



# Aktiespararna

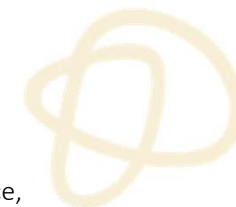
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August 31<sup>st</sup>, 2022  
Anna Ljung, CEO



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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 120m

On track for launch – capturing full value potential

- 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



EU



Japan

TAISHO PHARMACEUTICAL



Republic of Korea



Canada



Scandinavia



Israel

- Swedish MPA reference country for EU submission March 2022  
Product launch expected 2023
- 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

1) Other topical treatments demonstrating 30-54%.

# 100+ million patients need better treatment in EU/US only



**10%** of the population suffer from nail fungus<sup>1</sup>

**\$2bn** global onychomycosis market<sup>2</sup>

**7/10** doctors avoid prescribing terbinafine tablets due to patients' concerns for serious side effects, such as liver toxicity and drug-drug interactions<sup>3</sup>

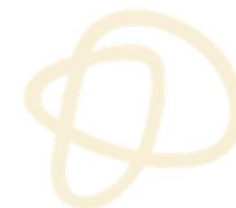


1) PLoS Pathog. 2014 Jun; 10(6): e1004105.

2) Moberg Pharma estimate, based on market data from Symphony Health Solutions (US Rx sales), Symphony IRI (US OTC sales), and market data from Moberg Pharma's partners.

3) LifeSci Physician Survey, April 4, 2017

# MOB-015 Overview of completed Phase 3 studies



## Key results

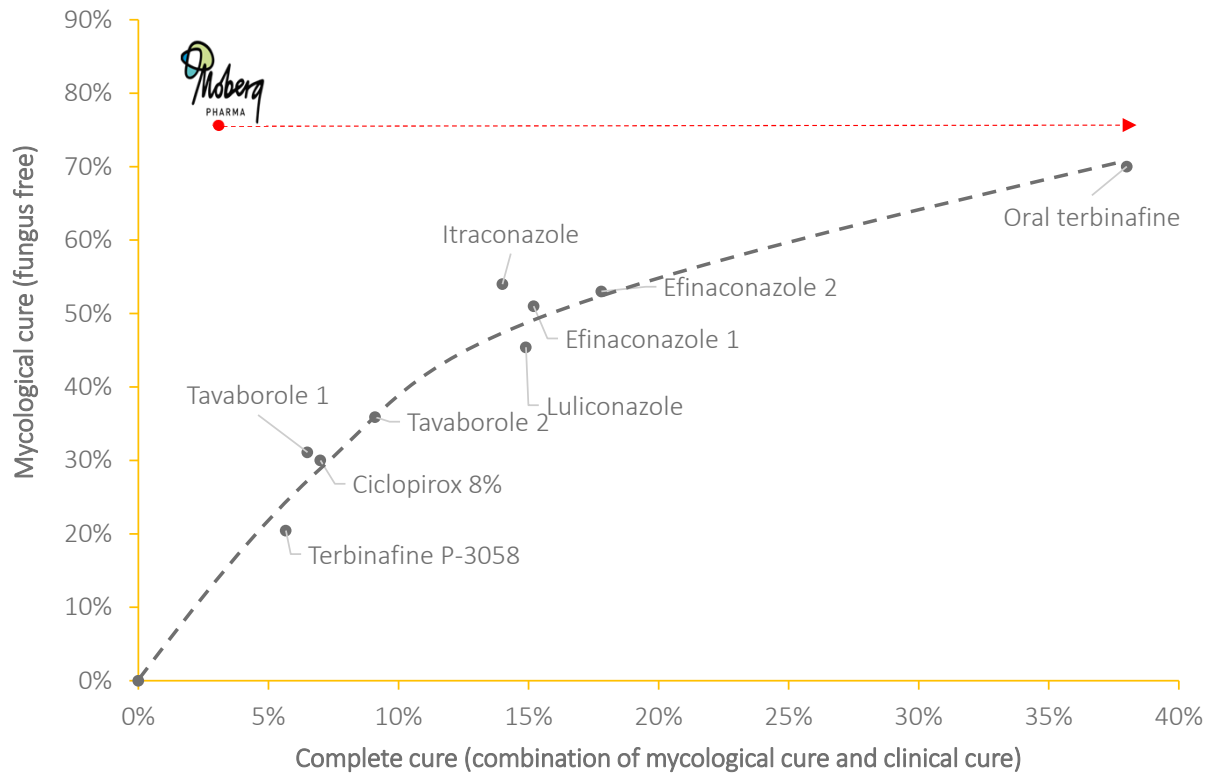
	Europe	North America
Number of patients	452	365
Comparator	8% ciclopirox	Vehicle
Complete cure @52w	Non inferiority met	Superiority met
Mycological cure rate @52w	84%	70%
Improvement of nail condition @12w (patient subjective score)	70%	82%

