

# Interim Report January – September 2023

November 7<sup>th</sup>, 2023



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# Potential new global market leader in Onychomycosis

## MOB-015 has demonstrated world-leading ability to kill nail fungus

Partnerships in place – potential milestones of USD 70m

Launch preparations ongoing – first approval received

- 76%<sup>1</sup> of patients became fungus free, in two phase 3-studies including 800+ patients
- Additional de-risked US phase 3 study based on completed phase 3 studies to enable US approval and strengthen claims globally
- Targeting category leadership with USD 250-500m potential global product sales





Republic of Korea

Canada

FU



Israel



Scandinavia

 Recommended for approval in EU
June 2023 – national approvals in 10 countries to date

- Proven commercial track record from Kerasal Nail<sup>®</sup> – built SEK 440 million franchise with 30% market share in the US
- Commercialization process to be repeated for MOB-015



- Following the positive outcome of the Decentralized Procedure in June, national approvals have been received in the following countries: Austria, Czech Republic, Denmark, Finland, France, Hungary, Ireland, Norway, Spain and Sweden.
- The commercial launch is planned to start in our home market, and we are working with launch preparations for Sweden together with our partner Allderma.
- Enrollment to the North American study completed early October, by a wide margin within 2023; 384 patients have been randomized at 33 study centers in the U.S. and Canada. Topline results are expected in January 2025.
- Moberg Pharma's rights issue of SEK 100 million was oversubscribed subscription rate 130%.
- Management changes where Robert Ehrl succeeds Jesper Lind as Head of Supply and Christina Erixon succeeds Agneta Larhed as Vice President Pharmaceutical Innovation & Development.

# **MOB-015 recommended for approval in EU**

**Recommended for national approval in 13 European countries** 

- The approval in the European Union represents the first marketing authorization for Moberg Pharma's new onychomycosis treatment worldwide.
- Approval supported by two Phase 3 trials where MOB-015 demonstrated superior levels of mycological cure (76% vs 28% to 42% for comparators), and a significantly better complete cure rate compared to vehicle, without any serious adverse reactions.
- MOB-015 a topical formulation of terbinafine, enabling effective concentrations of terbinafine to the nail and nail bed while avoiding the risk of systemic exposure seen with oral terbinafine use.
- National approvals received:
  - National approvals for prescription sales (Rx) in Czech Republic, Denmark, Finland, France, Ireland and Spain
  - National approvals for over-the-counter sales (OTC) in Austria, Hungary, Norway and Sweden
  - National approvals are expected to follow in Belgium, Italy and Netherlands during upcoming months



## **Commercialization rollout of MOB-015**



- Two-step process, driven by:
- 1. Moberg Pharma believe the results in the ongoing North American study is likely to strengthen the product claims further, including a **shorter dosing regimen** with the potential to deliver **superior complete cure** rates
- 2. Need to secure **sufficient API** for a pan-European launch
- 3. An early Scandinavian launch enables us to **gain valuable insights** into consumer behaviour, collecting patient feedback and provide user data to support direct to OTC/OTC-switches in more countries

## The North American Phase 3 study is progressing according to plan – enrollment completed Oct-23

- Similar design as the already completed North American study
  - Multi-center, double-blind, randomized, vehicle-controlled study
  - Includes 384 patients in North America
  - 33 clinics in the U.S. and Canada are treating patients
  - Topline data expected January 2025
- Purpose of the new study:
  - Enable market approval in the U.S.
  - Strengthen the product's clinical data and marketing claims globally
- The new study builds on the experience gained from the previous studies
  - Cooperation with the same CRO and lead investigator as in the previous North American study

#### Last five quarters

(SEK thousand)	Jul-sep	Apr-Jun	Jan-Mar	Oct-Dec	Jul-Sep
	2023	2023	2023	2022	2022
Continuing operations					
Net revenue	-	-	-	-	207
Gross profit	-	-	-	-	207
Selling expenses	-912	-817	-361	-540	-170
Business development and administrative expenses	-5,509	-4,392	-5,414	-5,160	-5,065
Research and development costs	-693	-1,109	-818	-225	-79
Other operating items	-147	1,024	-80	1,326	-157
Operating profit (EBIT)	-7,261	-5,294	-6,673	-4,599	-5,264
Total profit for the period	-5,766	-3,852	-5,030	-3,113	-4,250
Cash and cash equivalents	101,504	51,951	84,540	125,550	142,453
Investments in MOB-015	33,642	22,761	34,498	26,612	13,181
Total Assets	644,179	549,719	551,296	564,423	549,807

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Slight increase in costs attributed to preparations associated with pending launch in Sweden

Investments in MOB-015 in the ongoing US phase 3 study

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