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leading-edge medical innovation

2020 Q3 Interim Financial Statement

25 Nov 2020

Promore Pharma in Brief

- Two distinct, late stage, first-in-category products
- Human peptides for local administration with extraordinary safety

Ensereptide (PXL01)

Phase III

- Adhesions after tendon repair surgery
- Addressable EU market 300 MUSD
- No prescription drugs
- Indication broadening opportunities

Ropocamptide (LL-37)

(Phase III)

- Treating chronic wounds, mainly VLUs
- Addressable global market 3 BUSD
- No prescription drugs
- Indication broadening opportunities

Vision **To solve the global problems of scarring, adhesions and chronic wounds**

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Ropocamptide (LL-37)

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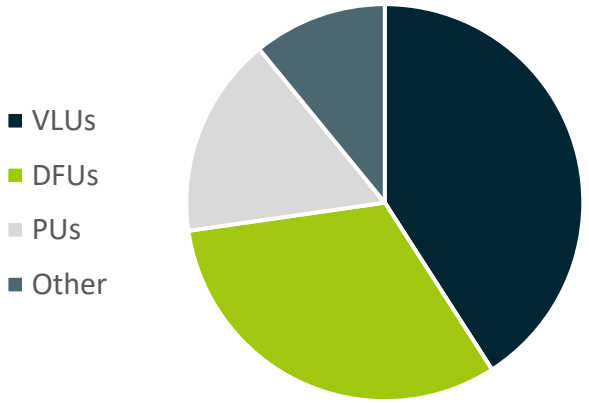
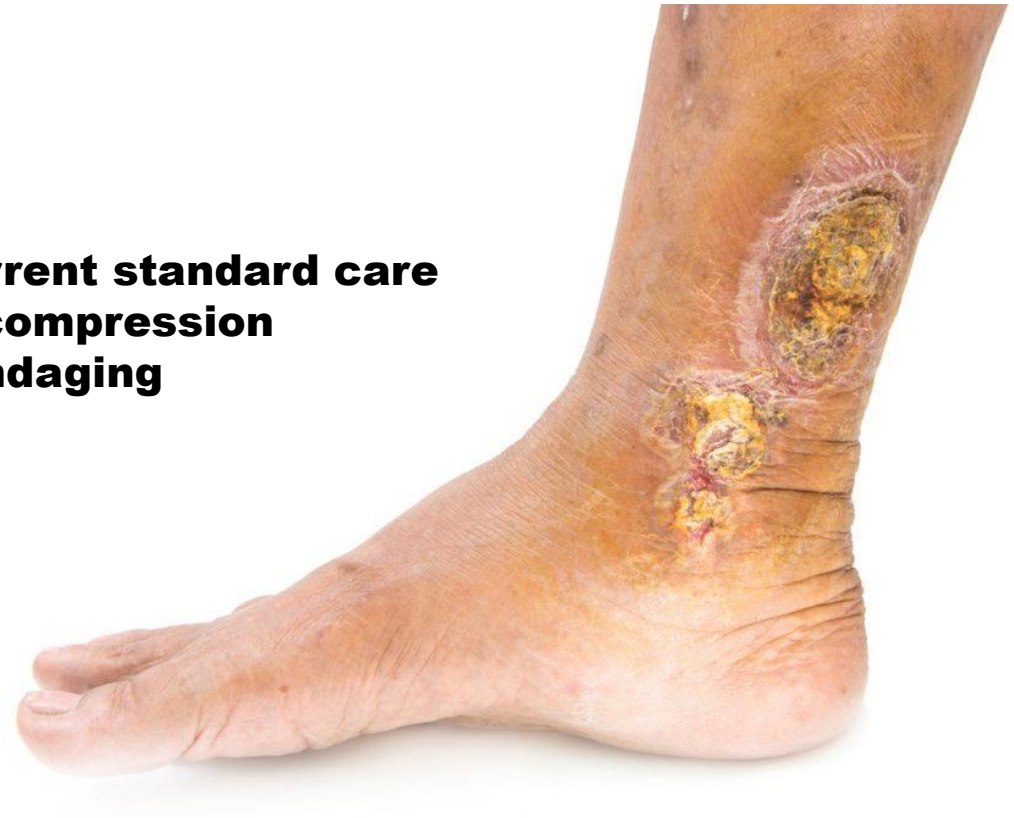
Venous Leg Ulcers (VLU)

- >15 million patients with **challenging wounds** on the major pharmaceutical markets: VLUs are the most prevalent category



Current standard care is compression bandaging



- No prescription pharmaceuticals for VLU.
- Low R&D competition
- Costs for treating a VLU exceed 10,000 USD per episode

