Annual Report 2019

PROMORE PHARMA

leading-edge medical innovation

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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, 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 is performing a clinical phase IIb study in patients with venous leg ulcers. 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.

Vision

The vision of Promore Pharma is to solve the global medical problems of scarring, adhesions and chronic wounds.

Strategy

Promore Pharma operates as a lean and cost-effective organization that primarily focuses on high level project management, i.e. coordinating the programs of the company between strategic partners, clinical research organizations and other service providers for example within manufacturing. Furthermore, the company is focused on maintenance and support of the patent portfolio that provides protection of the company's main programs.

In the future, when both the primary indications addressed by Promore Pharma's programs are expected to be close-to-market, the company intends to seek alliances with larger, fully integrated, multi-national companies for market launch. The company intends to explore the feasibility of developing pharmaceutical candidate products for adjacent indications. This could be accomplished either through strategic partnerships that can provide financing and operational resources or through small, well-controlled studies conducted in-house. Such strategic collaborations can be envisioned with both large and small development companies.

The text in English is a free translation of the Swedish original wording. In case of differences between the English translation and the Swedish original, the Swedish text will take precedence

Q1

- Phase III trial with ensereptide modified and the number of clinics in the study expanded

Q2

- Kerstin Valinder Strinnholm elected member of the Board of Directors
- Half of the patients recruited in HEAL LL-37

Q3

- Patent granted for ropocamptide in Japan

Q4

- The Board of Directors resolved on a rights issue of 75 MSEK, guaranteed to 80 percent
- ABG Sundal Collier engaged as liquidity provider
- Patent granted for ensereptide in USA
- Rights issue completed
- HEAL LL-37 recruitment completed early

Promore Pharma - Strengths and Competitive Advantages

Project portfolio of drug candidates in late stage clinical phase

- Two drug candidates in late stage clinical phase where safety and efficacy have already been shown in clinical trials.
- Phase III is being prepared for ensereptide in Europe and India to form the basis for EU market approval. The company has had a successful meeting with the US FDA.
- Phase IIb with ropocamptide, HEAL LL-37, is ongoing in Sweden and Poland. Data is expected to be presented in the fourth quarter of 2020.

Unmet medical need and lack of approved drugs

- Focus on indications where patients experience pain, reduced sensation and mobility and impaired quality of life. There are currently no approved drugs for venous leg ulcers or adhesions and the medical needs are therefore significant.
- Available treatments are medical devices and have limited efficacy. A few projects are in clinical development, all at an earlier stage than ensereptide. A few drug projects are under development in chronic wounds, mainly focused on diabetic foot ulcers.

Validated technology and strong patent protection

- Promore Pharma has validated its two projects in phase II studies and has shown efficacy in patients. The company's founders and various research groups have published a large number of articles that validate the biological mechanisms of the company's peptides.
- The company has established strong protection for the technologies through several patent families with an extensive run rate. The patent term for a product based on ropocamptide is valid until at least 2034, and for a product based on ensereptide, until at least 2030. For both of these products, there are opportunities for patent term extensions up to five years.
- Peptide drugs have historically also had lower generic competition compared to small molecules. This means a greater opportunity for high profitability, even after patent expiry.

Strong safety profile and low development costs

- The company's drug candidates are based on innate substances with a strong safety profile. They are administered locally and are also rapidly degraded in the blood, which means that the systemic exposure is minimal and thus the risk of serious side effects is very small. Ensereptide is administered as a single dose, which means that the risk of phase III failure due to unexpected side effects is considered very limited. It is otherwise a common cause of failure in late clinical stages of development.
- The good safety profile also means pharmaceutical authorities accept that the size of clinical trials can be reduced. Thus, the company's phase III studies for ensereptide are less extensive and the costs are lower than the average for the pharmaceutical industry.

Significant growth potential

- The company develops products for the bioactive wound care market, a market segment that is expected to grow by just over six percent per year over the next few years.
- The company sees good opportunities to develop its drug candidates for adjacent indication areas, such as prevention of adhesions after surgical treatment of disc herniation (*Degeneretive Disc Disorder, DDD*) and prevention of scarring of the skin after all types of surgical procedures, for example plastic surgery, caesarean section or burn injuries. The company also sees an opportunity in developing ropocamptide for diabetic foot ulcers, which are considered to be as common as venous leg ulcers but show faster growth due to increasing prevalence of diabetes, especially in the emerging markets.

Low fixed costs

- Promore Pharma has a business model that aims to keep fixed costs as low as possible. With limited resources, the company has taken two projects to phase II / III studies. The company also believes that it is possible to cost-effectively and independently commercialize ensereptide to prevent post-surgical adhesions. Hand surgeons are a highly specialized category of surgeons and surgical procedures take place in a few centers in Europe, hence it is possible for a smaller sales force to address all relevant surgeons.

Experienced and committed management team and board

- The company's senior executives have many years of experience from pharmaceutical development both in an entrepreneurial environment and in large pharmaceutical companies.
- The Board has solid experience in both pharmaceutical development and business development in the pharmaceutical industry

CEO Statement

At Promore Pharma, we are driven by a long-term commitment to research and development that can lead to drugs which can significantly improve the lives of patients with hard-to-heal wounds and various types of scarring, mainly as a result of surgery.

These conditions are causing pain, reduced mobility and impaired quality of life. We are confident that our drug projects have an important place to fill in the market segment of advanced wound care as they may imply a big change for patients who currently lack appropriate treatment. Promore Pharma has, according to the company's assessment, lower development risk than most other innovation companies in the pharmaceutical sector. The projects are in late stage clinical phase and many development risks have been eliminated and both projects have a strong safety profile, which means that the probability for failure due to unexpected side effects is low. We have a small and efficient organization and we can also carry out studies at a lower cost than what is customary in several other therapeutic areas.

We have made significant progress in our ropocamptide project, 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 in our clinical trial with ropocamptide (HEAL LL-37) could be completed according to plan. We have reached the goal of having 120 patients completing the entire study protocol. The project has four principle 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 where data is quality-assured and analyzed in detail by the company's management and external expert consultants. We expect to be able to present final data from the study during the fourth quarter of this year. As we have previously announced, the schedule will be further defined during the course of the year. If the data from the ongoing clinical trial shows a clear treatment effect, we believe that we have a very good opportunity to create great value by addressing a very large market; it is estimated that the cost of treating a single venous leg ulcer can exceed 10,000 USD per event. The number of patients in the traditional drug markets is estimated at 13-18 million. Our goal is to develop ropocamptide towards a treatment that can contribute to both improved treatment results and healthcare economy in the future.

During 2019, we have also taken important steps in our other program, ensereptide, regarding the preparation of PHSU03, our upcoming phase III study for prevention of adhesions after hand surgery. Late 2019, we made the decision to postpone the initiation of this clinical trial until we have secured enough capital or have a detailed financing plan to complete the clinical part of the project. We believe it is our ethical duty towards the patients and clinics that will participate in the trial. In the meantime, we are working on optimizing the supply chain for the investigational, medicinal product for the trial. The work has included evaluations of several manufacturing alternatives. Together with a supplier, we conducted a meeting with the Swedish Medical Products Agency in May, in a so-called industrial dialogue. We are very pleased with the outcome of the meeting as several uncertainties could be eliminated.

In the end of 2019, we carried out a rights issue, which resulted in net proceeds of approximately SEK 48 million, which provides the monetary resources for the coming year. Our most important operational goals for 2020 are to complete and com-

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pile data from HEAL LL-37 and to complete all preparatory work for PHSU03, so that this clinical phase III trial can start as soon as complementary capital has been secured in the form of a new share issue or with funds from a strategic deal.

The company has not yet been affected by any direct effects of the ongoing COVID-19 pandemic. However, a number of secondary effects such as delayed interactions with authorities, limitations in contacts with clinics in Sweden and in Poland, capacity constraints for suppliers and uncertainties on the financial markets will likely occur. We are currently investigating how this may affect our situation. At the same time, we are reviewing how we can reduce our costs so that we can extend the time horizon for our current cash, beyond what we originally planned for.

Finally, I would like to express my gratitude for all the hard work that made 2019 a year of significant progress for Promore Pharma. By continuing to develop the company’s two assets towards market registration and at the same time opportunistically seeking new strategic alliances that broaden the medical use of our projects, we can continue to deliver value to our shareholders.

Jonas Ekblom
President and CEO

Pharmaceutical naming is not something you decide upon on your own

Ensereptide and ropocamptide. These are the generic names for PXL01 and LL-37, as we have previously called them. Why are pharmaceutical names so difficult? And who decides the names?

Drugs often have several names. There is a complex system behind the naming of drugs, especially pharmaceutical drugs. In the majority of circumstances, drugs have three types of names:

- chemical names, the most important of which is the name given by the International Union of Pure and Applied Chemistry (IUPAC)
- generic or International Nonproprietary Names (INNs)
- trade names or brands, which are used to support marketing and sales

When a drug is first discovered, it is given a chemical name, which describes the atomic or molecular structure of the drug. The chemical name is thus usually too complex and cumbersome for general use. Next, a shorthand version of the chemical name or a code name (such as RU 486) is developed for ease of reference among researchers.

The generic name is assigned by national agencies, for example, in the United States, by the United States Adopted Names (USAN) Council. The World Health Organization administers the international nonproprietary name list.

The brand name is developed by the company requesting approval for the drug and identifies it as the exclusive property of that company. The brand name is often protected. When a drug is under patent protection, the company markets it under its brand name. When the drug is off-patent (no longer protected by patent), the company may market its product under either the generic name or brand name. Other companies that file for approval to market the off-patent drug must use the same generic name but can create their own brand name. In most cases, the generic name is used in combination with the company name.

Both the generic and the brand name must be unique to prevent one drug from being mistaken for another when drugs are prescribed and sold. To prevent this possible confusion, different authorities must agree to every proposed generic name (WHO/FDA) and brand name (local pharmaceutical authorities). Generic names are usually more complicated and harder to remember than brand names. They are constructed by an affix and a common stem, which classifies different pharmaceuticals into different categories and also separates pharmaceuticals within the categories. Many generic names are a shorthand version of the drug's chemical name, structure, or formula.

In contrast, brand names are usually catchy, often related to the drug's intended use, and relatively easy to remember to facilitate both prescribing and sale of the drug. The rules for how brands can be formulated have gradually been reinforced and should ideally consist of only one word. Numbers, capital letters and abbreviations should be avoided. The name cannot be similar to any INN or contain what WHO defines as INN common stem, letter combinations that indicate that the

product contains a certain substance or compound, such as -io that indicates iodine. Suffixes are usually approved only if they can be assumed to improve patient security.

Government officials, doctors, researchers, and others who write about the new compound use the drug's generic name because it refers to the drug itself, not to a particular company's brand of the drug or a specific product. However, doctors often use the brand name on prescriptions, because it is easier to remember and doctors usually learn about new drugs by the brand name. The term generic, when applied in other circumstances, is used to describe a less expensive, sometimes less effective or lower-quality copycat version of a brand-name product. However, most generic drugs, although less expensive than the comparable brand-name drug, are as effective and of the same quality as the brand-name drug.

Code name	Chemical name	Generic name	Brand
APAP	N-acetyl-p-aminophenol	acetaminophen (USA) paracetamol (ROW)	Tylenol (USA) Alvedon (Sweden)
CID4636	3-[(4,5-dihydro-1H-imidazol-2-yl) methyl]-6-(1,1-dimethyleth-yl)-2,4-dimethyl-phenol hydro-chloride	oxymetazoline	Otrivin Afrin Operil Oxyspray Facimin
LL-37	Leucyl-leucyl-glycyl-aspar-tyl-phenylalanyl-phenylalanyl-ar-ginyl-lysyl -seryl -lysylglu-tamyl- lysyl- isoleucyl-glycyl-ly-syl-glutamyl-phenylalanyl-lysyl -arginyl-isoleucyl-valylglutaminyl-arginyl- isoleucyl-lysyl-as-partyl-phenylalanyl-leucyl-ar-ginyl-asparaginylleucyl-valyl -prolyl- arginyl-threonyl-glutam-yl-serine, acetate salt	ropocamptide	Not determined
PXL01	N-Acetyl-L-glutamyl-L-al-anyl-L-threonyl-L-lysyl-L-cys-teinyl-L-phenylalanyl-L-glu-taminyl-L-tryptophanyl-L-glu-taminyl-L-arginyl-L-asparag-inyl-L-methionyl-L-arginyl-L-lysyl-L-valyl-L-arginyl-glycyl-L-prolyl-L-prolyl-L-valyl-L-seryl-L-cysteinyl-L-isoleucyl-L-lysyl-L-argininamide (5 → 22) disulfide, acetate salt	ensereptide	Not dermined

Chronic wounds cause immense healthcare costs

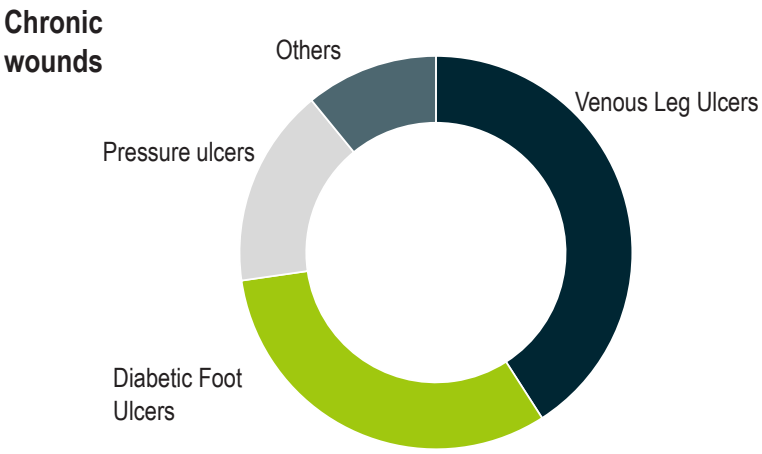
It is estimated that more than 15 million people in the traditional pharmaceutical markets suffer from chronic hard-to-heal wounds. Many patients have wounds for years. Although a fraction of patients do not actively seek care for their ulcers, which makes it difficult to estimate the number of patients, the costs of treating the wounds are enormous for the healthcare systems. The need for pharmaceutical products that can make a difference for the treatment of chronic wounds is very large.

