Phase IIb clinical trial of the LL-37 project (HEAL LL-37) is proceeding according to plan. The goal of the clinical trial is to evaluate the medical effect of two doses of LL-37 versus placebo. The aim is that approximately 120 patients shall complete the entire study protocol, which has three overall stages; (i) a three-week run-in period where all patients are treated with placebo with the purpose of identifying patients who do not have a chronic wound; (ii) randomization and treatment period when patients are treated with either LL-37 or placebo for three months; and (iii) a four-month follow-up period. During the second quarter of this year, we announced that approximately 50% of patients have been included. We intend to be able to complete the recruitment for the study at the beginning of the coming year.

During the third quarter, we began work on preparing a capital increase, in the form of a rights issue. The subscription period for the rights issue continues until November 28. With this share issue, we are securing the capital required for approximately one year. With these resources we will be able to complete the clinical trial HEAL LL-37 and prepare for the Phase III study with PXL01.

Regarding our Phase III clinical trial with PXL01, PHSU03, we have worked in the past year to optimize the production process and solve some remaining issues around the supply chain for the investigational medicinal product. We are constantly working to fine-tune the coordination between the various manufacturers that are involved in the production of our investigational drug, reduce significant uncertainties and raise the quality of the process. The work with the preparations for the PXL01 clinical phase III study continues, but additional capital will be required to initiate the recruitment of patients. In parallel with the work to secure capital, the company is constantly investigating new strategic alternatives that will enable us to reach our final goal of developing two drugs within bioactive wound care faster.

A couple of weeks ago we received another patent for PXL01 approved in the USA. This was an important step in our strategic work to create far-reaching intellectual property protection for our innovative prescription drug for the prevention of post-surgical adherence, and in this effort, it is essential to have long-term patent protection in the world's largest pharmaceutical market.

At Promore Pharma, we are now working on planning for the coming operating year. Our progress in the company's research program in 2019 gives me great hope for an exciting time ahead of us.

Solna, 22 November 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 20201. 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 defense 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 a 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

[1] 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 is currently being evaluated in 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 September 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 PHSU03 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 patients have been enrolled and started the treatment in the company's Phase II-study (HEAL LL-37) 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.

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.

Events after the reporting period

The Board of Directors resolved on a rights issue of 75 MSEK, guaranteed to 80 percent

The company announced in October that the Board of Directors had resolved to carry out a new share issue with preferential rights for the company's existing shareholders of a total of 75 MSEK excluding transaction costs. The rights issue was approved by the extraordinary shareholders meeting on 22 October 2019. The rights issue is guaranteed up to 80 percent through subscription undertakings and underwriting commitments, including a pro rata commitment from the Company's largest shareholder Midroc New Technology AB. The purpose of the rights issue is to ensure the continued successful development of the company's two drug candidates in accordance with the company's business plan and strategy. The subscription period is ended 28 November 2019.

ABG Sundal Collier engaged as liquidity provider

The company announced in October 2019 that ABG Sundal Collier ASA had been engaged as liquidity provider. The liquidity provision assignment is offered in accordance with the rules of Nasdaq Stockholm AB's and means that the liquidity provider quotes a buy and sell volume corresponding to at least 15,000 SEK, with a maximum spread of 4% between the bid and ask price. The purpose is to promote the liquidity in the trading of the share.

Patent granted for PXL01 in the US

In November 2019 the company announced that the US patent authority formally granted a patent regarding the formulation of PXL01 in combination with high molecular hyraluronic acid. The patent is valid until at least January 2030.

Finansiell information

Net sales and result third 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 third quarter 2019 company net sales amounted to 1.3 (1.0) MSEK, primarily attributable to the re-invoicing of consulting costs. The net loss for the period was 6.7 (-7.4) MSEK, which was explained by lower costs for company's clinical program compared with the third quarter 2018, when a number of preparations were done before the start of the HEAL LL-37 trial, but higher external costs in the third quarter 2019 because of costs associated with the rights issue conducted by the company.

Net sales and result first nine 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 nine months 2019, the company's net sales amounted to 2.5 MSEK (1.1 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 nine months 2019 these costs decreased to 11.7 (19.9) MSEK explained by lower costs for the company's development programs. In the first nine months of 2018 Investigational Medicinal Product was manufactured for HEAL LL-37 and number of preparations were done before the start of the trial. The company also made a milestone payment related to PXL01 in the first nine months in 2018.

Other external costs increased the first nine months 2019 to 6.3 (3.9) MSEK, mainly due to costs associated with preparations for the ongoing rights issue and higher consultancy fees in 2019.

Personnel expenses were principally unchanged the first nine months 2019 compared to the same period in 2018 and amounted to 3.1 (3.1) MSEK.

Net loss for the first nine months 2019 amounted to 19.4 (-25.3) MSEK, corresponding to a loss per share of SEK 0.96 (loss per share of 1.25).

Liquidity and financing

The cash flow from operating activities during the first nine months 2019 amounted to -18.1 (-23.8) MSEK, explained by an improved operating result. The cash-flow from investments during the period amounted to 0.2 (0.4) 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. In the first nine months in 2018 the company made a loan installment.

The company's cash and cash equivalents amounted to 12.9 MSEK per 30 September 2019, as compared to 39.5 MSEK per 30 September 2018.