Risk factors: obesity, smoking and sedentary lifestyle

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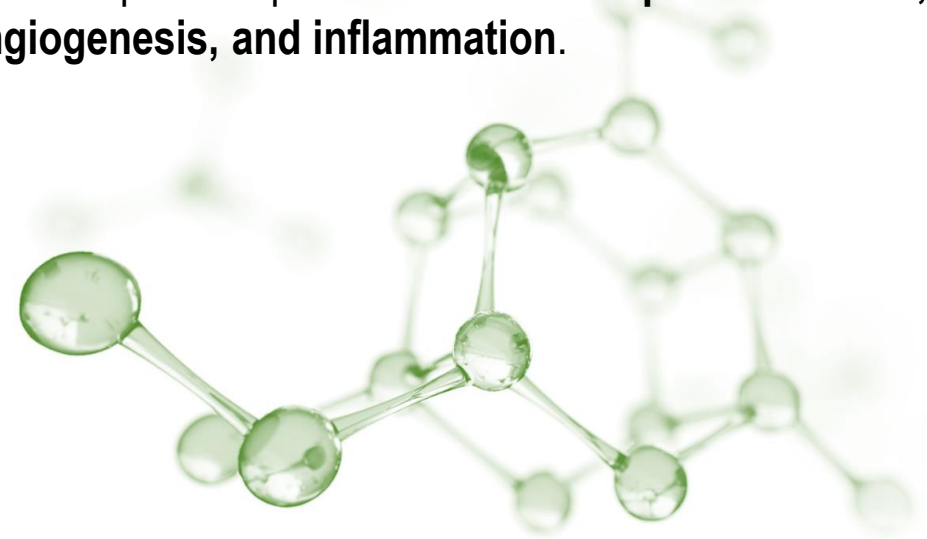
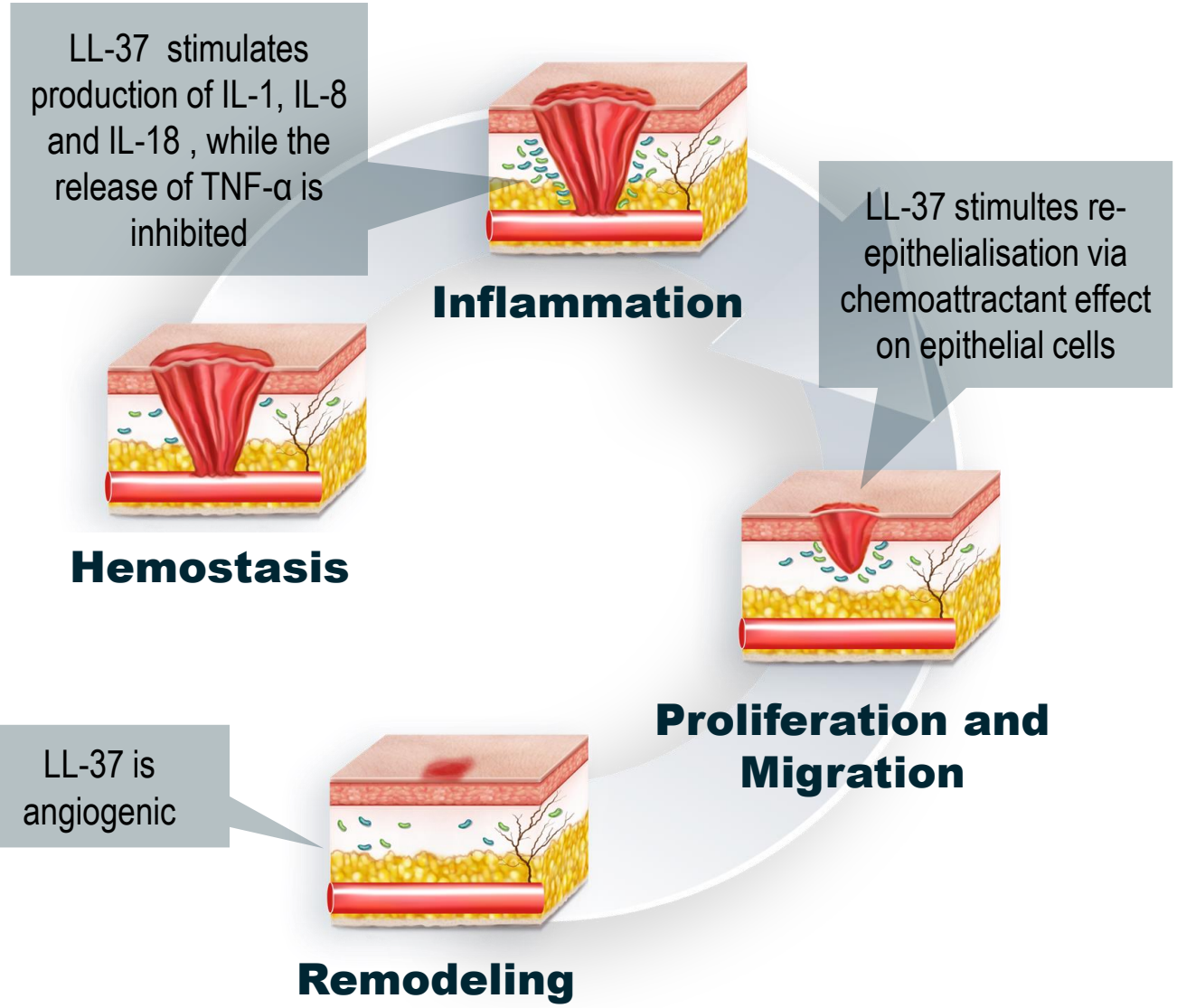
Ropocamptide in Wound Healing

LL-37 is multi-functional peptide that is expressed in the skin, where it is **up-regulated in response to injury and trauma.** Chronic wounds (VLUs and DFUs) are depleted in LL-37.

LL-37 promotes wound healing by stimulating several wound repair components such as **re-epithelialisation, angiogenesis, and inflammation**.





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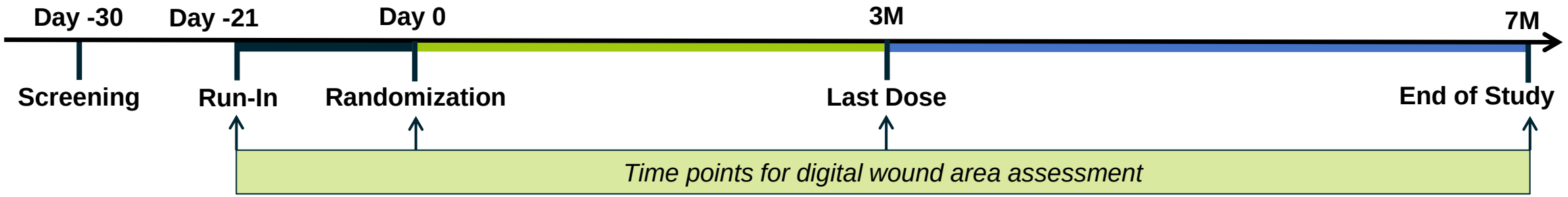
HEAL LL-37: Phase IIb Trial in VLUs

