Moberg Call Notes – February 13, 2024

Spoke with Anna Ljung (CEO) and Kristofer Krolak (Valor Securities) for approximately 35 minutes. This was an introductory call, organized the discussion around a timeline of events for the next few years.

2024

- Terclara Launch in Sweden
    - Initial supplies in Q1, also spend Q1 educating physicians and pharamacists for start of high season in Q2.
    - In Q2, Allderma will engage in TV advertising, deliver posters/marketing material to pharmacies.
    - Q2 and Q3 focused on sales during high season. Sales data from Sweden will be an important data point in negotiations with potential new partners in U.S. and other geographies.
    - Manufacturing of Terclara is done by a German company, previously manufactured older Moberg topical products.
- API Suppliers
    - Existing API supplier stopped making terbinafine, working to qualify two new API suppliers.
    - Terbinafine supply is currently a bottleneck, but once a new API supplier is qualified, the supplier can start terbinafine supply in short order.
    - Expect API supplier qualification in Q2.
    - Launch in other Nordic countries limited by terbinafine supply.
- Financials
    - Small amounts of revenue in Q1/Q2. Potential for revenue in Q3 for high season.
    - Quarterly cash burn now in the 10-15mm SEK range.

New Partners

- U.S.
    - The plan is to license the dermatologist-focused sales to a U.S. partner.
        - Moberg will engage a banker to run an auction process for the rights.
        - Potential partners will look at the Swedish launch data and U.S. Phase 3 readout in early 2025.
    - Moberg intends to keep the podiatrist-focused sales internal.
        - Moberg previously entered the U.S. with Kerasal by acquiring a small company with complementary products and an existing sales force. The plan is to look for a similar acquisition.
        - Expect the U.S. sales force to be 30-40 reps up and running when FDA approves MOB-015 in late 2026/early 2027.

2025

- U.S. Phase 3 readout in early 2025
    - The goal is the most competitive mycological and complete cure rate. The expectation is to beat Jublia's complete cure rate.
    - Phase 3 readout will be catalyst for new partnerships in U.S. and other geographies.

    - File an NDA with FDA by end of 2025, expect FDA approval in late 2026/early 2027.
- File variation in EU with claims and data from U.S. Phase 3.

2026

- EU launch with Bayer will target Q2/Q3 high season pending securing adequate supply of terbinafine and EU variation with new claims from U.S. Phase 3.

2027

- U.S. launch with dermatology partner and internal podiatrist sales force.

Market sizing

- Current TAM estimates are based on taking existing market share with data from previous products.
- Anna agreed there is an opportunity to also grow the market by treating currently untreated patients.
- "We are Swedish, so we like to be conservative."

Competition

- Sandoz's terbinafine topical is not a competitor on mycological cure rate, the vehicle does not work as well to penetrate the nail. The Phase 3 trial was discontinued because it did not work.
- However, there is risk that Sandoz taints the well because people cannot distinguish between P-3085 and MOB-015 since both are terbinafine topicals. Therefore, important to work with Bayer to educate the EU market.

Biggest Worries

- Clinical risk – mitigated by using the same clinical trial infrastructure as previous trial (same investigators, same sites).
- Regulatory risk – mitigated by existing approvals in 13 EU countries, but U.S. is a risk.
- Market risk – mitigated by finding the right partners.