High costs and large impact on quality of life

Chronic wounds are usually defined as wounds that do not show signs of healing within six weeks despite regular cleaning and wound care. Chronic wounds are divided into three main categories: venous leg ulcer, diabetic foot ulcer and pressure ulcers. They can often be painful, bleed or liquidate, emit bad odor, and limit the mobility of the patients. In severe cases, the patient may be required to stay bedridden or need to amputate a foot or lower leg. Patients typically need professional care two to three times per week; hence, the treatment of chronic wounds requires extensive resources from the health care system. It is estimated that the health care cost for treating one single chronic wound exceeds 10 000 USD. In the United States alone, the aggregated healthcare costs for patients with hard-to-heal ulcers are estimated to exceed USD 25 billion annually. In Scandinavia, chronic wounds are estimated to account for two to four percent of the total spending in society on health care.

15 000 000
patients with chronic wounds on the traditional pharmaceutcial markets

10 000 USD
health care cost for treating one single wound

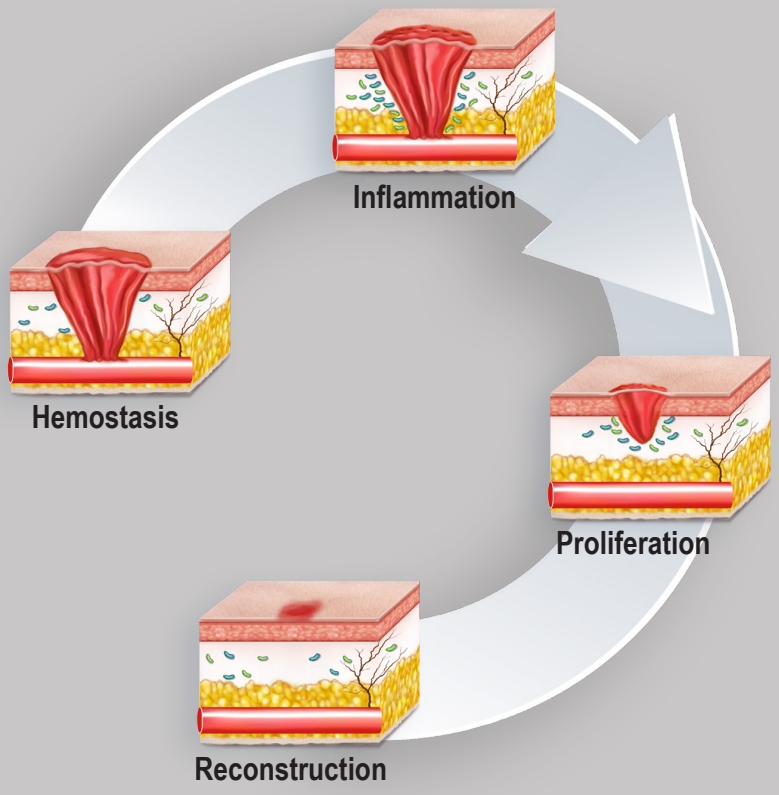


Wound healing process

Wound healing occurs in four phases;

- hemostasis (arrest of local blood flow);
- inflammation;
- proliferation (cell division with replication of similar cells); and
- reconstruction.

Immediately after an injury, hemostasis occurs preventing further blood loss. This occurs through fibrin formation. Growth factors from platelets initiate the subsequent inflammatory process. In the inflammatory phase, immune cells (lymphocytes, macrophages and neutrophils) are recruited to the wound area to remove bacteria and non-viable tissues as well as initiate vascular regeneration. As the inflammatory phase subsides, the proliferation phase begins. During this phase, the number of fibroblasts, a type of connective tissue cells that produce collagen, are attracted and propagated. This causes the wound to seal. Finally, the tissue is reconstructed in the final wound healing phase, the reconstruction phase, and then takes on a more permanent structure, which often, but not always, look as healthy tissue.



2-4%

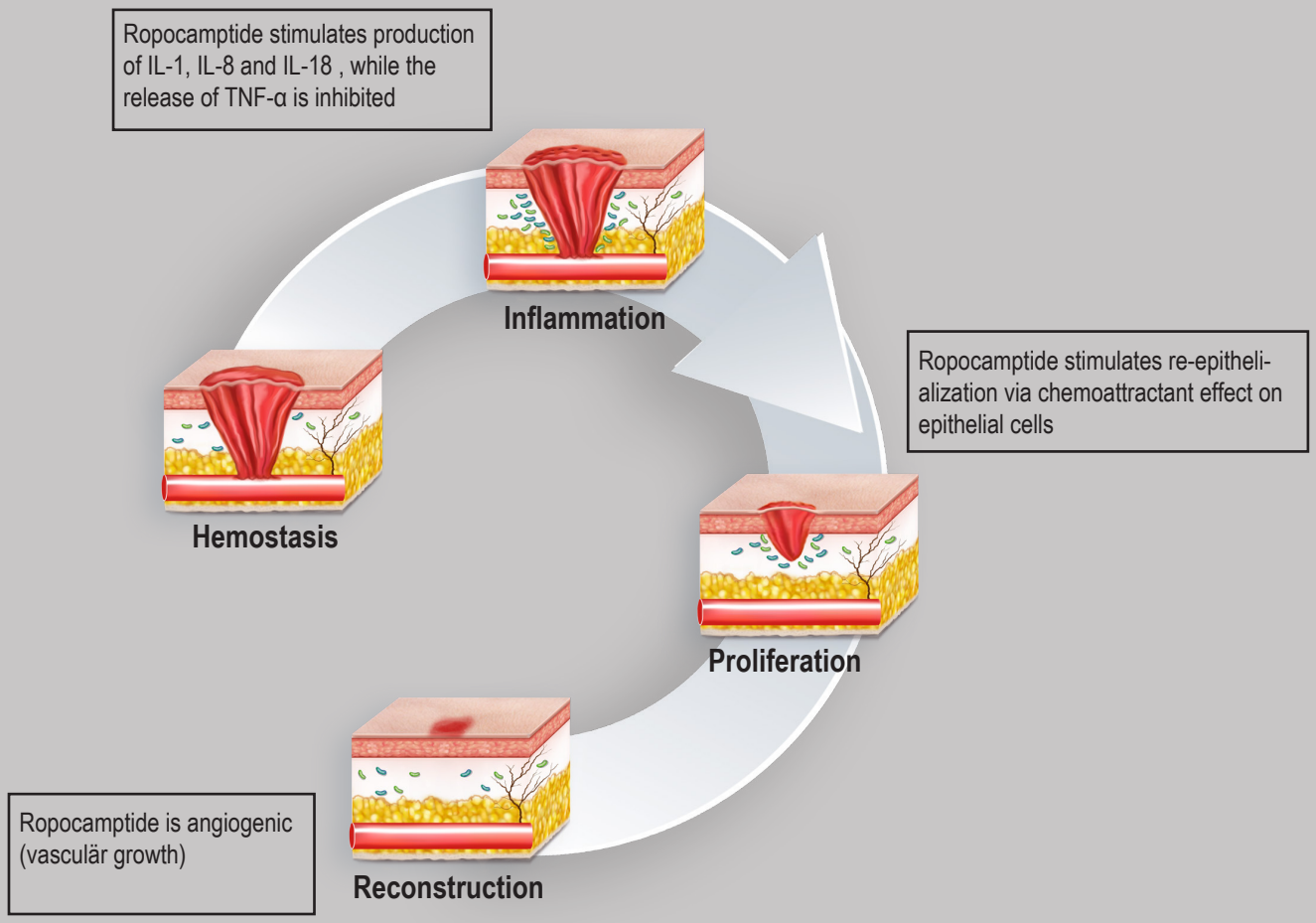
of the total health care spending in Scandinavia spent on treating chronic wounds

80

studies on venous leg ulcers registered compared to 2,000 lung cancer studies

Venous leg ulcers are the largest group and accounts for approximately 40 percent of all chronic wounds. The most common cause of venous leg ulcers is venous insufficiency, which means that blood circulation in the legs does not work well. It is a result of dysfunctional valves. The legs get swollen and are more easily wounded, because the skin becomes brittle and when blood circulation is deteriorated, the wounds also become harder to heal. The risk of getting venous leg ulcers increases with increasing age and obesity. Despite limited efficacy, the market today is dominated by medical devices. The research efforts to find new pharmaceuticals is, despite the high need, not very extensive within the wound care area. According to Clinicaltrials.gov there are some eighty studies registered focusing on venous leg ulcers, of which twelve are pharmaceuticals. For diabetic foot ulcers the number is about 300. This can be compared with about 3,000 Type II diabetes studies and 2,000 lung cancer studies.

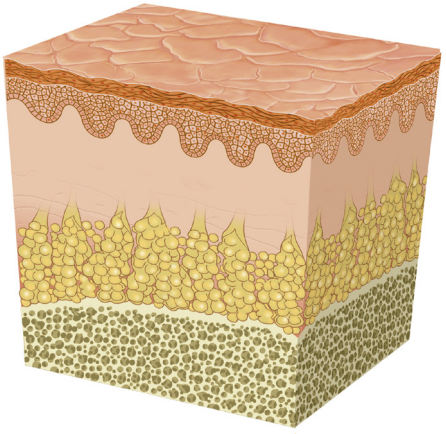
Standard treatment is dressings that aim to keep the wound moist, in order to stimulate healing as well as compression treatment, which means that elastic bandages or specialized hosiery are applied around the wound. The wound is cleansed when the dressing is changed and may need to be cleaned from dead tissue and skin debris. If the ulcer smells bad, it may be due to colonization of bacteria and other microorganisms, which requires some antimicrobial treatment.

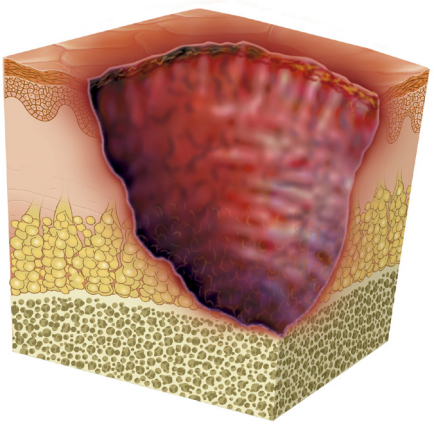


Mechanism of action

Ropocamptide is part of a human antimicrobial protein (LL-37; cathelicidin) and this protein has been shown to be important in the wound healing process. Endogenous LL-37 is present in the lesion of an acute wound and is up regulated (local levels increase) within a few hours after an injury of the skin. During the normal wound healing process, wounds begin to heal from the edge and then toward the wound center; hence it is important that endogenous LL-37 is present in the wound bed. Venous leg ulcers lack endogenous LL-37 in the wound, unlike all acute wounds. By adding endogenous LL-37 to a venous leg ulcer, the wound may restart the body's wound healing process as the chronic wound becomes more like an acute wound that usually heals rapidly. It has not yet been determined precisely how v impacts wound healing, but the peptide affects several mechanisms. Endogenous LL-37 attracts inflammatory cells, including monocytes and granulocytes, by stimulating a specific receptor ("FPR2"). The inflammatory phase of wound healing may also be regulated through the release of a group of proteins and peptides that can control inflammatory processes (cytokine release). Keratinocytes in the skin epithelium are activated by endogenous LL-37 by stimulation of unknown receptors, which in turn leads to activation of growth factors in the top skin layer (EGF receptors) and subsequent cell migration. This is thought to lead to re-epithelialization of the wound. Production of vascular growth factors (VEGF) and activation of endothelial cells on the inside of the blood vessels are probably also important com-ponents of the increased vessel formation that can be observed after treatment with endogenous LL-37.