- Primary endpoint met in two Phase 3 studies, EU and North American
- High mycological cure with earlier onset than oral terbinafine
- Safe and well tolerated

# Superior mycological cure – expecting to increase complete cure



Oral and topical treatments of nail fungus



Concentration of terbinafine 1000x in the nail and 40x in the nail bed when treated with MOB-015 compared to oral terbinafine.

Patients prefer an efficacious topical to oral terbinafine due to risk for severe side effects.

Source: U.S. prescribing information for each drug; for P-3058, [clinicaltrialsregister.eu/ctr-search/trial/2015-000561-31/results](http://clinicaltrialsregister.eu/ctr-search/trial/2015-000561-31/results).

# Additional Phase 3 study with attractive commercial impact



## Shorter dosing regimen

- A regimen with daily dosing for 8-12 weeks followed by once weekly treatment, is highly attractive, and expected to maintain high mycological cure to deliver high complete cure
- This will significantly strengthen claims globally for MOB-015



## Patient benefit

- Shorter daily dosing for only 8-12 weeks would be a **significant improvement for patients**, leading to improved convenience and compliance
- 75% of patients see improvements already at week 12<sup>1</sup>



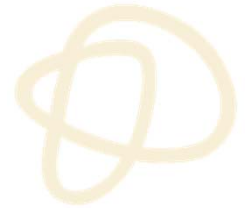
## Competitive advantage

- Main topical competitors have 48 weeks daily treatment, but poor compliance. Average consumption is 12-16 weeks<sup>2</sup>
- MOB-015's dosing regimen will compare to oral treatment but without the safety issues of oral treatments



1) Based on current Phase 3 data. 2) Based on US prescription data.

# Key Opinion Leaders strongly support the concept



Dr Boni Elewski  
Professor and Chair of the  
Department of Dermatology  
University of Alabama

*“The high mycological cure rate demonstrated is very impressive and given the rapid onset of the antifungal effect, MOB-015 offers exciting benefits. I will definitely use it for my patients. A higher complete cure rate is likely to be achieved with a shorter treatment period and this would also be much more attractive to patients.”*



Dr Aditya Gupta  
Professor, Department of Medicine  
University of Toronto

*“I am a strong supporter of this concept. With an optimized dosing regimen this product has **great potential** and **may become the preferred therapeutic option**, not only for monotherapy, but also as maintenance therapy to reduce recurrence after oral treatment.”*



Dr Jan Faergemann  
Professor in Dermatology  
Sahlgrenska Academy  
University of Gothenburg

*“Based on decades of experience with terbinafine and the excipients used in MOB-015, I believe a shorter treatment period has the potential to provide higher complete cure rates. **Killing the fungus is the driver of also reaching complete cure.**”*

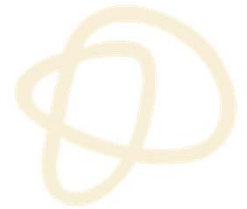


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## Additional phase 3 study in North America initiated

