

Year-End Report January – December 2024

February 13th, 2024



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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 ongoing under brand name Terclara[®]

- 76%¹ 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[®] – built SEK 440 million franchise with 30% market share in the US
- Commercialization process to be repeated for MOB-015

Significant events during Q4 2023 to date



MOB-015 is now on the shelves of pharmacies around Sweden under the brand name Terclara[®]. Manufacture and transport of MOB-015 ahead of launch has been completed according to schedule.

Progress in efforts to secure long term supply of terbinafine, with an anticipated application submission expected shortly.

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.

Management changes where Robert Ehrl succeeds Jesper Lind as Head of Supply and Christina Erixon succeeds Agneta Larhed as Vice President Pharmaceutical Innovation & Development.

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.



Our partner Allderma AB, a company which specialises in the sale of over-the-counter (OTC) pharmaceuticals – has now launched sales of MOB-015 under the Terclara[®] brand.

The majority of pharmacies throughout Sweden have decided to start selling Terclara®

- Production and inselling to pharmacy chains has been completed on schedule,
- Pharmacies fill up the shelves now during the "February window,"
- Work is ongoing to inform doctors and pharmacy staff about the unique advantages of Terclara®
 - fine-tuning of marketing materials
 - followed by targeted marketing to consumers, including digital marketing starting from March and TV commercials from April onwards.

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)		Oct-dec	Jul-sep	Apr-Jun	Jan-Mar	Oct-Dec
		2023	2023	2023	2023	2022
Continuing operations						
Net revenue		-	-	-	-	-
Gross profit		-	-	-	-	-
Selling expenses		-1,167	-912	-817	-361	-540
Business development and administrative expenses		-6,288	-5,509	-4,392	-5,414	-5,160
Research and development costs		-1,037	-693	-1,109	-818	-225
Other operating items		257	-147	1,024	-80	1,326
Operating profit (EBIT)		-8,235	-7,261	-5,294	-6,673	-4,599
Total profit for the period	۲	-6,445	-5,766	-3,852	-5,030	-3,113
Cash and cash equivalents	•	60,555	101,504	51,951	84,540	125,550
Investments in MOB-015	٣	33,215	33,642	22,761	34,498	26,612
Total Assets	-	634,732	644,179	549,719	551,296	564,423



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

Investments in MOB-015 in the ongoing US phase 3 study, recruitment finalized, expect lower R&D expenditures going forward

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