Study Basics

- Recruiting 144 patients included (randomized) in 2 countries (Sweden, Poland)
- 3-week run-in on placebo; followed by treatment with active or placebo for 3 months (application 2 times per week); 4 months follow-up
- 3 arms with 40 subjects in each: 2 doses of ropocamptide vs. placebo



The subjects are randomized to three groups

- Placebo (N=40)
- LL-37 0.5 mg/mL (N=40)
- LL-37 1.6 mg/mL (N=40)

Criteria for Evaluation

- % completely healed wounds
- Multiple secondary endpoints
- Safety and tolerability

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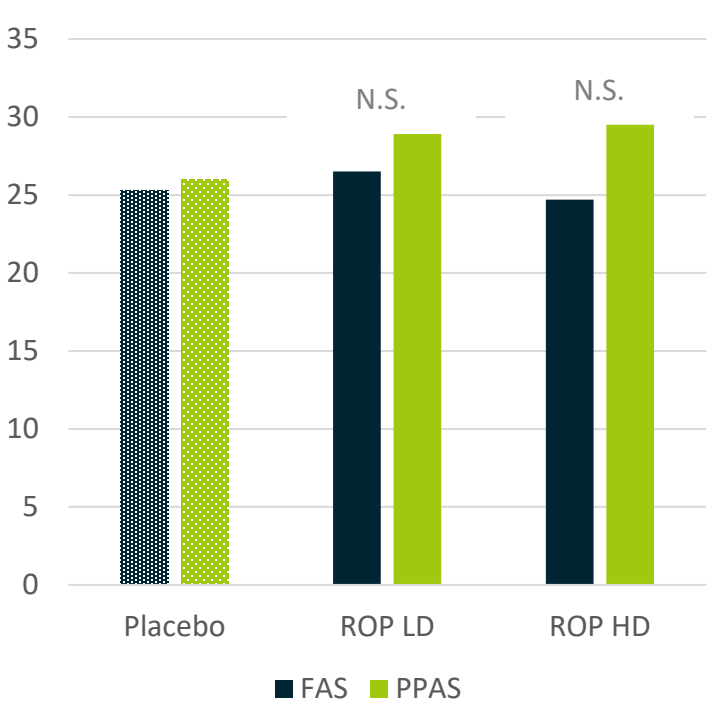
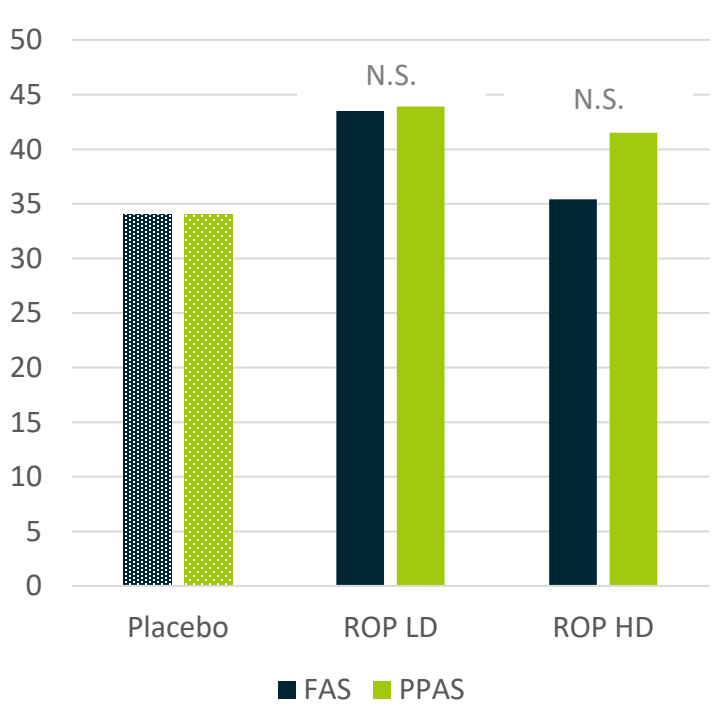
Efficacy in Global Study Population

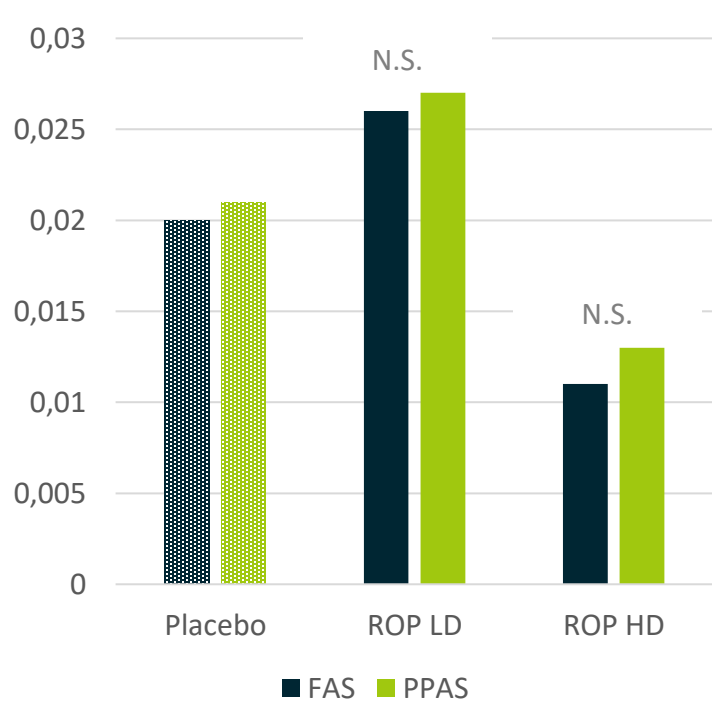
Frequency of Complete Closure (%)



Frequency of 70% Closure (%)