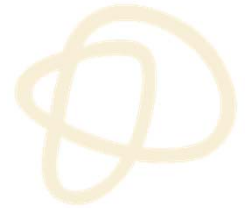
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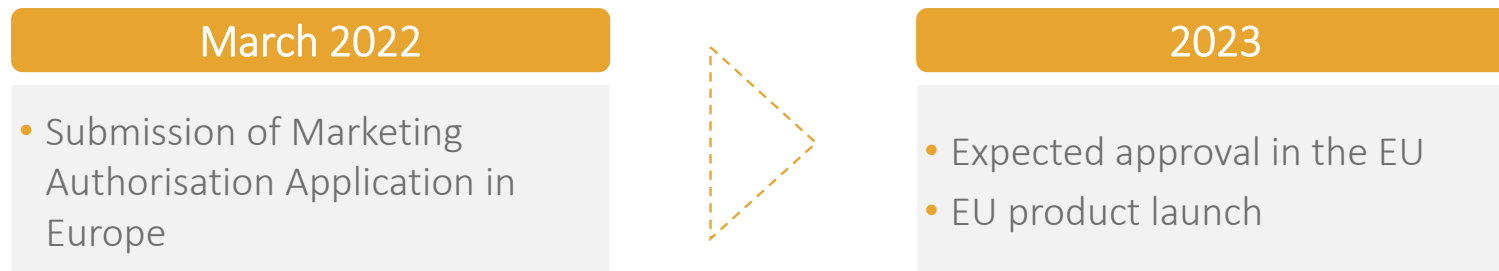
The new North American Phase 3 study has started and is fully financed thanks to the guaranteed rights issue.

- Similar design as the already completed North American study
  - Multi-center, double-blind, randomized, vehicle-controlled study
  - Scheduled to include 350 patients in North America
  - Patient enrollment ongoing
- 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

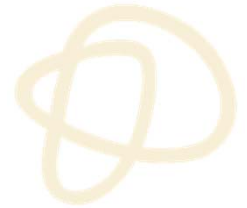
# Advancing towards market launch – filing for EU approval



- Moberg Pharma has submitted its marketing authorization application for MOB-015 in March 2022
  - The Medical Products Agency in Sweden is reference member
  - Submitted in Europe through the decentralized procedure
  - Full application, which offers the possibility of data exclusivity for up to 10 years following market approval
  - Market approval is expected in 2023
- EMA's Paediatric Committee approval (September 2021) paved way for EU submission
  - Supplementary pediatric study during and after approval process for MOB-015



# USD 250-500m potential global product sales for MOB-015



**US**  
USD 150 - 300m

## US Rx<sup>1</sup> potential:

USD 150 - 300m (400 - 600 thousand units à USD 375 - 500/unit after GTN discount i.e. pricing on par with branded competitors and a target market share of 8 - 12%)

**Other Rx markets**  
USD 50 - 100m

## Other Rx markets, e.g. Japan and Canada:

USD 50 - 100m (USD 40 - 100/unit ex factory and targeting a market share of 10 - 20%)

**OTC markets**  
USD 50 - 100m

## OTC markets in EU and RoW:

USD 50 - 100m (3.5 - 7 million units à EUR 15/unit ex factory)

1) Medical prescription.

# Strong commercial partners in place



**USD 200m+**

EU OTC market for topical onychomycosis



- The world leader in OTC antifungal treatments with the brand Canesten
- Up to EUR 50 million in milestone payments with EUR 1.5 million upfront
- Royalties and supply fees for delivered products

**USD 290m**

Japanese market for branded drugs for onychomycosis



- Up to USD 50 million in milestone payments, with USD 5 million upfront
- Royalties and supply fees for delivered products

**USD 58m**

Canadian market for onychomycosis prescription drugs



- Up to USD 14.6 million in milestone payments, with USD 0.5 million upfront
- Royalties on future net sales in Canada

**USD 40m**

Korean market for topical drugs for onychomycosis



- Korean dermatology market leader, excellent coverage of dermatology clinics
- Distribution agreements with attractive margins

**USD 10m**

Scandinavian OTC market for topical onychomycosis



- Allderma is managed by the team responsible for the successful Nordic launch of Nalox<sup>®</sup>, our first-generation nail fungus product