The potential role of ropocamptide in wound healing has also been demonstrated in an *ex vivo* experiment, where the regeneration of cells (re-Epithelialization and proliferation) in skin biopsies was stopped with an antibody to ropocamptide. Animal studies have also shown that ropocamptide stimulates the recovery of blood vessels, which is an important part of wound healing.





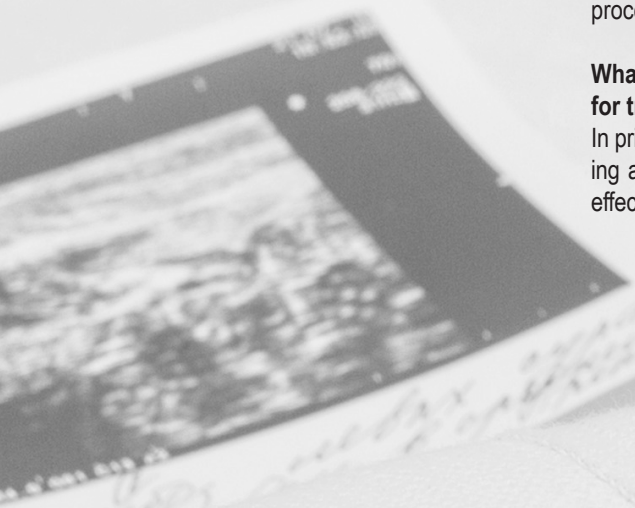
Ropocamptide can also be used to treat Diabetic Foot Ulcers

There are clear research findings that indicate that ropocamptide may also stimulate the healing of diabetic foot ulcers. For example, diabetic foot ulcers, like venous leg ulcers, are deficient of endogenous LL-37 in the wound. Promore Pharma, therefore, considers that diabetic foot ulcers represent a good opportunity for an additional indication for ropocamptide. There are about 425 million patients in the world with diabetes, which is expected to increase to 642 million people by 2040. In the United States, approximately 900,000 people are afflicted by a diabetic foot ulcer out of a diagnosed diabetes population of approximately 21 million. However, CDC estimates that the number of people with diabetes in the United States is significantly higher. Diabetic foot ulcers account for about 10 to 15 billion USD in healthcare costs annually. Today, the market is dominated by medical devices, although there are also pharmaceutical products approved for the treatment of diabetes foot ulcers, such as Regranex. Regranex is sold for approximately 560 - 1 000 USD per package (15 g) which corresponds to product volume for treating a median-sized wound (approximately 2 cm^2) for four weeks, or between 1,680 and 3,000 USD for a normal 12-week treatment cycle. Promore Pharma estimates that ropocamptide has the potential to show better efficacy and significantly less side effects than, for example Regranex, which, since 2008, carries a so-called black box warning on the US market. This means that the product may only be used in exceptional cases due to increased risk of skin cancer associated with treatment. The product is no longer sold in Europe.

There are also a number of projects currently undergoing clinical trials for this indication. It is difficult to determine to what extent other projects undergoing development can be compared to ropocamptide. Peptides based on recombinant growth factors, for example, PDGF, FGF or EGF, have traditionally been associated with a risk of carcinogenicity, which, in contrast, is not seen as a significant risk of ropocamptide. In summary, this means that the ropocamptide project holds a strong position when compared to the competition, i.e. other pharmaceutical products undergoing development for the treatment of severe leg ulcers.

Interview with Mona Ståhle, professor at Karolinska Institute and founder

You were one of the founders of one of Promore Pharma's predecessor companies. Can you tell us a little about what led to your research results on the importance of ropocamptide in wound healing?
Wound healing is a multifaceted medical problem that lies in between endocrinology, vascular biology, and immunology. Endogenous LL-37 was initially studied on the basis of its antimicrobial properties. There are three discoveries that underlie the idea of using ropocamptide to stimulate wound healing. When we studied normal wound healing in human skin, we saw that endogenous LL-37 was formed in the cells that formed the new skin and when we, in the laboratory, inhibited the formation of endogenous LL-37, the healing stopped. When examining hard-to-heal leg ulcers in humans, we discovered, to our surprise, that endogenous LL-37 was largely missing. Could healing of these wounds be stimulated by adding endogenous LL-37 to the wound? At the next stage we discovered that vitamin D stimulated production of endogenous LL-37 in the skin the most. Vitamin D is formed in the same skin cells under the influence of sunlight and then the idea was born that this is perhaps nature's own mechanism for protecting the skin against both bacteria and damage, through endogenous LL-37 using Vitamin D. Endogenous LL-37 appears to have an impact on all phases of the wound healing process.



What is your view on the need for drugs for treating chronic wounds?
In principle, effective drugs for wound healing are lacking and the need for new and effective treatment is enormous. There are estimates that indicate that the treatment of hard-to-heal wounds today accounts for about 5% of the total healthcare cost in Scandinavia. The disease population increases from year to year, as the average life expectancy increases worldwide and there is a strong correlation between age and the incidence of hard-to-heal wounds.

What do you think of available treatments today?
Although some new forms of treatment have emerged in recent decades, such as various pressure-controlling treatments and vascular surgery, it is still quite evident that today's tools are inadequate.

What are your expectations for the Phase II study HEAL LL-37?
The study is designed to investigate the proportion of patients treated with ropocamptide who achieve complete healing of their venous leg ulcers after three months of treatment. From the clinical trial conducted by Promore Pharma previously, the test drug appears to be safe and well tolerated in the two doses investigated in this phase IIb study. We hope, of course, that the strong efficacy data that was shown in the previous study can be repeated, now in a significantly larger patient population.

Do you think ropocamptide can also be used for diabetic foot ulcers?
Although the etiology of venous leg ulcers and diabetic foot ulcers differs considerably, there are indicative data suggesting that ropocamptide may have a therapeutic value even in diabetic foot ulcers. This should be investigated in a separate clinical study, which I see as a natural continuation if the outcome of the ongoing study is positive.

" This is perhaps nature's own mechanism for protecting the skin against both bacteria and damage, through endogenous LL-37 using Vitamin D.
Endogenouos LL-37 appears to have an impact on all phases of the wound healing process."

Harry Hansson, patient and contact person at RiksSår

Chronic wounds mainly affect the elderly. According to studies in the UK, 2% of the UK population over the age of 80 has a chronic wound. Last year, the average age of patients in Sweden with hard-to-heal ulcers was 79 years. The presence of venous leg ulcers, in particular, is linked to factors that usually follow increasing age, where the main cause is insufficient blood flow in the legs. However, patients are found in all age groups. Harry Hansson was only in his 20s when he had a venous leg ulcer.

Harry was a cancer patient as a child. He underwent both surgery and radiation therapy and recovered after some time. But the treatments may have adversely affected his blood flow and already in his twenties he had several blood clots in his leg. This led to wounds emerging in the same area that were difficult to heal. During a vacation in Costa Rica, he discovered that all the smaller wounds on his body disappeared after extensive swimming in salt water, except the slightly larger wound on the leg that had emerged following the clots. Once back in Sweden, Harry contacted primary care, where his wounds were treated without success. After a long treatment period without the wound showing any signs of healing, Harry found Sårcentrum in Karlskrona. There, a change was made. They started by removing the antibiotic treatment that Harry had and started pressure treatment. He also received a so-called pinch graft, a form of skin transplant done in small islands over the wound. Three years later, the wound had finally healed. *"It affected my everyday life because it was like living with a plastered leg. It was difficult to take a shower and swim, something I really appreciate, was out of the question."*

Harry has had hard-to-heal wounds even after the first, longer episode. Today, Harry has had a stent on his left leg where his previous wounds occurred. A stent is a short, tubular metal structure that can be expanded. The stent is inserted into a blood vessel using a balloon catheter to prevent new blood clots. "*But I still pay close attention to getting small wounds or injuries on the leg where I previously had the hard-to-heal wounds*". Harry knows that a new small wound can mean a new hard-to-heal leg ulcer that requires long-term and extensive treatment.

Today, Harry does voluntarily work as a patient and family contact for RiksSår, the Swedish national quality register for hard-to-heal wounds. He is one of the initiators of the Patient Association and helps patients and relatives on a daily basis with advice and contacts to those who have better knowledge in the area of wound care and also informs them of the rights the patients have. He is not aware of the clinical trial HEAL LL-37 but says *"I really welcome new treatments, especially to reduce the use of antibiotics which may seem to be decreasing but is still too large and therefore constitute a risk for society".*

" It affected my everyday life because it was like living with a plastered leg. It was difficult to take a shower and swim, something I really appreciate, was out of the question."

Pharmaceutical development and the approval process

Development of pharmaceuticals is a long and costly process and extensive clinical studies must be carried out. From discovery until the drug can receive market approval, it usually takes at least 10 to 15 years. In the studies carried out before market approval can be obtained, the safety and efficacy of the drug are checked to provide basic information about how the drug will work in humans. This control is carried out in several different phases that are time and cost-intensive and whose results are difficult to predict.

The different phases can be divided into the initial research phase, the nonclinical phase and the clinical phases I, II and III. After market approval, phase IV can also be implemented. Each phase focuses on studying different aspects of the product. To be able to carry out clinical studies, the company also needs to develop a manufacturing process that meets the quality requirements of relevant authorities.

Research phase and nonclinical phase

During the initial research phase, work is being done to develop and test new substances. During the nonclinical phase, tests are performed in both test tubes, live tissues and animals. Specific animal tests are required. During the nonclinical phase, the purpose is to determine whether the drug is well tolerated in animal models and that the drug product demonstrates sufficient safety margin in relation to the doses that may be relevant in human studies. Should a substance display inappropriate properties, seen as adverse reactions, toxicity and other undesirable effects, the studies will end. It is estimated that for every 25 000 substances tested at the laboratory level only 25 substances are tested in humans.

Clinical stage

Permissions from relevant regulatory authorities are required to conduct clinical trials. For the US market, an authorized IND (Investigational New Drug) application is required from the US Food and Drug Administration (FDA). Within the EU, the equivalent is an approved clinical trial application (CTA) from the European Medicines Agency (EMA) or relevant supervisory authority in the country or countries within the European Union in which the study is intended to be conducted. The application should include a description of the results of the preclinical phase studies and a clear plan for the implementation of clinical trials. In addition to these conditions, approval of study protocols by competent ethics committees in which studies are conducted is also required.

Phase I

In a Phase I study, the drug is first tested in humans. This is usually done on a small group of healthy people (5-9 people), normal-weighted volunteers who are always men. This because women's reproductive capacity is more sensitive if it appears that the substance is toxic. A Phase I study mainly examines the safety of the drug but also how the drug is absorbed, distributed, decomposed and excreted in the body as well as its effects. In a Phase I trial, only a small fraction of the amount that is given to experimental animals is administered in man, because the effect on people is completely unknown at this stage.

Phase II

In the Phase II study, the drug is given to a larger group of patients suffering from the current disease (20 - 300) to study whether the drug has the desired effect (PoC), but safety remains an important parameter. During phase II, dose studies are usually also conducted to determine a therapeutic dose range, that is, those doses that provide good therapeutic effect, without unacceptable side effects. The optimal dose is then typically used in subsequent phase III.

Phase III

Phase III studies are typically performed on a very large patient group (300 - 30 000) to finally define how useful the drug is to treat the current disease. This patient group should, as far as possible, mimic the population for which the finished drug should be used as weight, age, gender, etc. The

drug compares the study with the current standard treatment or with placebo (sugar pills) if there is no standard treatment for the current disease.

Phase IV

After the drug has received market authorization, been approved and become commercially available, the development continues; often by gathering additional information from large patient groups to detect unusual side effects or additional treatment effects.

The approval process

Once the clinical trials have been completed and it can be found that the drug provides satisfactory results, the company submits a dossier that forms the basis for a review by the relevant drug authorities around the world. The relevant authorities evaluate the information from the preclinical and clinical studies, including a risk / benefit assessment, where the benefit of the drug is balanced against the risk of possible side effects. Companies often apply for the subsidy to be granted. In Sweden, this is done at the Dental and Pharmaceutical Benefits Agency.

Drugs in the EU can be approved through a variety of procedures. Through a central procedure, a drug can be approved for sale in all EU countries at the same time. The application is made to the EEA and a final decision on the matter is taken by the European Commission. There is also a decentralized procedure, where the re¬view and decision is made through a main investigator from one EU member state. Thereafter, the competent authority of each country issues approval for its country. These procedures have a timeframe that must not exceed 210 days. Additionally, there is also an opportunity for the drug to be approved in an EU country through a national procedure.

The rules for market approval in the United States are similar to the European rules at all levels. In the United States, drugs are approved by the FDA through a New Drug Application (NDA). The FDA review has two different levels, Standard or Priority. Most drugs are undergoing standard review and the goal is to complete this within ten months. An approval for a new drug in the United States requires evidence from two different Phase III studies.