Wound Healing Rate (day^{-1})



No differences reaching statistical significance when all patients are included in analysis

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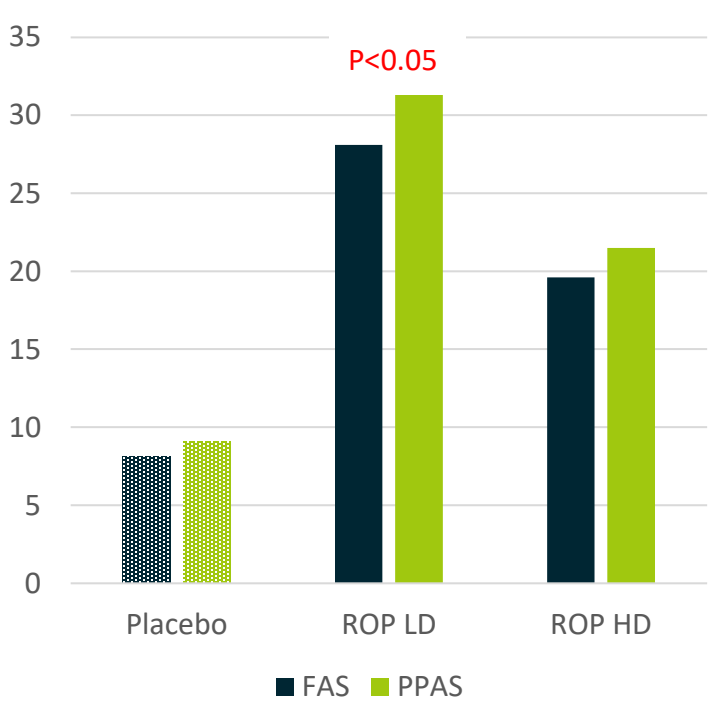
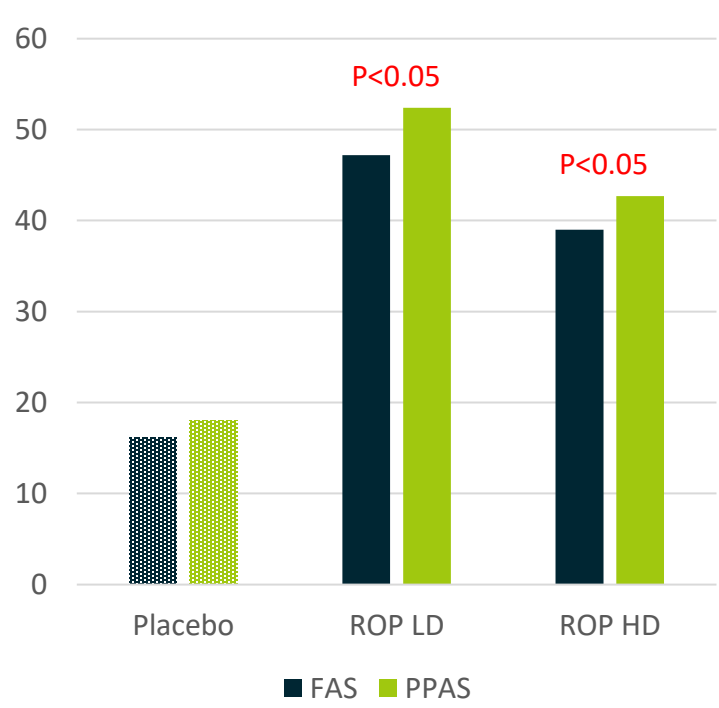
Efficacy in Patients with Large Wounds (≥10 cm^2)

Frequency of Complete Closure (%)



Frequency of 70% Closure (%)



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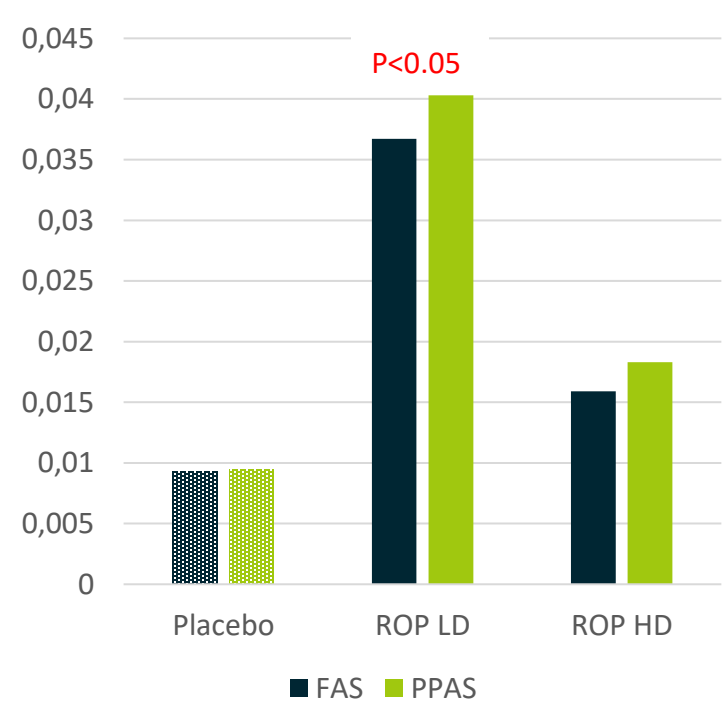