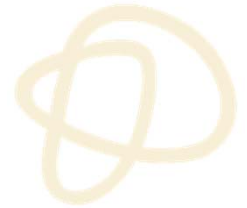
**USD 7m**

Israeli market for topical drugs for onychomycosis



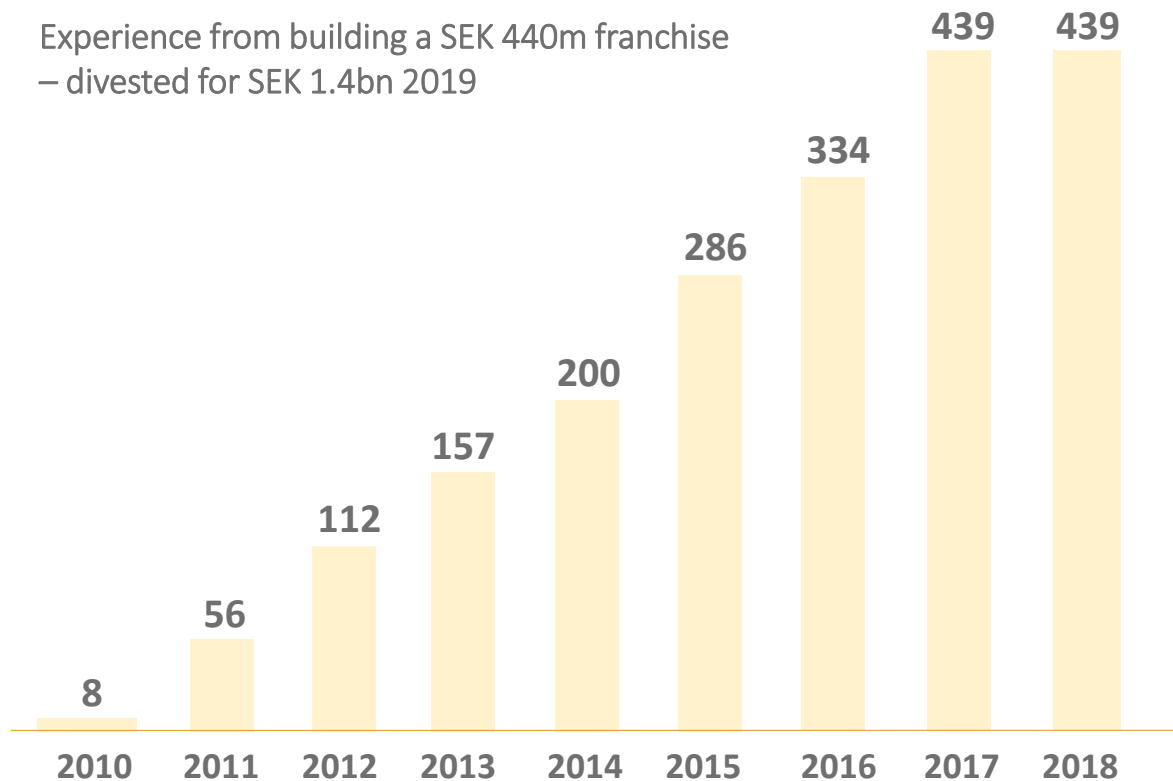
- A leading provider of extended topical and other specialty pharmaceuticals in Israel
- Distribution agreements with attractive margins

# Excellent commercial track record from Kerasal Nail



## Net Sales, SEKm

Experience from building a SEK 440m franchise  
– divested for SEK 1.4bn 2019



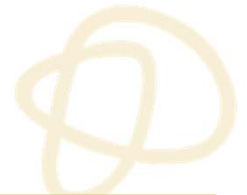
Proven commercial track record with leading OTC brand Kerasal Nail® for nail fungus

- Distributors in 30+ markets
- Direct sales in the U.S. with **#1 position, 30% market share** and available in more than 30,000 U.S. stores

Commercialization process to be repeated for MOB-015

- Focus on podiatrists: >40% US prescriptions
- DTC marketing to U.S. consumers
- Co-promotion with U.S. derm company

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