A clinical Phase II or III trial

Informed consent

A clinical study can generally only be performed if the study participants have given their written consent to participate after being informed about the purpose and what participation means. The consent should be voluntary, distinct and precise.

Run-in period

A run-in period is a period after screening but before randomization that is used to identify patients suitable for the study. During a run-in period, all patients receive the same treatment, for example, active treatment, placebo or no treatment at all. A run-in period enables selection of patients for randomization, for example, patients who are not compliant with the prescribed treatment are excluded in accordance with predefined criteria in the clinical study protocol. There are studies showing that about 5% of all clinical trials use some kind of run-in period.

Randomization

The patient is randomly allocated to a treatment group. Randomization is a prerequisite to correctly assess the probability that the study's results arose from the effect of chance based on the statistical methods that are being used.

Treatment period

The patient is treated for a period long enough for the efficacy to be demonstrated. Data from the study is collected in a format that can later be analyzed, reported and published in a safe way. A data collection form is created based on an approved research plan / research protocol and should be completed well in advance of the start of study.

Follow-up

Follow-up of the patient normally takes place for a time after treatment is completed. This can be done, for example through patient visits or telephone calls. For some types of studies, there are regulatory requirements on how long follow-up must be and what needs to be investigated. In some types of studies, interim analyses are performed. These are analyses that are done during the course of the study and aim to make a recommendation on whether the study is to be continued or stopped prematurely and is therefore usually done when the study is investigating a potentially toxic substance. Since an interim analysis affects the sample size in the study, it is important that it is carefully planned already in the clinical study protocol. These analyses are usually carried out by the study's data safety and monitoring board (DSMB) which is an independent review group.

Clean file

When data collection in a clinical study is completed, data should be reviewed and it should be ascertained that all information entered into the database and data collection forms (CRF) is complete and accurate. In case of uncertainties, questions are asked to the examiner. The database is explained clean ("Clean file") when all data is checked, supplemented and corrected.

Database lock

When the database has been checked, supplemented and corrected it is locked and thereafter no changes can be made to the data collected in the study. The statistical analysis can be initiated.

Statstical analysis

When the database is locked, the study can be unblinded and information on which patient has received what treatment can be obtained and processing and analysis of data can be done. Even before the study was started a plan for how data management and analysis should be carried out was created. The plan is reviewed and the time plan for delivery of data from the study is defined.

Clinical study results

When the results of a study have been evaluated, they can be announced. Initially, there may be a few variables, such as the result of the primary end-point. All the data analyzed will be documented in a clinical study report. The report should be sent to drug authorities in the countries where the study was conducted within twelve months from the completion of the study.

HEAL LL-37

In HEAL LL-37, a three-week placebo treatment is applied in combination with compression bandaging. This is done to identify patients who are under-treated and thus do not have a chronic ulcer. Patients who are under-treated and do not have a true chronic ulcer, often experience a notable healing with only standard or placebo treatment. At the end of the three-week placebo treatment, the size of the wound is checked. With a proven healing with only placebo treatment through a relevant decrease in wound size, the patient is not moved to randomization.

In HEAL LL-37, patients are divided into three different groups, two groups where patients receive ropocamptide (0.5 and 1.6 mg / mL) and one placebo group.

Treatment lasts for thirteen weeks, twice a week in conjunction with regular wound re-dressing. At every second visit, a more comprehensive examination is done and the wound is measured and photographed using a system specially developed for this type of analysis. The study has been conducted at fifteen clinics in Poland and Sweden.

Follow-up in HEAL LL-37 is ongoing for four months. Patients make two visits during the follow-up period, where various examinations and photography of the wound are done.

In HEAL LL-37 a very important part of the process to check, complete and correct data is an independent analysis of all digital photographs included in the study.

Promore Pharma believes that database lock in HEAL LL-37 will be done no later than in the third quarter. The statistical analysis is then to be initiated.

The statistical analysis plan (SAP) has been adopted as of April 30, 2020. Such a plan is a requirement and must be established before database lock and unblinding. In HEAL LL-37 the statistical analysis and preparation of a preliminary final clinical study report will take about 3-4 months. Evaluation of a large number of outcomes (so-called clinical endpoints) will be performed with the purpose of assessing whether the candidate drug is safe and tolerable. Analyses with the purpose of finding out if one of the two dose groups of ropocamptide results in statistically significant improvement in wound healing compared to the placebo group.

In most clinical trials, a large number of different endpoints are investigated. At the end of a clinical trial, some endpoints may be easy to calculate and compile; for example, survival in a cancer study, while others may require extensive computational work. The clinical study protocol in HEAL LL-37 does not allow for any interim results. This means that all essential conclusions will be presented at one occasion, which is expected to take place during the fourth quarter of 2020.

HEAL LL-37 - Fas IIb

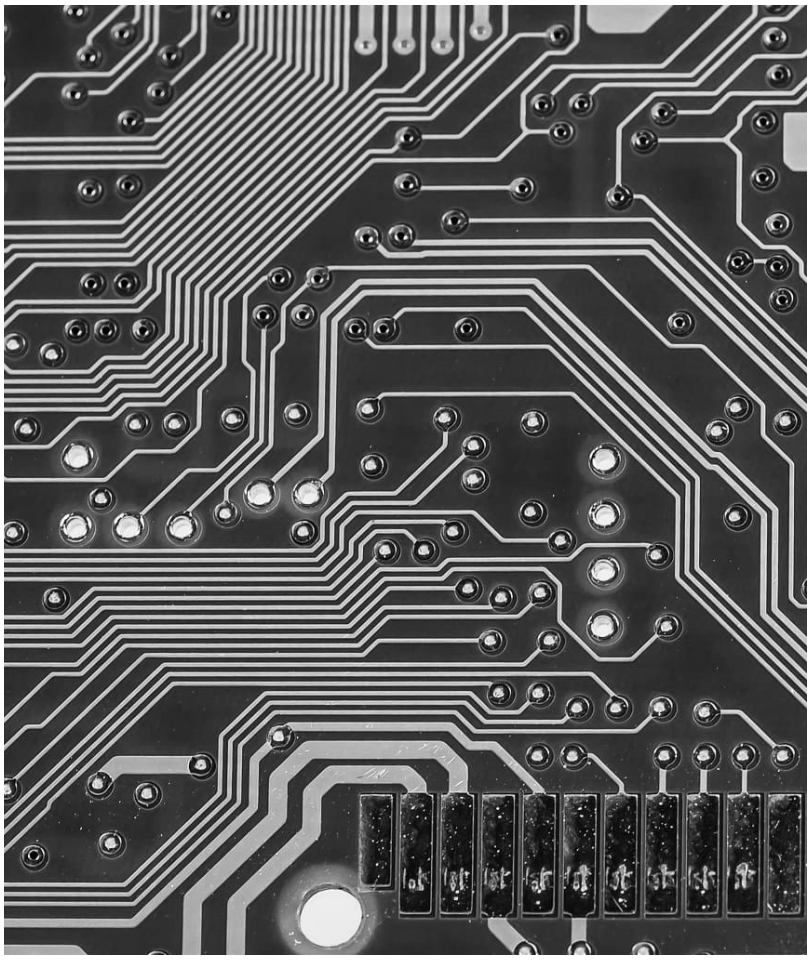
A Study in Patients with **H**ard-to-Heal Venous Leg Ulcers to Measure **E**fficacy **a**nd Safety of **L**ocally Administered **LL-37**

Promore Pharma received approval to start HEAL LL-37 in the summer of 2018. HEAL LL-37 is a randomized and double blind clinical Phase IIb trial on patients with venous leg ulcers. In October the same year, the company could announce that the first patient was recruited and in December 2019, the patients estimated to be required to reach the aim of having 120 patients completing the clincal study protocol. In March 2020 the company could, despite the ongoing challenges for the health care system both in Poland and Sweden following the COVID-19 pandemic, complete the study according to plan and approximately 120 patients have now finished the treatment period. Promore Pharma hopes the study will show that ropocamptide significantly improves the probability for accelerated healing rate of chronic wounds.

Digital Image Processing

In today's digital life, digital images are everywhere around us. An image is a visual representation of an object, a person, or a scene. A digital image is a two-dimensional function f(x, y) that sometimes is a projection of a 3-dimensional scene into a 2-dimensional projection plane.

Actual digital image processing started after the invention of digital computers and related technologies, including image storage, display and transmission. Since the 1960s, all of the components that make up an image processing system have become more powerful and available at a lower price. The use of digital image processing techniques has grown tremendously and the techniques are now used in almost every part of our life. It also means three dimensional assessments have become mainstay with applications in astronomy, medical image processing, mining, product inspection and facial recognition.



Digital Image Processing in Medicine

Applications of digital image processing techniques are now used in numerous medical applications; involving image enhancement, image compression and object recognition. In radiology, digital processing is pivotal: computed tomography scan (CT scan), positron-emission tomography (PET) and nuclear magnetic resonance (NMR) spectroscopy are important medical equipment based on image processing. With these technologies it is becoming increasingly facile to identify tumors or other small tissue abnormalities. Three-di-

mensional analysis has made it feasible to precisely measure and create custom-tailored prostheses and implants, as well as matrices for regenerative medicine.

Digital Image Analysis in Wound Assessment

Wound healing is a complex and dynamic process, which varies with the changing health status of the individual. The knowledge about the healing stages provide a framework for an understanding of the basic principles of wound healing and the phases of healing. This helps the healthcare professionals to understand and to develop a skill which is required to take care of the wound, body and to overcome the task of complex tissue repair. Wound image analysis finds its application in health care to monitor the extent of wound healing and to decide the course of treatment. To demonstrate the effects of a new drug in wound healing techniques, the wound surface area is one of the most important variables. The healing process is a phenomenon which can be visually assessed by an observer but in qualitative terms only. Manual wound measurement is done by tracing the wound boundary and then calculating the area of wound. Thus, it is error prone and a tedious task. Therefore, Promore Pharma is using another concept, SilhouetteLite+, for assessment of the chronic wounds. SilhouetteLite+ has been developed by ARANZ Medical, a New Zealand based company. SilhouetteLite+ is comprised of an application and a range finding sensor for different Apple® products. SilhouetteLite+ enables users to take wound images, obtain non-contact 2D precise and corrected measurements, and record patient notes on a device. With the SilhouetteLite system, a number of artefacts can be eliminated, which usually occur with normal photography such as sensitivity for lighting, contrast and the angle of the camera lens. The data collected at the patient's bedside is synchronized with SilhouetteCentral™ over a secure connection when available.

When an image is captured using SilhouetteLite+, the range measurement from the camera to the scene is also captured and stored. This provides digital reference information that allows for normalization of the information. Using this range and knowledge of the camera properties, a scaled version of the captured scene can be made so that the properties of the wound are converted to computed 2-dimensional estimates. This process is referred to as planimetry.

The type of information that can be derived from such planimetric analysis include:

- Precise estimation of wound area
- Estimation of wound perimeter
- Information on wound texture

Each patient will have multiple images taken over time, so that dynamics of changes in the wound (healing or deterioration) can be assessed in patients receiving active drug or placebo.

In the clinical HEAL LL-37 trial, the following simplified workflow has been deployed:

Step 1
Image capture at pre-defined patient visits

Step 2
The database is consolidated with all relevant patient information during the course of the treatment period

Step 3
An independent assessor reviews all wound images to ensure that artefactual information is removed or annotated

Step 4
The clinical trial data base is locked

Step 5
Data from the database is processed and analysed in accordance with the Statistical Analysis Plan of the study

Ensereptide – a therapeutic peptide capable of preventing adhesions and scars

The underlying cause of scarring is similar in various clinical situations such as scarring of the skin, after trauma or burn wounds, or unfa vorable postoperative adhesions - permanent adhesions between tissue surfaces that should normally be separated. It is a well-known fact that increased inflammation and fibrin formation after surgery are two key mechanisms that strongly contribute to scarring.

Ensereptide is a synthetic peptide based on the human peptide lactoferricin, part of the breast milk protein lactoferrin. Ensereptide has several mechanisms of action. For instance, ensereptide is immunomodulatory; the peptide inhibits release of pro-inflammatory cytokines, such as IL-1β, IL-6 and IL-8, as well as TNF-α . Ensereptide also increases fibrinolytic activity by inhibiting PAI-1 production. Both of these properties are thought to be the key for the peptide to prevent scars and adhesions.

Many patients with widely different complications

Postoperative adhesions are permanent interactions between tissue surfaces that should normally be separated and are one of the most common and costly complications of surgery. The costs are estimated at between USD 1 and 2 billion annually only in the United States. The corresponding figure in Sweden is estimated at between 400 and 600 MSEK. The types of complications that arise as a consequence of post-surgical adhesions are dependent on where in the body they occur. They can cause, for example, pain, infertility, decreased function and mobility, need for secondary surgical treatments, and difficulties in undergoing future surgical procedures. Extrapolations from a comprehensive Scottish study indicate that an estimated 200 people per 100 000 in a normal population are hospitalized every year as a result of complications associated with post-operative adhesions (all types). Based on that study, there are correspondingly two million patients annually in the US, EU and Japan. Naturally, the number of patients who have medical issues but are not requiring hospitalization is many-fold higher.