There is a clearcut medical benefit of ropocamptide in large VLUs

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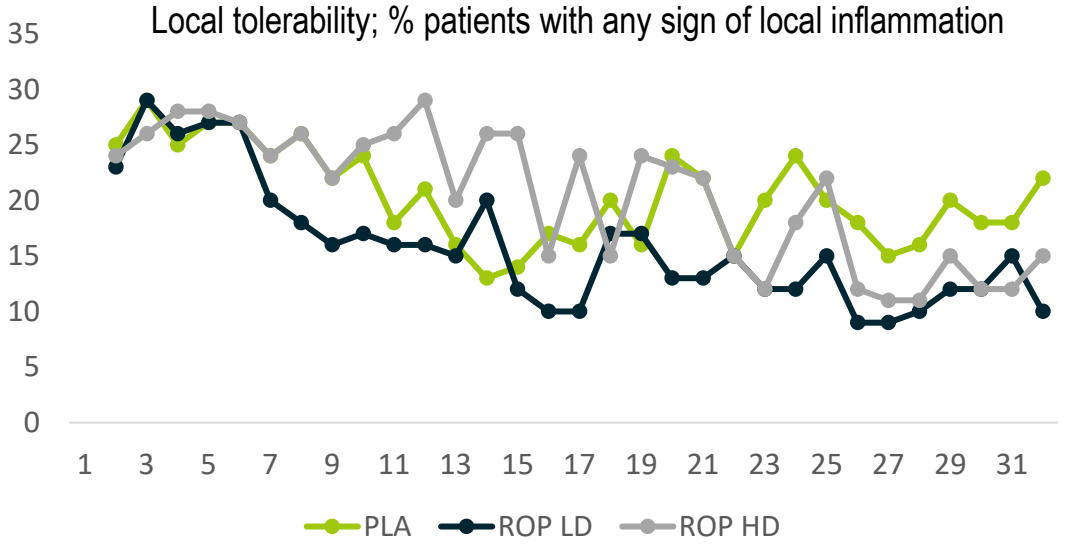
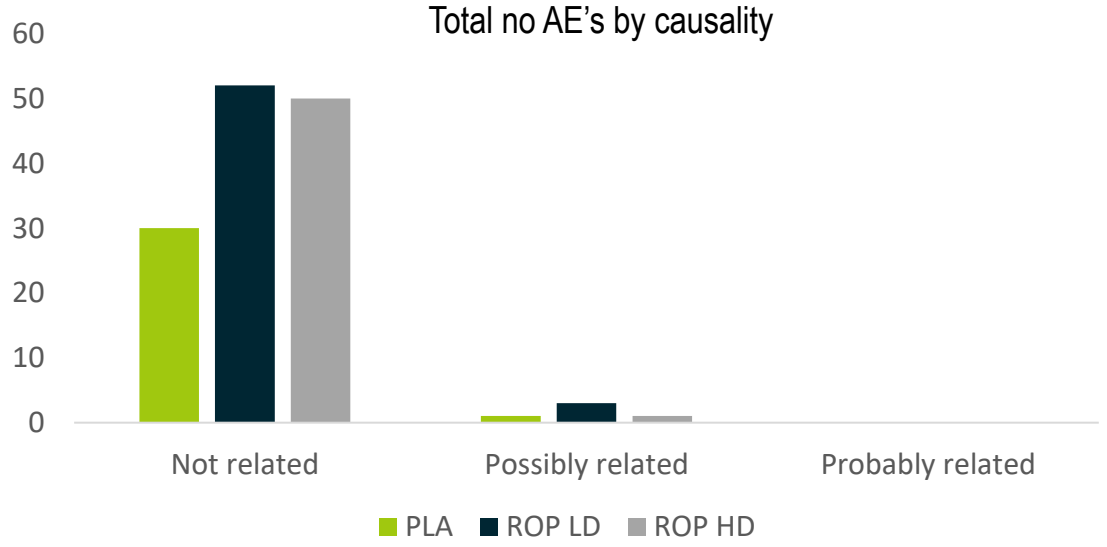
Safety and Tolerability

- A somewhat higher number of moderate AEs were seen in the treated groups which was related to reports of wound infection and erysipelas of moderate/severe intensity
- Most AEs were judged as not related to the study medication
- None of the reported SAEs were considered to be related to study drug treatment as estimated by Principal Investigator and Monitor





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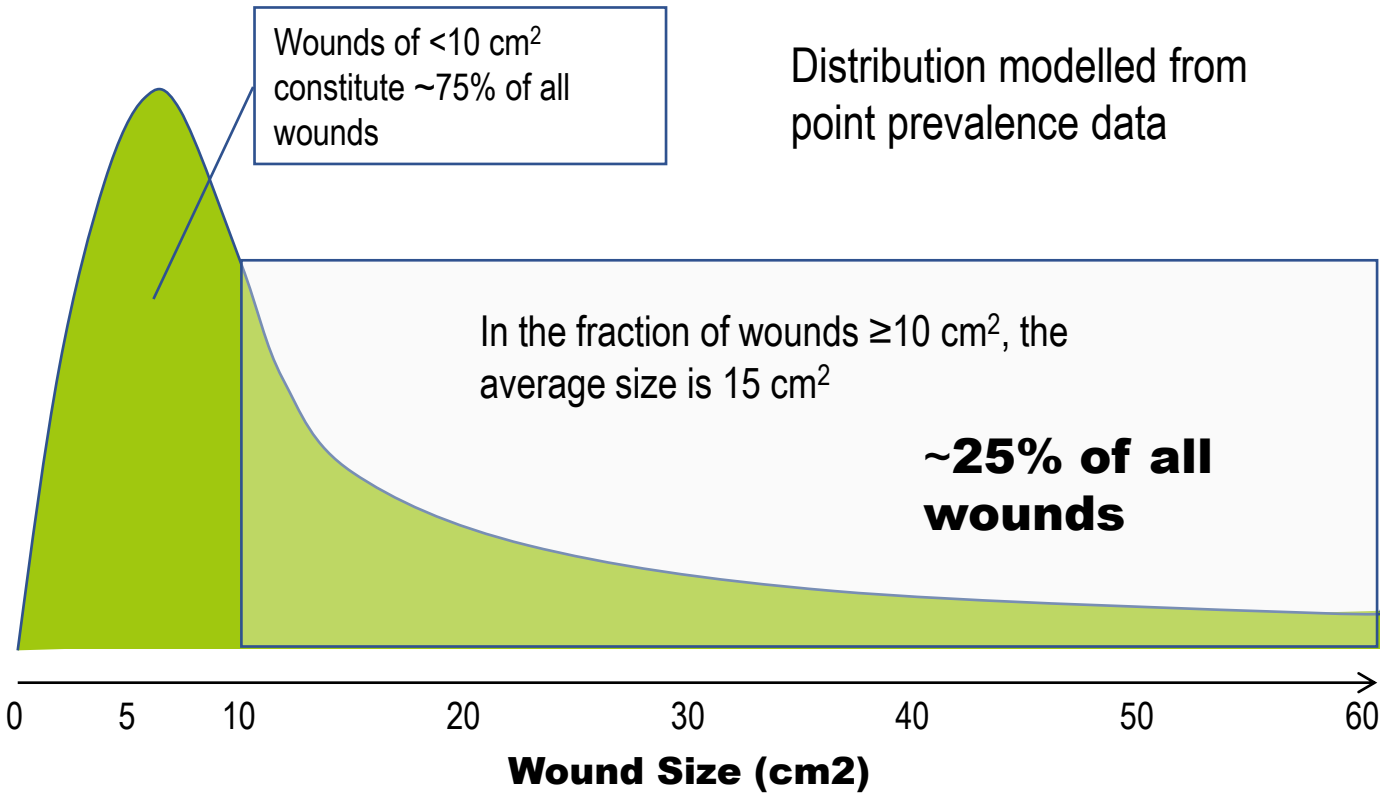
Wound Size and Treatment Costs

