Moberg Pharma – Call with Anna Ljung (May 7, 2024)

1. Allderma Relationship & Revenue Recognition Mechanics
    a. Moberg → Allderma → Wholesalers → Pharmacy
    b. Sell-in revenue recognition policy: Moberg receives payment and recognizes revenue when box shipped to Allderma.
        i. Allderma holds some inventory, but Moberg's minimum production batch size (i.e., production order with Contract Pharma is sized for launch in more than one country) is larger than Allderma's minimum order size, so Moberg will hold the remainder in inventory as fulfill future Allderma orders.
        ii. Moberg has a near real time look at end demand. Short turnaround time to fulfill an order from a pharmacy.
2. Q1 Sales & Margin
    a. Warned to not read too much into/extrapolate to other markets from very early data in Sweden.
        i. "Not even real sales in Q1 because it's before consumer marketing started."
        ii. Do not use as a "guide" going forward, will have to be a bit more patient to see future quarters.
    b. Sweden is not a typical market because although gross margins will be higher, Moberg will invest in marketing that will impact operating margin.
3. How did they design the current U.S. phase 3 dosing regimen to mitigate risk from the whitening issue?
    a. Most important data points came from the two completed phase 3 trials in EU and US.
    b. Photographs from previous trials.
        i. Including photos from Kerasal trials, which is the same vehicle as Terclara.
    c. Discussions with key opinion leaders who analyzed the photos in detail.
    d. Discussions with investigators that conducted the trials.
    e. From previous trials, not much whitening happened at week 4 or 8, but between week 8 and 12, a lot of whitening appeared.
        i. This has been consistent through many patients in all the trials.
    f. Discussions with key opinion leaders on how the chemistry of urea, propylene glycol, and lactic acid cause a moisturizing effect.
    g. From previous studies, there is already an excess of terbinafine in the nail at week 12, so the mycological cure rate will be fine.
    h. Phase 2 trials had a longer washout period (12 weeks), so the risk posed by whitening to the complete cure rate was not known when the first phase 3 was designed.
    i. In first US phase 3, they unfortunately did not take pictures at week 48 (which Anna said is "disturbing in hindsight"), but the physician's clinical assessment at week 48 is a good proxy for those photos.
4. Phase 3 timeline
    a. Last patient will finish treatment in October 2024.
    b. Then you need to culture the nails for a few weeks to see if any fungus grows.
    c. Then a few weeks for statistical analysis.
    d. Except results will be ready to publish in January 2025 barring something random that causes a few weeks slippage (i.e., someone gets sick, etc…)
5. "Pay per completed cycle" in the U.S.

    a. The way payors think about different treatments is to compare the cost for full treatment regimen, believes Moberg will have a significant advantage over the other branded products on the market.
        i. Jublia is once daily for 48 weeks vs. Terclara one daily for 8 weeks + weekly for 48 weeks.
        ii. Every 8 or 9 Jublia tubes can be replaced with 1 or 2 Terclara tubes to complete treatment.
            1. Made "not pricing per milliliter" comment.
6. Price vs volume trade off in U.S.
    a. Jublia has chosen an aggressive (high) pricing strategy, which has advantages, but there is a price to pay in terms of tiering, co-pay, sales staffing.
    b. On the other hand, the generics are very cheap, so Terclara will not be able to compete with low prices, but Terclara should not compete on price because it is a superior product.
    c. "It's a matter of finding a pricing point that will enable us to get the right tiering and it's not obvious what that actually means until you have negotiations with different insurance companies to see where we end up."
        i. Big difference between having the patient need to first try a different topical versus a patient needing to first try a different topical and then oral.
        ii. If we end up in the right tier, we not only get the patients that are required to start with Penlac or another treatment before Terclara, but also get the patients that have already failed with a different treatment and can move directly to Terclara.
    d. Smarter to start with a higher price because you can lower price if the tiering is not good enough, but impossible to start with a lower price and then raise it.
    e. Finding the right partner to conduct these insurance negotiations is of paramount importance.
7. New patent
    a. Whitening effect can form basis of new patent which will have initial term until 2041.
    b. Patent application is ongoing, but no reason to push forward until after the current U.S. phase 3 generates data.
    c. Having solid clinical data that supports the hypotheses is vital part of the patent application.
8. Baltic Sea Foundation
    a. Swedish government fund has been invested since the founding of Moberg in 2006.
    b. "Very good long-term relationship with them, ideal long-term investor in the company"
9. Swedish wholesale sales data
    a. "It's not very accurate"
    b. Has seen data from two different sources and the two sources had different numbers.
    c. Issue is that the data is not Moberg's sales or sales to end users, but data from wholesalers in the middle so numbers could be affected by inventory movements and timing effects.

Gemini 1.5 Summary

This is a detailed summary of the conversation between an investor and Anna, the CEO of a pharmaceutical company called Moberg Pharma, which recently launched a topical nail fungus treatment called Terclara.

Revenue Recognition and Financials:

- Moberg recognizes revenue on a sell-through basis, meaning when they deliver the product to their distributor, Allderma.
- The investor is concerned about the accuracy of publicly available wholesale data and Anna confirms it's unreliable due to timing differences and inventory levels.
- Moberg currently holds a substantial inventory of Terclara, partly due to larger batch sizes intended for a pan-European launch.
- The investor inquired about the increase in operating liabilities on the cash flow statement, which Anna attributes to changes in payables, primarily related to their completed Phase 3 trial.
- The investor also asked about the increase in "current non-interest-bearing liabilities" on the balance sheet, which Anna explains is related to inventory and liabilities towards the CRO and physicians involved in the trial.

Phase 3 Trial and Product Efficacy:

- The discussion revolves around the design of the ongoing Phase 3 trial for Terclara, particularly the rationale behind the dosing regimen (daily for eight weeks, then weekly for 48 weeks).
- Anna explains this is based on extensive data from previous Phase 2 and 3 trials, including photographic evidence, physician assessments, and expert opinions.
- The "whitening effect" observed in previous trials, while initially a concern, provided insights for the new dosing regimen and is the basis for a new patent application.
- The last patient in the current Phase 3 trial will complete the study in October 2023, with data expected to be published in January 2024.

U.S. Market Entry Strategy:

- Moberg is actively seeking a U.S. partner to navigate market access and insurance negotiations.
- The investor and Anna discuss pricing strategies, particularly in comparison to their main competitor, Jublia.
- Anna believes Terclara's "pay-per-completed cycle" pricing model, based on the entire treatment regimen, will be advantageous compared to Jublia's aggressive pricing.
- They acknowledge the importance of securing favorable tiering with insurance companies to ensure patient access and market penetration.

Patents and Intellectual Property:

- Moberg has filed a new patent application related to the "whitening effect" observed with Terclara, which could potentially extend patent protection until 2041.
- They are awaiting data from the ongoing North American Phase 3 trial to strengthen this patent application.

Other Important Points:

- The Baltic Sea Foundation, a Swedish governmental fund, is Moberg's largest shareholder and has been a long-term investor since 2006.
- Moberg recently received regulatory approval for Terclara in Italy, making it the seventh country out of 13 in the planned launch to approve it as an over-the-counter treatment.
- The company is in the process of qualifying new suppliers for Terbinafine, the active ingredient in Terclara.
- The investor and Anna agree to meet in person at a conference in San Diego in early June.

Overall, the conversation highlights Moberg's recent successes with the launch of Terclara, their strategic focus on securing a U.S. partnership, and their commitment to maximizing the drug's market potential through patent protection and effective pricing strategies.