Large medical need

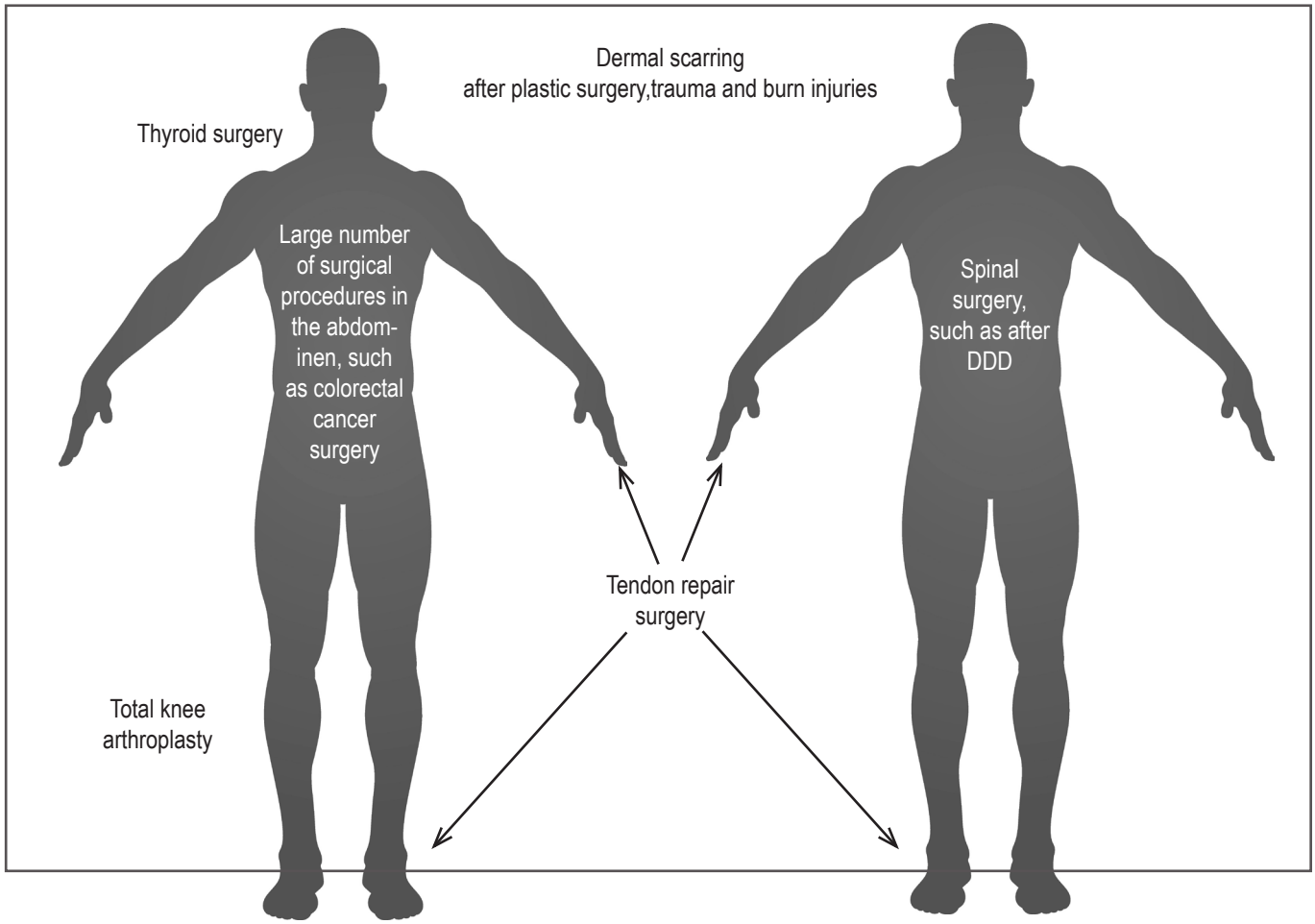
Existing products for the treatment of post-operative adhesions are all registered as medical devices and are based on physical barriers that separate the damaged tissue surfaces. Ensereptide has the potential to be the first drug to prevent adhesions and is expected to show better efficacy and safety profile compared to competing products. There is a growing need and interest for adhesion-preventing drugs. This is driven by an increasing annual number of surgical procedures in the world, and not least, an increased number of so-called lifestyle-induced disorders, such as obesity, and injuries caused by sport- and hobby-related activities. According to Markets & Markets, this segment of the wound care market will grow between 8 and 9 percent annually over the next five years.

First indication - preventing adhesions after tendon repair surgery

Promore Pharma initially focuses on preventing adhesions after flexor tendon repair surgery in the hand. The rationale for selecting this indication involve:

1. Tendon repair in the hand represents an area of high medical need due to high incidence of adhesions;
2. The same surgical method is used in flexor tendon repair worldwide and the methods used for clinical evaluation of hand function are standardized and quantifiable
3. Tendon injuries are common among young patients, which means that the risk of comorbidity is low and the economic need for society is large since they are in working age; and
4. Hand surgery is a distinct specialty among surgeons, which facilitates recruitment in clinical studies, but also the marketing and sale of an approved future product.

Flexor tendon injuries are both occupational injuries and injuries that arise from leisure activities, for example through sports activities. A common reason for laceration of a flexor tendon, are cutting injuries with sharp tools, for instance when an avocado



is de-pitted in the hand. Tendon injuries affect about one per 1,000 per year, which corresponds to, approximately 300,000 injuries annually only in the United States, where lesions in the hand amount to about one third. The estimated incidence of tendon injuries in the hand is assumed to be relatively similar throughout the Western world since occupational safety regulation is similar and recreational activities are largely comparable. It is well documented that significantly more men than women suffer from these type of injuries. A large population-based study suggests that the proportion of men is four to five times higher than the proportion of women.

During tendon repair surgery, the surgeon makes one or more small incisions in the skin over the damaged tendon (unless the skin is already damaged and the tendon is visible), sews the ends of the tendon with special stitches that are extra durable (Kessler sutures) and seals the wound. Ensereptide is administered in conjunction with the surgical procedure when the tendon is repaired and mixed in a hyaluronic acid gel. The gel is applied around the damaged tendon, between the tendon and the tendon sheath, using a catheter before the surgical wound is sealed.

The procedure is followed by intensive physiotherapy for up to twelve weeks to reduce the risk of adhesions and thereby regain mobility. Even a minor reduction in mobility can have a major impact on the patient's quality of life. If the mobility of one finger decreases by ten degrees, the patient loses significant fine motor skills and may experience difficulties with, for example, buttoning buttons, eating with sticks or using a small keyboard. If the patient's mobility is greatly reduced, it can also affect the ability to work. In addition, nerve damage due to trauma can often lead to reduced sensitivity. In some cases, the patient also suffers from pain or stiffness and reduced force in the injured finger. It is estimated that between 20 and 50 per cent of all patients that undergo tendon repair in the hand are affected by permanent impaired mobility.

Tenolysis - an additional surgical procedure with new risks for adhesions

Tenolysis is recommended for patients who have significant problems with mobility and pain after tendon repair surgery. Tenolysis involve removal of adhesions in a secondary surgical procedure. According to the company's Phase II study on ensereptide, approximately 30 percent of patients who did not receive ensereptide were recommended to undergo tenolysis. Tenolysis is a much more complicated surgical procedure than the initial tendon repair and is associated with risks for new adhesions. The cost is estimated at least 14,000 USD compared to the initial late surgery, which costs about 10,000 USD. From an economic perspective, the company's Phase II results also show that the number of patients recommended for tenolysis after flexor tendon surgery in the hand can be reduced by up to 65 percent when treated with ensereptide.

PHSU03 - Phase III in Europe and India with ensereptide

Promore Pharma is working on the preparation of PHSU03, a Phase III clinical trial in patients undergoing flexor tendon repair surgery in the hand. The intention is to show that ensereptide improves hand mobility after tendon repair surgery by preventing adhesions. If the trial generates the anticipated results, this data can form the basis for an application for market approval in Europe.

The company intends to enroll approximately 600 patients with a damage in Zone 1 or Zone 2 in the deep flexor tendon of the hand. The intention is that at least 420 patients or more will complete the study protocol. Patients are divided into three arms, two arms where patients receive PXL01 (5 mg / ml resp 2 mg / ml) in hyaluronic acid and a placebo arm. PXL01 is a one-time treatment and is given in conjunction with the surgical procedure. The study is randomized and double blind. Primary endpoint is mobility in the most distal joint (DIPAM, Active Motion in the Distal Interphalangeal Joint) six months after treatment. In addition, a number of other efficacy variables, quality of life estimates and safety variables are investigated. The frequency of subsequent tenolyses is also investigated. The participating patients will make their last follow-up visit 12 months after surgery.

The study will be conducted at approximately fifteen clinics in Sweden, Poland, Germany, Italy and India. Moreover, an additional number of EU countries are under evaluation. The main contract research organization (CRO) is Kentron Biotechnology Pvt Ltd, supported by local CROs in the individual countries.

Promore Pharma conducted a Phase I clinical trial of ensereptide during 2009. The study included 15 healthy volunteers at one single site in Sweden. The aim was to study safety and local tolerance as well as the pharmacokinetic properties of the drug candidate. The treatment was well tolerated without any clinically significant observations related to ensereptide in regard to vital signs or clinical chemistry. The systemic exposure of ensereptide was very low in all dose groups, indicating that a very small proportion (not measurable) reaches the bloodstream. Ensereptide has also undergone one randomized double-blind Phase IIb trial involving 138 patients with flexor tendon injuries in the hand. In the study, either placebo or a single dose of ensereptide (20 mg/ml) mixed with highly viscous hyaluronic acid was applied in conjunction with the surgical procedure. The differences between ensereptide and placebo were assessed for up to 12 months with regard to efficacy and safety. The study was conducted at 16 clinics in Sweden, Denmark and Germany.

The mobility in the most distal finger joint (total mobility DIPAM; Active Motion in the Distal interphalangeal joint) is considered to be the most reliable marker for mobility after a hand injury because the mobility of this joint is entirely controlled by the deep digital flexor tendon, which was damaged in all patients included in PHSU02. At all times after surgery (four, six, eight, twelve weeks and six and twelve months after surgery), DIPAM improved for patients in the ensereptide group compared with the placebo group. The largest relative difference was observed at six months after surgery (mean and median values versus placebo were 56 degrees compared to 43 degrees and 60 degrees, respectively, compared to 41 degrees with a statistical significance of 0.02). In discussions that the company organized with medical and clinical key opinion leaders, it has been established that a clinically relevant level of increased mobility is ten degrees. Thus, the improvement observed in the completed phase II study with ensereptide was both statistically significant and medically relevant. In addition, a number of other endpoints were investigated, including the percentage of patients recommended for tenolysis. The study showed that ensereptide could reduce the need for tenolysis by 65 percent, which is a very important result from a social and, thus, pricing perspective.

Other indications using ensereptide

Preventing dermal scarring

Scarring commonly occurs after most surgical procedures, including procedures such as plastic surgery and caesarean sections, and this seems to happen regardless of how the surgery is sealed. Severe dermal scarring may also occur in conjunction with the healing of burn injuries. Promore Pharma has shown that ensereptide has relevant pharmacological properties to prevent such scarring.

WHO estimates that the number of surgical procedures performed in the world exceeds 300 million annually, of which approximately 100 million in the western world, where a proportion of patients may benefit from treatment with a product based on ensereptide. Dermal scarring can have both physical and psychological consequences, from reduced mobility and function to emotional trauma. There is a significant demand for effective treatment that prevents scarring and numerous products have been launched on the market, such as oils, creams, gels, dressings and sprays. The market for these products is expected to grow by 10 - 11 percent on average per year over the next few years, reaching over 31 billion in USD 2022. Market growth is driven by increased focus on personal care and an increasing inci¬dence of skin complaints. Consumer surveys show that a very large proportion of patients undergoing plastic surgery would pay to reduce or prevent scarring. The number of plastic surgery procedures is over 10 million a year in the world. It is also likely that a large proportion of the women who undergo caesarean section would request a drug that prevents scars. The number of caesarean sections in the US and the EU amounts to approximately 2.5 million per year.

Despite extensive medical needs and a clear demand, there are currently no drug products available on the market to prevent dermal scarring. There are estimates that an effective treatment to prevent scarring would have a market potential of over USD 4 billion in the US alone.