An average VLU is ~6-7 cm²



- Most wounds in HEAL LL-37 had a duration of >6 months
- Patients having VLUs larger than 10 cm2 and having a wound duration of >6 months have a weekly treatment cost 3x per week* compared to small ulcers with short duration
- Given the longer treatment time required, an average large wound is associated with 6-15x times the treatment cost as compared with a small VLU with short duration*
- Both doses of ropocamptide reduced the time to complete closure versus placebo in the HEAL LL-37 trial

*Ebbeskog, B. Et al. (1996) Scand J Prim Health Care 14: 238-243

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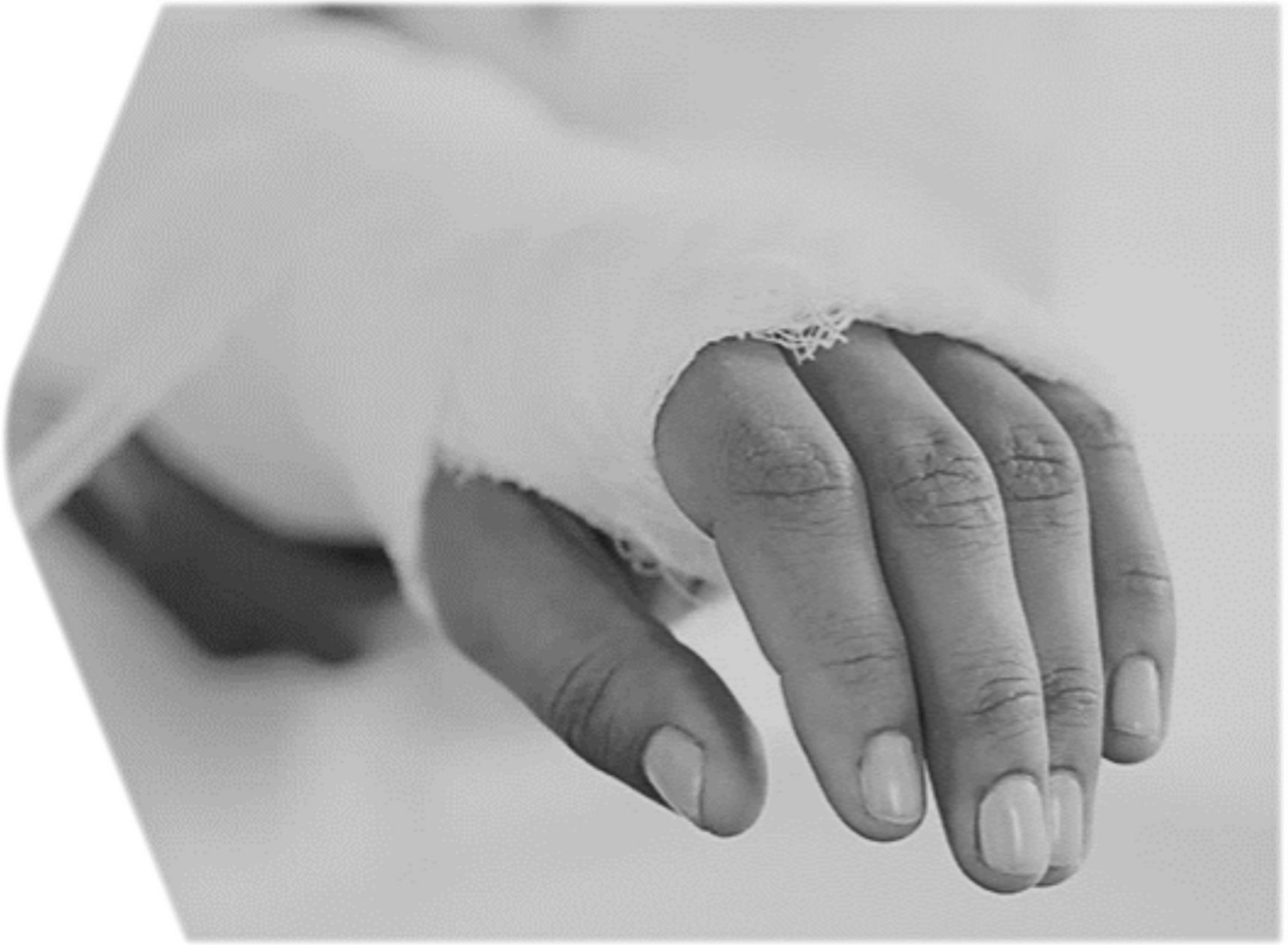
Ensereptide (PXL01)