Auxiliary information

Number of shares

Promore Pharma's share is listed on 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 was 20,235,090 (20,235,090). The average number of shares in the third quarter 2019 was 20,235,090 (20,235,090) and in the first nine months 2019 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 46,798 per 30 September 2019. 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 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

Year-end Report 2019	18 February 2020
Annual General Meeting 2020	26 May 2020
Interim report 1 January – 31 March 2020	26 May 2020

Review by auditor

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

Solna 22 November 2019

Göran Pettersson

Chairman

Marianne Dicander Alexandersson

Torsten Goesch

Satyendra Kumar

Göran Linder

Kerstin Valinder Strinnholm

Consolidated income statement

Amounts in SEK	1 July - 30 September 2019	1 July - 30 September 2018	1 January - 30 September 2019	1 January - 30 September 2018	1 January - 31 December 2018
Operating income					
Net sales	1 284 395	1 015 254	2 465 439	1 072 516	2 446 785
Other operating income	10 688	-1 289	5 388	684 887	683 892
Operating expenses					
Commodities and supplies	-4 439 169	-6 421 959	-11 703 929	-19 904 279	-24 452 267
Other external expenses	-2 271 509	-762 175	-6 278 505	-3 885 866	-5 841 185
Personnel costs	-972 572	-964 198	-3 144 966	-3 102 495	-4 189 945
Depreciation and impairments on fixed assets	-304 286	-304 286	-912 857	-912 857	-1 217 143
Other operating expenses	-20 967	-8 732	-67 043	-94 153	-106 367
Operating loss (EBIT)	**-6 713 420**	**-7 447 385**	**-19 636 473**	**-26 142 247**	**-32 676 230**
Financial items		0			0
Net financial items	28 317	-141 205	144 937	830 891	193 147
Profit/loss after finanical items	**-6 685 103**	**-7 588 590**	**-19 491 536**	**-25 311 356**	**-32 483 083**
					0
Profit/oss before tax	**-6 685 103**	**-7 588 590**	**-19 491 536**	**-25 311 356**	**-32 483 083**
Tax	-	-	-	-	-
Profit/Loss for the period	**-6 685 103**	**-7 588 590**	**-19 491 536**	**-25 311 356**	**-32 483 083**

Consolidated balance sheet

Amounts in SEK	30 September 2019	30 September 2018	31 December 2018
ASSETS			
FIXED ASSETS			
Intangible fixed assets	912 857	2 129 999	1 825 714
Tangible fixed assets	0	0	0
Financial fixed assets	2 809 597	3 580 621	2 809 597
Total fixed assets	**3 722 454**	**5 710 620**	**4 635 311**
CURRENT ASSETS			
Short term receivables	2 834 717	3 871 112	2 082 163
Cash at bank and in hand	12 952 003	39 466 465	30 882 428
Total current assets	**15 786 720**	**43 337 577**	**32 964 591**
TOTAL ASSETS	**19 509 174**	**49 048 197**	**37 599 902**
EQUITY AND LIABILITIES			
EQUITY			
Share capital	809 404	809 404	809 404
Other equity including the result for the period	12 946 171	39 609 434	32 437 707
Total equity	**13 755 575**	**40 418 838**	**33 247 111**
LONG-TERM LIABILITIES			
Other liabilities to credit institutions	714 038	714 038	714 038
Other liabilities	351 614	357 962	280 860
Total long-term liabilities	**1 065 652**	**1 072 000**	**994 898**
CURRENT LIABILITIES			
Accounts payable	2 186 731	6 485 911	1 310 633
Other current liabilities	2 501 216	1 071 448	2 047 260
Total current liabilities	**4 687 947**	**7 557 359**	**3 357 893**
TOTAL EQUITY AND LIABILITIES	**19 509 174**	**49 048 197**	**37 599 902**

Consolidated cash flow analysis

Amounts in SEK	1 July - 30 September 2019	1 July - 30 September 2018	1 January - 30 September 2019	1 January - 30 September 2018	1 January - 31 December 2018
OPERATING ACTIVITIES					
Operating profit	-6 713 420	-7 447 385	-12 923 053	-18 694 862	-32 676 230
Adjustments for items not included in cash flow	304 876	304 279	602 930	602 824	1 153 159
Tax paid	0	0	0	0	0
Cash flow from operating activities before changes in working capital	**-6 408 544**	**-7 143 106**	**-12 320 123**	**-18 092 038**	**-31 523 071**
Increase/decrease other current receivables	-685 434	-710 916	-67 120	-863 023	215 010
Increase/decrease other current liabilities	229 734	1 167 519	1 100 320	1 817 317	-1 214 628
Cash flow from operating activities	**-6 864 244**	**-6 686 503**	**-11 286 923**	**-17 137 744**	**-32 522 689**
Cash flow from investing activities	90 928	187 119	129 814	170 370	471 896
Cash flow from financing activities	0	0	0	-38 981	-38 981
Cash flow for the period	**-6 773 316**	**-6 499 384**	**-11 157 109**	**-17 006 355**	**-32 089 774**
Cash and cash equivalents at the beginning of the period	**19 725 319**	**45 965 847**	**30 882 428**	**62 972 202**	**62 972 202**
Exchange rate difference cash and cash equivalents		0	0	0	
Cash and cash equivalents at the end of the period	**12 952 003**	**39 466 463**	**19 725 319**	**45 965 847**	**30 882 428**

Changes in equity for the group

	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			-19 491 536	-19 491 536
Amount at the end of the period (30 September 2019)	**809 404**		**12 946 171**	**13 755 575**

	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			-26 383 872	-26 383 872
Amount at the end of the period (30 September 2018)	**809 404**		**38 536 918**	**39 346 322**

For additional information, please contact

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