Promore Pharma announced in September 2018 that the company will explore the feasibility of using ensereptide for prevention of dermal scarring. This will be done through a clinical phase I/II study (PHSU05) which will be performed in Sweden and co-ordinated by Fredrik Huss, Associate Professor in Plastic Surgery at Uppsala University Hospital. The study will run in parallel with PHSU03

Preventing fibrosis after spinal surgery

Degenerative disc disorder (DDD) is one of the most common causes of low back and neck pain and affects approximately 30 million people worldwide every year. DDD is a bulge (hernia) in an intervertebral disc. It occurs in a disc that has undergone some degree of age change, meaning that there is a crack in the disc's soft core. In this crack, parts of the inner core of the disc may come out as a hernia. Usually a herniated disc occurs without any triggering event, but they can also occur as a result of lifting, back bending, back twisting or other accident. Treatments such as physical therapy or anti-inflammatory medications may provide adequate relief of troubling symptoms. However, surgery is often recommended if the conservative treatment options do not provide relief within two to three months. The surgical procedures used are spinal fusion, lumbar laminectomy or microdiscectomy. The number of relevant surgical procedures is between one and two million on the large pharmaceutical markets. The health care cost for a surgical procedure varies depending on how extensive the procedure is, but normally amount to between 5,000 USD and 65,000 USD. The surgical intervention can cause epidural fibrosis (scar) and these are assumed to be a common reason for failure of surgical interventions in DDD. The products available to prevent scarring are mainly medical devices, many based on hyaluronic acid. There are no prescription products available that prevent scarring in connection with spinal surgery.

Promore Pharma announced in May 2018 that the strategic collaboration with PRP was extended with an out licensing agreement for ensereptide used for spinal surgery. PRP will fully fund the development of ensereptide to prevent fibrosis after surgical treatment of DDD. The agreement gives Promore Pharma a share of any future milestone payments to PRP and a double-digit royalty on global sales of the product. As part of the original agreement between the two companies from March 2016, PRP received the rights to develop and commercialize a medical device for spinal surgery and only in certain Asian markets. The new agreement means an expansion of the strategic collaboration to include a license to develop a pharmaceutical product worldwide.

The Share

Promore Pharma's share has traded since 6 July 2017 on Nasdaq First North Growth Market in Stockholm with ticker PROMO and ISIN code SE0009947740,

Number of shares

The number of shares at the end of 2019 was 36,428,362 (20,235,090). The average number of shares in 2019 was 21,392,995 (20,235,090).

Warrants

Promore Pharma issued, in connection with the listing 2017, 6,523,560 warrants. The subscription price was determined according to the terms and conditions of the warrants to 23.30 SEK per share on 31 January 2019. The subscription period ended on 22 February 2019.

There are additional outstanding warrants, which entitle the holders to subscribe for 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 of 5.0%. The exercise price for the warrants is 13.30 SEK, but will be adjusted to the share's quota value (SEK 0.04) if certain milestones are reached in the development program. The warrants can be used until 31 December 2022.

Share price and turnover

Promore Pharma's share price on 30 December 2019 was 3.68 SEK, which means a total market cap of about 134 MSEK. The highest price during 2019 was 14.54 SEK and the lowest 3.20 SEK. In 2019 a total of 2,992,462 shares were traded on Nasdaq First North Growth Market at a total value of approximately 28 MSEK.

Shareholders

At the end of 2019 Promore Pharma had close to 800 shareholders. The three largest shareholders Midroc New Technology AB, PharmaResearch Products Ltd. and Rosetta Capital IV Sarl owned 17, 877,526 shares at the end of 2019, corresponding to 75 per cent of the shares in the company.

Certified Adviser

Companies listed on Nasdaq First North Growth Market are required to have an agreement with a certified adviser. Promore Pharma's certified adviser is Redeye.

Shareholder	No of shares	%
Midroc New Technology	13,626,438	37.4
PharmaResearch Products	7,468,132	20.5
Rosetta Capital IV Sarl	6,291,592	17.3
Avanza Pension	860,707	2.4
Arne Andersson	748,161	2.1
Nordnet Pensionsförsäkring	710,225	1.9
Mikael Lönn	348,750	1.2
Råsunda Förvaltning	427,964	1.2
Jens Miöen	348,570	1.0
Philip Diklev	316,098	0.9
Chalmers Tekniska Högskola	256,710	0.7
Others	4,917,375	13.5
Total	**36,428,362**	**100.0**


PROMORE PHARMA
leading-edge medical innovation

Administration Report

The Board of Directors and the President hereby presents this annual report for the financial year 2019-01-01--2019-12-31.

General information about the business

Promore Pharma is a biopharmaceutical company specialized in the development of therapeutic peptides for the bio-active wound care market. The company's aim is to develop two first-in-category products for indications where very few or no efficacious prescription pharmaceuticals are available, thus addressing high unmet medical needs. Promore Pharma's two projects, PXL01 and LL-37, are in late stage clinical phase.

PXL01 is being developed to prevent post-surgical adhesions and scarring and is being prepared for clinical Phase III studies on patients undergoing tendon repair surgery in the hand. Postsurgical adhesions constitute a substantial medical problem after most surgical procedures, and particularly in conjunction with hand surgery. Flexor tendon injuries and repairing of these injuries result in adhesion formation around the tendon, which restricts the gliding function of the tendon, leading to decreased digit mobility and impaired recovery of normal hand function. Small decreases in mobility greatly impact the quality of life due to difficulties in performing easy tasks, such as closing buttons or using a keyboard. Tendon injuries affect more than 1,000,000 persons per year on the traditional pharmaceutical markets, of which around 30% are in the hand. Permanent limitations in mobility are especially noticeable after tendon injuries in the hand where it is estimated that up to 50% never recover full flexibility and strength in the hand.

The company's other candidate drug, LL-37 is being developed to stimulate healing of chronic wounds. The company is currently performing a clinical Phase IIb study (HEAL LL-37) on patients with hard-to-heal venous leg ulcers (VLUs), where recruitment began in 2018 and last patient in was achieved in December 2019. VLU constitutes the largest category of all chronic, or hard-to-heal, ulcers. On the traditional pharmaceutical markets, there are an estimated 13-18 million patients with VLUs and these wounds constitute the largest category of all chronic, or hard-to-heal, ulcers. VLUs represent significant challenges to patients and healthcare systems since they are frequent, costly to manage, recurring, and may persist for months or years. Standard treatment consists of compression bandaging and there are no approved prescription pharmaceuticals for VLUs on the traditional pharmaceutical markets. The cost for treating one VLU episode exceeds 10,000 USD. The company, therefore, considers that there is a great need for the candidate drug, both from the perspective of both the patients and the healthcare system.

Promore Pharma's main focus in 2019 was the conduct of the clinical trial HEAL LL-37. The aim with HEAL LL-37 was that 120 patients with VLUs in Sweden and Poland should complete the study protocol. In March 2020, the company could announce that, despite current challenges within the health care systems in both Poland and Sweden following the COVID-19 pandemic, the study had been carried out according to plan and that approximately 120 patients had completed the treatment phase. Promore Pharma envisions that the study will show that treatment with LL-37 significantly increases the probability of an accelerated wound healing of chronic wounds. In 2019, the company also worked with preparations for the clinical Phase III study with PXL01 that will be conducted in the 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. In the last quarter, a rights issue was completed, which provided gross proceeds of approximately 60.1 MSEK. The proceeds will be used to finalize the ongoing clinical phase IIb trial with LL-37 (HEAL LL-37) and to complete the preparations for the planned phase III trial with PXL01 (PHSU03). Additional

capital will be required to start recruitment of patients in PHSU03 and to complete the trial.

The company sees good opportunities to also develop the candidate drugs for other adjacent indications, such as prevention of dermal scars or treatment of diabetic foot ulcers.

The company does not have any revenues from product sales and until the company's products start generating revenues or can be out-licensed, the company is dependent on external financing to secure continued operations.

The company's registered office is in Solna.

Significant events during the financial year

Phase III trial with PXL01 modified and the number of clinics in the study expanded
The company announced in February 2019 that they are 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 one of the manufacturing permits required according to agreed timelines, 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 in 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. Kerstin has also Board assignments in several other companies, such as Camurus AB (publ), Klifo A/S, Gedea AB and her own consultancy company Cavastor AB.

Half of the patients recruited in HEAL LL-37
The company announced in June 2019 that half of the patients have been enrolled and started the treatment in the company's Phase II-study (HEAL LL-37) with the company's product candidate LL-37 for treatment of venous leg ulcers.

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.

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 was 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 was to ensure the continued successful development of the company's two drug candidates in accordance with the company's business plan and strategy.

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 hyaluronic acid. The patent is valid until, at least, January 2030

Rights issue completed
The company announced in December 2019 that the rights issue was completed. The issue was subscribed to 80 percent, providing gross proceeds of approximately 60.1 MSEK. A total of approximately 43.1 MSEK, corresponding to 57.4 percent of the rights issue, was subscribed for with subscription rights. A total of approximately 8.2 MSEK, corresponding to 10.9 percent of the rights issue, was subscribed for without subscription rights and the remaining part of the gross proceeds, corresponding to approximately 8.8 MSEK, or 11.7 percent of the total rights issue, was subscribed for by guarantors. The proceeds will be used to finalize the ongoing clinical Phase IIb trial with LL-37 (HEAL LL-37) and to complete the preparations for the planned Phase III trial with PXL01 (PHSU03). Additional capital will be required to start recruitment of patients in PHSU03 and to complete the trial.

HEAL LL-37 recruitment completed early
The company announced in December 2019 that all patients for the company's Phase IIb study with LL-37 for treatment of VLUs have been recruited. The aim with the phase IIb study with LL-37 was that 120 patients with VLUs in Sweden and Poland should complete the study protocol. All patients that were assessed to be required had been recruited at 15 clinics in Poland and Sweden.

Significant events after the reporting period

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) with LL-37, a new candidate drug for treatment of VLUs. The aim with 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 sys-

tems 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. Promore Pharma envisions that the study will show that treatment with LL-37 significantly increases the probability of an accelerated wound healing of chronic wounds. 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 six month long notice period.

Shares and ownership

Promore Pharma's share has been 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 December 2018 was 20,235,090 (20,235,090). The average number of shares in 2018 was 20,235,090 (16,612,447). 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, 6,523,560 warrants. The subscription price was determined according to the terms and conditions of the warrants to 23.30 SEK per share on 31 January 2019. The subscription period ended on 22 February 2019. There are additional outstanding warrants, which entitle the holders to subscribe for 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 of 5.0%.

Group structure

Promore Pharma owns 100% of the shares in the subsidiary Pergamum AB.

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 Oy 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 45,818 per 31 December 2019. The board of directors of the company has decided that this holding shall be divested in a stepwise fashion.

Board and organization

The company's Board consists of five regular members, including the Chairman of the Board, who are elected for the period up to the end of the 2018 Annual General Meeting. The Board members are Göran Pettersson (Chairman of the Board), Marianne Dicander Alexandersson, Torsten Goesch, Satyendra Kumar, Göran Linder and Kerstin Valinder Strinnholm.

Promore Pharma has a small and cost-effective organization that is primarily 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. As of 31 December 2019, the company had one employee.

Effects of the COVID-19 pandemic

The company has not yet been affected by any direct effects of the ongoing COVID-19 pandemic. The company could, for instance, announce that 120 patients completed the treatment period in HEAL LL-37 in March 2020, which was fully according to plan, despite the challenges the health care system has had following the Coronavirus outbreak. However, a number of secondary effects, such as delayed interactions with authorities, limitations in contacts with clinics in HEAL LL-37, capacity limitations or difficulties in getting access to suppliers and uncertainties on the financial markets, will potentially arise.

Risks

Promore Pharma's main operations are drug development, which is to a large extent both highly risky and capital-intensive. The development of drugs is subject to extensive and strict regulations under the supervision of regulatory authorities in each relevant market. Promore Pharma is dependent on the company's drug candidates gaining success during the clinical trials. The drug candidates are in late development, but they are still subject to extensive regulation and control before market authorization can be obtained. The development required may also be subject to delays and additional costs. For the development, manufacturing, marketing and sales of drug candidates, authorization and different types of permits are required from relevant regulatory authorities. These processes can be time-consuming and even after authorization, the company is obliged to comply with certain regulatory requirements with a risk of revocation. If market authorization is obtained, there is still a risk that the company will not achieve the desired level of price and market acceptance from healthcare providers, patients and payers. The pharmaceutical industry is also a competitive market characterized by global competition, rapid technological development and comprehensive investment requirements. The market has growth opportunities and many smaller and growing players enter the market. There is a risk that other companies will develop products that prove to be superior to the company's drug candidates, or not as good, but still achieving better market acceptance. The company may also be subject to product liability requirements both during the development process and if the drug candidate is launched on the market. Patent and intellectual property rights are a key asset in the company's business and thus any future success depends largely on the ability to maintain existing patent protection and to develop the patent portfolio for future commercialization. As with medical and commercially successful drugs, there is a risk that competitors try to circumvent the company's patents or that an attempt is made to invalidate the company's patent.