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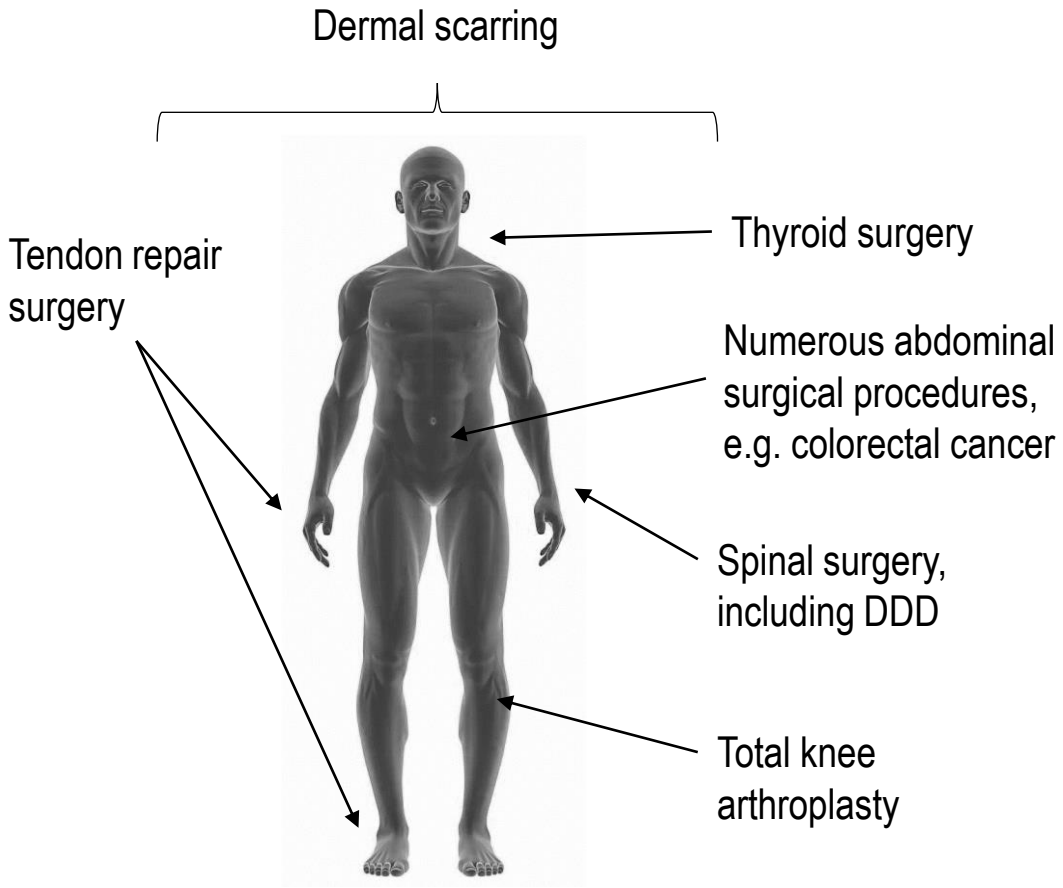
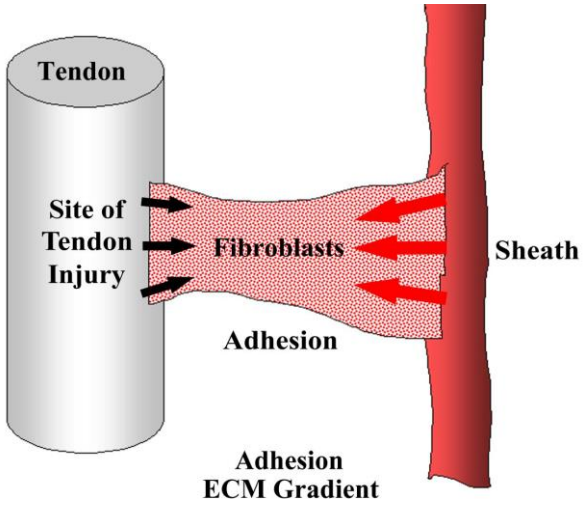
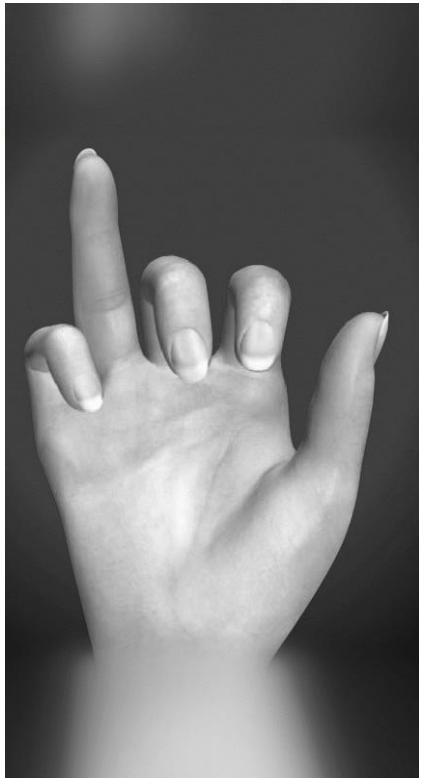
Adhesions and Scars