Promore Pharma's organization consists of a few employees, most of whom perform their work within the framework of consultancy assignments. The significant experience of these employees is crucial to Promore Pharma's success and losses in this regard could lead to delays or disruptions in the company's operations. The company also operates through a number of partners and advisors that are necessary for the development of drug candidates. Like the company's employees, Promore Pharma's success depends on maintaining these relationships.

Outlook

Promore Pharma initiated a Phase IIb clinical trial for LL-37 (HEAL) in 2018 where data is expected to be presented in the fourth quarter of 2020. The company is also preparing a Phase III clinical trial for PXL01. Promore Pharma's projects are in late stage clinical phase, and Promore Pharma estimates that the projects have solid market opportunities if the results from clinical studies are good. The company has no revenue from drug candidates yet and is thus dependent on external funding to ensure continued operation. The rights issue carried out in 2019 did not generate enough proceeds to start recruitment of patients in PHSU03 and cannot be started before additional capital has been secured.

Proposed distribution of unappropriated income

The Board of Directors proposes that the profit available for distribution:

retained profit	85,816,384
loss for the year	-27,440,036
	58,376,348
be distributed as follows	
to be carried forward	58,376,348

Multi-year summary

Group	2019	2018	2017	2015/16 (18 mon)	
Net sales	3,928	2,447	632	87	
Profit after financial items	-28,865	-32,483	-8,432	-11,370	
Total assets	68,734	37,600	71,348	13,132	
Return on equity (%)	neg	neg	neg	neg	
Operating margin (%)	neg	neg	neg	neg	
Equity/assets ratio (%)	75.9	88.4	92.1	26.0	

Parent Company	2019	2018	2017	2015/16 (18 mon)	2014/15
Net sales	3,928	2 417	612	0	0
Profit after financial items	-27,440	-31,428	-22,010	-6,878	631
Total assets	75,887	43,351	75,974	16,764	2,037
Return on equity (%)	neg	neg	neg	neg	146,6
Operating margi (%)	neg	neg	neg	neg	neg
Equity/assets ratio (%)	79.3	91.9	93.8	47.9	21.1

For definitions of key ratios, please see Accounting and valuation policies

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Group Income Statement

	Not	2019-01-01 - 2019-12-31	2018-01-01 - 2018-12-31
Net sales		3,927,800	2,446,784
Other operating income		-7,249	683,892
		3,920,552	3,130,676
Operating expenses			
Commodities and supplies		-20,298,050	-24,452,266
Other external expenses		-7,204,699	-5,779,863
Personnel expenses	2	-4,200,280	-4,251,268
Depreciation/amortisation and impairments, non-current assets		-1,217,142	-1,217,142
Other operating expenses		-69,734	-106,367
Total operating expenses		**-32,989,905**	**-35,806,906**
Operating profit		**-29,069,354**	**-32,676,230**
Result from financial investments			
Result from other securities and receivables held as non-current assets		299,773	246,102
Other interest income and similar income items		-88,437	-36,162
Interest expenses and similar expense items		-7,388	-16,793
Financial net		**203,948**	**193,147**
Profit after financial items		**-28,865,406**	**-32,483,083**
Profit before tax		**-28,865,406**	**-32,483,083**
Profit for the year		**-28,865,406**	**-32,483,083**
Of which, attributable to Shareholders in Parent Company		-28,865,406	-32,483,083

Group Balance Sheet

	Not	2019-12 -31	2018-12 -31
ASSETS			
Non-current assets			
Intangible non-current assets			
Goodwill		608 572	1 825 714
Financial non-current assets			
Other securities held as non-current assets	3, 4	2 809 597	2 809 597
Total non-current assets		**3 418 169**	**4 635 311**
Current assets			
Current receivables			
Accounts receivable		2,857,273	697,646
Other receivables		1,659,555	995,669
Prepaid expenses and accrued income		256,425	388,848
		4,773,253	**2,082,163**
Cash and bank balances		60,543,047	30,882,428
Total current assets		**65,316,300**	**32,964,591**
TOTAL ASSETS		**68,734,469**	**37,599,902**
LIABILITIES AND EQUITY			
Equity			
Equity attributable shareholders in parent company			
Share capital		1,457,135	809,404
Other equity, including profit for the year		50,736,737	32,437,707
Equity attributable shareholders in parent company		52,193,872	33,247,111
Total Equity		**52,193,872**	**33,247,111**
Liabilities	5		
Liabilites to credit institutions		714,038	714,038
Other liabilities		370,486	280,860
Total non-current liabilities		**1,084,524**	**994,898**
Current liabilities			
Accounts payable		12,224,595	1,310,633
Income tax liability		145,560	149,139
Other liabilities		137,706	186,203
Accrued expenses and deferred income		2,948,212	1,711,918
Total current liabilities		**15,456,073**	**3,357,893**
TOTAL LIABILITIES AND EQUITY		**68,734,469**	**37,599,902**

Statement of changes in equity

Group	Share capital	Other equity including profit for the year	Total
Amount at beginning of year	809,404	32,437,707	33,247,111
New issue	647,730	47,164,437	47,812,167
Profit for the year		-28,865,406	-28,865,406
Amount at the end of the year	**1,457,134**	**50,736,738**	**52,193,872**

Group cash flow statement

	Not	2019-01-01 -2019-12-31	2018-01-01 -2018-12-31
Operating activities			
Profit after financial items		-28,865,406	-32,483,083
Adjustment for items not included in cash flow		1,006,995	960,012
Cash flow from operating activities before changes in working capital		**-27,858,411**	**-31,523,071**
Cash flow from changes in operating capital			
Change in accounts receivable		-2,159,627	201,941
Change in operating receivables		-531,463	13,069
Change in accounts payable		10,913,962	-2,098,409
Change in operating liabilities		1,184,218	883,781
Cash flow from operating activities		**-18,451,321**	**-32,522,689**
Investing activities			
Acquisition of other financial noncurrent assets		299,773	471,896
Cash flow from investing activities		**299,773**	**471,896**
Financing activities			
New share issue		47,812,167	0
Amortisation of debt		0	-38,981
Cash flow from financing activities		**47,812,167**	**-38,981**
Cash flow for the year		**29,660,619**	**-32,089,774**
Cash and cash equivalents at start of year			
Cash flow for the year		30,882,429	62,972,202
Cash and cash equivalents at year end		**60,543,047**	**30,882,429**

Parent company income statement

	Not	2019-01-01 - 2019-12-31	2018-01-01 - 2018-12-31
Net sales		3,927 804	2,416,784
Other operating income		-8,432	8 ,538
Total income		**3,919,372**	**2 425,322**
Operating expenses			
Commodities and supplies		-19,835,130	-23,808,764
Other external expenses		-7,165,281	-5,654,690
Personnel expenses	2	-4,200,280	-4,251,323
Other operating expenses		-69,215	-101,698
Total operating expenses		**-31,269,906**	**-33,816,475**
Operating profit		**-27,350,534**	**-31,391,153**
Result from financial investments			
Result from other securities and receivables held as non-current assets		-88,437	-36,162
Other interest income and similar income items		-1,065	-277
Interest expenses and similar expense items		**-89,502**	**-36,439**
Financial net		**-27,440,036**	**-31,427,592**
Profit after financial items		**-27,440,036**	**-31,427,592**
Profit for the year		**-27,440,036**	**-31,427,592**

Parent company balance sheet

	Not	2019-12-31	2018-12-31
ASSETS			
Non-current assets			
Financial non-current assets			
Participations in Group companies	6, 7	10,398,333	10,398,333
Current assets			
Accounts receivable		2,857, 273	697,646
Receivables from Group companies		4,945,455	5,004,244
Taxes recoverable		143,209	143,209
Other receivables		1,507,051	776,751
Prepaid expenses and accrued income		256,425	305,609
		9,709,413	**6,927,459**
Cash and bank balances		55,779,664	26,024,798
Total current assets		**65,489,077**	**32,952,257**
TOTAL ASSETS		**75,887,410**	**43,350,590**
LIABILITIES AND EQUITY			
Equity			
Restricted equity			
Share capital		1,457,134	809,404
Statutory reserve		380,349	380,349
		1,837,483	**1,189,753**
Unrestricted equity			
Share premium reserve		176,693,219	129,528,782
Profit or loss carried forward		-90,876,835	-59,449,244
Profit for the year		-27,440,036	-31,427,592
		58,376,348	**38,651,946**
Total equity		**60,213,831**	**39,841,699**
Non-current liabilities	5		
Bond loans		370,486	280,861
Current liabilities			
Accounts payable		12,048,448	1,166,462
Income tax liabilities		145,560	0
Other liabilities		171,780	220,277
Accrued expenses and deferred income		2,937,305	1,841,291
		15,303,093	**3,228,030**
TOTAL LIABILITIES AND EQUITY		**75,887,410**	**43,350,590**

Statement of changes in equity

Parent company	Share capital	Statutory reserve	Unrestricted equity	Profit for the year	Total
Amount at beginning of year	809,404	380,349	70,079,539	-31,427,592	**39,841,700**
New share issue	647,730			47,164,437	**47,812,167**
Disposition according to decision by AGM			-31,427,592	31,427,592	**0**
Profit for the year				-27,440,036	**-27,440,036**
Amount at year-end	**1,457,134**	**380,349**	**38,651,947**	**19,724,401**	**60,213,831**

Parent company cash flow statement

	Not	2019-01-01 -2019-12-31	2018-01-01 -2018-12-31
Operating activities			
Profit after financial items		-27,440,036	-31,427,591
Adjustment for items not included in cash flow		89,626	-11,027
Cash flow from operating activities before changes in working capital		**-27,350,410**	**-31,438,618**
Cash flow from changes in operating capital			
Change in accounts receivable		-2,159,627	201,941
Change in operating receivables		-622,327	40,704
Change in accounts payable		10,881,986	-2,086,490
Change in operating liabilities		1,193,077	940,222
Cash flow from operating activities		**-18,057,301**	**-32,342,241**
Investing activities			
Acquisition of other financial non-current assets		0	0
Cash flow from investing activities		**0**	**0**
Financing activities			
New share issue		47,812,167	0
Amortisation of debt		0	-38,981
Cash flow from financing activities		**47,812,167**	**-38,981**
Cash flow for the year		**29,754,866**	**-32,381,222**
Cash and cash equivalents at start of year		26,024,798	58,406,020
Cash and cash equivalents at year end		**55,779,664**	**26,024,798**

Notes to the financial statements

Note 1 Accounting and valuation policies

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").

The amounts stated in the Annual Report are in Swedish kronor (SEK).

Unless otherwise stated below, assets and liabilities are measured at historical cost. Receivables and liabilities in foreign currencies are measured at the closing rate. Exchange gains and losses on operating receivables and operating liabilities are recognised in the operating profit.

Financial instruments are measured at historical cost, adjusted for any impairments. Any need for impairments is based on the difference between the carrying amount on the one hand and fair value less cost of selling on theother. Holdings that are traded on an active market are treated as a securities portfolio.

Pension plans are recognised in accordance with the simplification rule, under which the cost is recognised as the premiums are paid.

Revenue recognition
Revenue is recognised at the fair value of what has been received or will accrue to the company and Note until the income can be calculated reliably.

Consolidated accounts

Consolidation method
The consolidated accounts have been prepared in accordance with the acquisition method. This means that the indentifiable assets and liabilities of acquired activities are reported at market value according to established acquisition analysis. If the acquistion value of the business exceeds the estimated mig to the acquistion analyses, the difference is reported as goodwill.

Transactions between Group companies
Intra-group receivables and liabilities and transactions between group companies as well as unrealized gains are eliminated in their entirety. Unrealized losses are also eliminated unless the transaction corresponds to a write-down requirement.

Changes in internal earnings during the fiscal year have been eliminated in the consolidated income statement.

Intangible non-current assets and property, plant and equipment
Intangible non-current assets and property, plant and equipment are recognised at historical cost less accumulated amortisation and depreciation, after adjustment for any revaluations or impairments.

Amortisation/depreciation is applied as of when the asset is placed in service. Property, plant and equipment that is of minor value within the meaning of the Swedish Income Tax Act (1999:1229) are recognised as an expense on the first accounting occasion. The historical cost of property, plant and equipment is allocated to components if the asset consists of major components with considerable differences in their useful life.

Depreciation and amortisation is based on the estimated useful life, as follows:

Goodwill 20%

Key ratio definitions

Net sales
Operating revenue, invoiced costs, page revenue and revenue corrections.

Profit after financial items
Profit after financial income and expenses, but before taxes.

Total assets
The company's total assets.

Return on equity (%)
Profit after financial items as a percentage of adjusted equity (equity are untaxed reserves less deferred tax).

Operating margin (%)
Operating profit as a percentage of sales.

Equity/assets ratio (%)
Adjusted shareholders' equity (equity and untaxed reserves less deferred tax) as a percentage of total assets.

Note 2 Average number of employees

Group

	2019	2018
Average number of employees	1	1

Parent company

	2019	2018
Average number of employees	1	1

Note 3 Other securities held as non-current assets

Group

	2019-12-31	2018-12-31
Opening balance, accumulated historical cost	36,726,452	37,175,387
Sales	-249,359	-448,935
Closing balance, accumulated historical cost	**36,477,093**	**36,726,452**
Opening balance, accumulated impairments	-33,916,855	-34,139,995
Sales	249,359	448,936
Impairments for the year	0	-225,796
Closing balance, accumulated impairments	**-33,667,496**	**-33,916,855**
Closing balance, book value	**2,809,597**	**2,809,597**

Note 4 Other securities held as non-current assets

Group

	Book value	Market value
Other securities held as non-current assets	2,809,597	3,704,862
	2,809,597	**3,704,862**

Note 5 Non-current liabilities

Group

	2019-12-31	2018-12-31
Falling due more than five years after the balance sheet date		
Other liabilities	370,486	280,860
Liabilities to credit institutions	714,038	714,038
	1,084,524	**944,898**

Parent company

	2019-12-31	2018-12-31
Portion falling due more than five years after the balance sheet date		
Other liabilities	370,486	280,860
	370,486	**280,860**

Note 6 Participations in Group companies

Parent company

	2019-12-31	2018-12-31
Opening balance, accumulated historical cost	10,402,588	10,402,588
Closing balance, accumulated historical cost	**10,402,588**	**10,402,588**
Opening balance, accumulated impairments	-4,255	-4,255
Closing balance, accumulated impairments	**-4,255**	**-4,255**
Closing balance, book value	**10,398,333**	**10,398 333**

Note 7 Participations in Group companies

Parent company

Name	Share of equity	
Pergamum AB	100%	
	Organisational number	**Reg office**
	556759-9203	Solna

Solna 30 April 2020

Göran Pettersson
Chairman

Marianne Dicander Alexandersson

Torsten Goesch

Satyendra Kumar

Göran Linder

Kerstin Valinder Strinnholm

Jonas Ekblom
president and CEO

Our Auditor's Report was submitted on 4 May 2020

Ola Spinnars
Authorised Public Accountant

Auditor's Report

To the general meeting of the shareholders of Promore Pharma AB (publ.)
Corporate identity number 556639-6809

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of Promore Pharma AB (publ.) for the year 2019-01-01—2019-12-31.

In our opinion, the annual accounts and consolidated accounts,have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and group as of 31 december 2019 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Basis for Opinions
We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director
The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or mistake.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility
Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or misstake, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or mistake and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or mistake, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from mistake, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriations of accounting policies used and the reasonableness of accounting estimates related disclosures made by The Board of Di-

rectors and the Managing Director.

- Conclude on the appropriateness of The Board of Directors and the Managing Director use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts, or if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of The Board of Directors and the Managing Directors of Promore Pharma AB (publ.) for the year 2019-01-01—2019-12-31 and the proposed appropriations of the company's profit or loss. We recommend to the general meeting of shareholders that the loss be dealt with in accordance with the proposal in the statutory administration report and that the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss are based primarily on the audit of the accounts. Additional audit procedures performed are based on my professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Stockholm 4 May 2020

Finnhammars Revisionsbyrå AB
Ola Spinnars
Authorized Public Accountant

Annual General Meeting 2020

The Annual General Meeting of Promore Pharma AB (publ) will be held on Tuesday, 26 May 2020 at 2 pm, in the premises of Advokaterna Liman & Partners, Grev Turegatan 38, Stockholm. Registration begins at 1:30 pm.

Information about precautions due to the new corona virus
Due to the regulations to reduce the risk for further spread of the infection of the new corona virus, the company would like to wish to remind you of the option not to attend the meeting in person, but instead participate through a proxy. The CEO's address will be recorded and published on the company website. The company will follow the development carefully and may take further precautionary measures if considered necessary.

Notice
Notification of attendance should be made to the company not later than 19 May 2020 and may be given in writing to the company by e-mail to info@promorepharma.com or by mail to Promore Pharma AB, Fogdevreten 2, SE-171 65 Solna, Sweden or by telephone on +46-(0)8-124 548 59. When giving notification, please state your name or company name, personal ID or company registration number, address and daytime telephone number as well as the number of advisors.

Nominee registered shares
To be entitled to attend the meeting, holders of nominee registered shares must instruct the nominee to have the shares registered in the holder's own name, so that the holder is entered in the share register kept by Euroclear Sweden AB as of 19 May 2020. Registration in this way may be temporary.

Shareholders wishing to register their shares in their own name should inform the bank or nominee well before this date.

Proxy and proxy form
Anyone who does not attend the meeting in person may exercise its right at the meeting via a proxy in possession of a signed and dated form of proxy. The form of proxy may be obtained from the company and it is also available on the company's website: www.promorepharma.com at least three weeks immediately before the meeting. Representatives of a legal person must attach a copy of the registration certificate or equivalent documentary authority. To facilitate entry to the meeting, forms of proxy, registration certificates and other documentary authority must be received by the company at the above-stated address, in good time before the meeting

Shareholder information
Interim reports, annual reports and press announcements from Promore Pharma are available on the company's website promorepharma.com and can be ordered from Promore Pharma AB, Fogdevreten 2, SE-171 65 Solna. The annual report for 2019 in printed form will be sent to all who so requests and is always availble to download from the company's website promorepharma.com.

Financial calendar

Interim report Q1 2020	26 May 2020
AGM 2020	26 May 2020 at 2 pm
Interim report Q2 2020	25 Aug 2020
Interim report Q3 2020	24 Nov 2020

Board of Directors

Göran Pettersson
Board member and Chairman since 2015.
Born: 1945.
Göran was previously Chairman in Axelar AB, Medivir AB (publ) and OxyPharma AB, Board member in Recipharm AB (publ) and CEO of Astra Pain Control, Kabi Pharmacia UK Ltd, KabiPharmacia Terapeutics AB and Meda Sverige AB. He holds an M. Pharm Sc. from Uppsala University and an MBA from IHM in Stockholm.
Other assignments: Göran is deputy chairman in Mobidiag Oy and chairman in Mobidag Sverige AB. He is board member in G. Pettersson & Partners AB, Pfizer Pensionsstiftelse I and Brf Trumslagaren 3. He is deputy board member in Karl Jungstedt AB.
Independent in relation to Promore Pharma and its senior executives: Yes.
Independent in relation to major shareholders: Yes.
Share Holding in Promore Pharma: No current holding.

Marianne Dicander Alexandersson
Board member since 2017
Born: 1959.
Marianne was previously CEO of Kronans Droghandel AB, Sjätte AP-fonden and Global Health Partner AB and deputy CEO of Apoteket. She holds an M.Sc. in Chemical Engineering from Chalmers Technical College in Gothenburg.
Other Assignments: Marianne serves as Chairman of Sahlgrenska Science Park AB; Board Member and CEO of MDA Management AB; Board member of Recipharm AB (publ), Enzymatica AB (publ), Praktikertjänst Aktiebolag, Camurus AB, AdderaCare AB,TLV - The Dental and Pharmaceutical Benefits Agency and Member of the Council at Skandia AB.
Independent in relation to Promore Pharma and its senior executives: Yes.
Independent in relation to major shareholders: Yes.
Share Holding in Promore Pharma: No current holding

Torsten Goesch
Board member since 2015
Born: 1959.
Torsten is Partner of Rosetta Capital Ltd where he manages investments in five funds. He serves as Board Member of several biotechnology companies and has served on the Boards of Enobia Ltd, Cytochroma Ltd and STI Ltd. He holds an M.D. and a Ph.D. from Heinrich Heine University Düsseldorf, Germany and an MBA from the Kellogg School of Management in Evanston, USA.
Other Assignments: Torsten serves as Chairman of Biosergen AS and Dilafor AB; Board Member of Rosetta Capital Ltd, Forward Pharma, Modus Therapeutics AB, Karolinska Development Invest AB and Eyesense AG.
Independent in relation to Promore Pharma and its senior executives: Yes.
Independent in relation to major shareholders: No.
Share Holding in Promore Pharma: No current holding.

Satyendra Kumar
Styrelseledamot sedan 2016
Född: 1954.
Satyendra är rådgivare till styrelsen för Pharma-Research Products Ltd. Han har tidigare arbetat med licensiering, allianser och affärsutveckling för Daewoong Pharmaceu-tical Company Ltd och med etablering av internationell distribution för Samyangs verksamhet inom medicin-teknik och läkemedel. Satyendra har en MD från Birla Institute of Technology and Science i Pilani, Indien samt en PhD från Seoul National University i Seoul, Korea.
Oberoende i förhållande till Promore Pharma och dess ledande befattningshavare: Ja.
Oberoende i förhållande till större aktieägare: Nej.
Innehav i Promore Pharma: Äger inga aktier i bolaget.
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Göran Linder
Board member since 2015
Born: 1962.
Göran serves as Senior Executive in several investment companies. He was previously a board member in, amongst others, Transic AB, Jensen Devices AB, Airgrinder AB and Lamera AB. Göran holds an M.Sc. from the KTH Royal Institute of Technology in Stockholm.
Other assignments: CEO and Board member in Midroc New Technology AB, Midroc Invest AB and Midroc Finans AB. Board member in Powercell Sweden AB (publ), Powercell Warrants One AB, Nilsson Special Vehicles Aktiebolag (publ), Pergamum AB, Minesto AB (publ), Minesto Warrants One AB, Crunchfish AB (publ), Blippit AB, M&J by Malin & Johanna AB and QCG Sweden AB.
Independent in relation to Promore Pharma and its senior executives: Yes.
Independent in relation to major shareholders: No.
Share Holding in Promore Pharma: No current holding.

Kerstin Valinder Strinnholm
Board member since 2019
Born: 1960.
Kerstin has been responsible for business development and business strategy at Nycomed (now Takeda) and previously held leading positions in marketing and business development at Astra and AstraZeneca. She holds a degree from the journalism program at the University of Gothenburg.
Other Assignments: Board member of Corline Biomedical AB (publ), Camurus AB (publ), KVS Invest AB, Cavastor AB, Gedea Biotech AB and Klifo A/S.
Independent in relation to Promore Pharma and its senior executives: Yes.
Independent in relation to major shareholders: Yes.
Share Holding in Promore Pharma: No current holding.

Management and Auditor

Jonas Ekblom
President & Chief Executive Officer (CEO)
Born: 1965.
Jonas has worked over 25 years in the Life Science sector. He is an associate professor in pharmacology at Uppsala University, he has a B.Sci. in chemistry from University of Stockholm, and a Ph.D. in experimental neurology from Uppsala University, post-doctoral studies at University of Southern California, School of Pharmacy in Los Angeles, USA. He has also received education in strategic planning and business management. Jonas has previously held executive roles in biotech companies in Sweden, Switzerland and US. Most recently, he served as CEO for the Swiss biotech BOWS Pharmaceuticals SA, and prior held senior and executive positions in Pharmacia, Biovitrum, Sequenom and Invitrogen (now Thermo Fisher).
Other Assignments: Board member of EffRx Pharmaceuticals SA and World 5 Ventures, as well as principal of his own consultancy practice Edge of the World Strategies Corporation.
Share Holding in Promore Pharma: 15 000 shares.

Jenni Björnulfson
Chief Financial Officer (CFO)
Born: 1971.
Jenni has extensive professional experience from the financial markets having worked with corporate finance for over ten years with Handelsbanken Markets and Alfred Berg Fondkommission/ABM AMRO. Jenni has also worked as a stock analytics at Standard & Poor's and at ABG Sundal Collier. She has been business area manager at Global Health Partners AB. Jenni has a Master of Science from Stockholm School of Economics and has served as CFO of Promore Pharma since 2016.
Other Assignments: Jenni is a board director in Hemcheck Sweden AB (publ) and is principal of her own consultancy practice The C Story AB.
Share Holding in Promore Pharma: 7,000 shares.

Margit Mahlapuu
Chief Scientific Officer (CSO)
Born: 1972.
Margit has close to 20 years of experience in pharmaceutical research and development. She has had assignments at companies such as AstraZeneca, Arexis and Swedish Orphan Biovitrum. Margit holds a professorship in molecular medicine at University of Gothenburg, Sweden. She has a Ph.D. in molecular and cellular biology from the University of Gothenburg. Margit joined the company in 2007 and has since then been responsible for regulatory affairs and clinical development.
Other Assignments: Margit is a director of the board in Sixera AB, she is CEO of IP holding companies ScandiCure AB and Alexera AB and her own consultancy practice Arexela AB.
Share Holding in Promore Pharma: No current holding.

Auditor

Ola Spinnars, Finnhammars Revisionsbyrå

PROMORE PHARMA

Fogdevreten 2
171 65 Solna
Telefon: +46 8 124 548 59
E-post: info@promorepharma.com

Organisationsnummer: 556639-6809
promorepharma.com