Adhesions may form after almost any type of surgery

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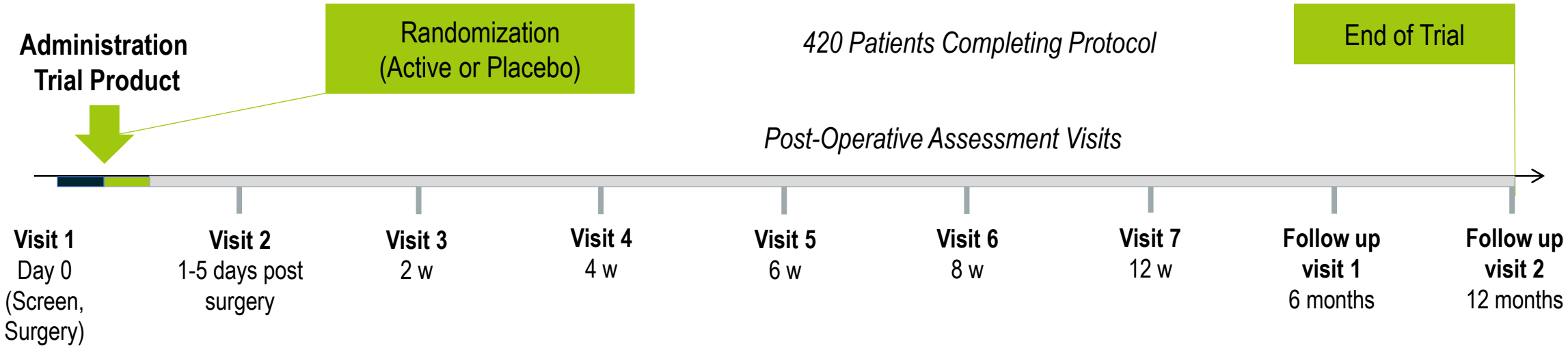
Phase III Study Planned in EU

Study Basics PHSU03

- ~600-700 patients with accidental transection of flexor tendon in zone II of the hand
- Single administration in conjunction with surgery of ensereptide (two doses) vs. placebo (saline) (1:1:1)
- Efficacy and safety followed until 12 months post-surgery
- Study centers in Sweden, Germany, Poland, Italy and India



Planned to initiate patient enrolment in H2 2021

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Business Strategy

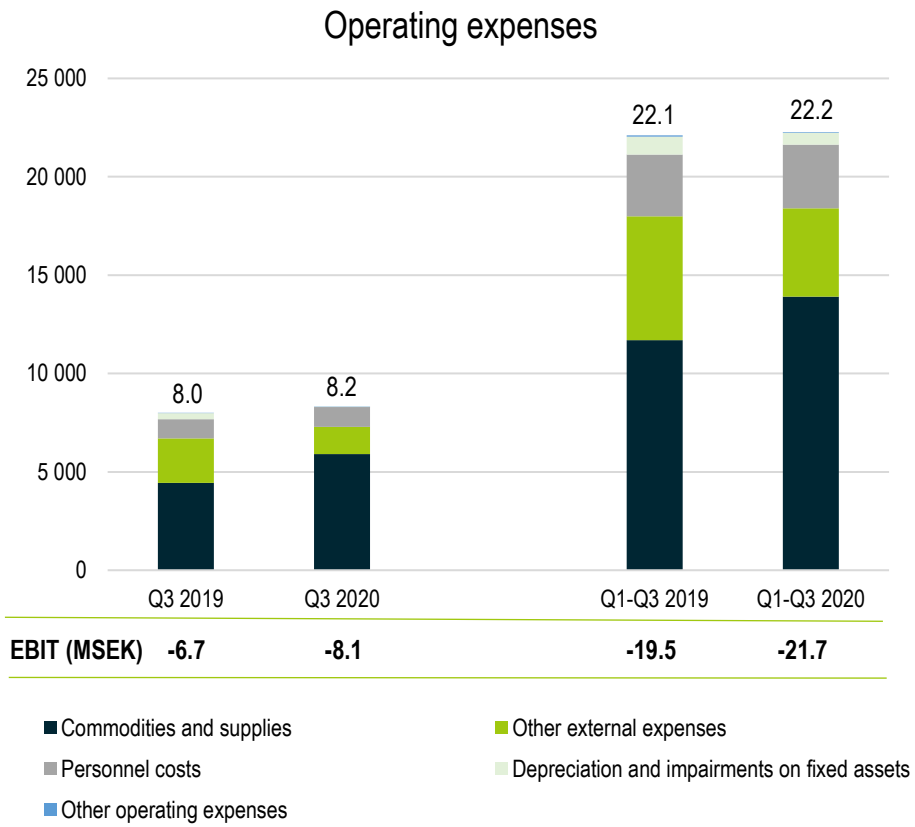
Take ensereptide to market in EU

- Phase III program (PHSU03) being prepared in EU and India
- Market Authorization and Commercialization
  - Develop ensereptide to MA in EU
  - Either commercialize first indication independently in EU or through partnerships
- Seeking partnerships for both other territories (ex-EU) and indications

Partnering ropocamptide

- Phase IIb (LL-37 HEAL) completed in EU with positive results in a group of patients with a high unmet medical need
- After completion of the final study report, the company shall evaluate the optimal path forward for the program
- Promore Pharma ultimately desires to seek one or several partnerships with multi-national companies for confirmatory trials and MA

Q3 2020 Financial Data



- The operating expenses were very much in line with last year, both in Q3 and accumulated
  - The somewhat better EBIT last year relates to revenues from past on costs
- Commodities and supplies relates to R&D expenses, which are up this year as we are entering last phase of HEAL LL-37
  - This development is according to plan
- Total cash flow in Q3 was SEK -8,6m (SEK -6.8m last year)
  - SEK -29.2m accumulated (SEK -17.9m)
- Cash position of SEK 31.3m by the end of September 2020
  - 30 June 2020: SEK 39.9m
  - 30 Sep 2019: SEK 13.0m

Costs in line with last year, and well in line with study process

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Concluding Remarks

1. Late stage clinical development phase
2. Unmet medical need – no pharmaceutical products
3. Validated technology with strong IP protection
4. Strong safety profile and low development costs
5. High growth potential
6. Low fixed costs and significant strategic partnerships in place

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