

Due Diligence for a Pharmaceutical Company Assessing Multi-Therapy IP Asset Acquisition

A U.K.-based liquid pharmaceutical company engaged Clarkston Consulting to perform commercial, operational, and quality due diligence to evaluate an IP asset acquisition of two separate therapy suites from a U.S.-based company. Since the non-tablet target therapies align with their portfolio, the potential acquisition serves as a good expansion opportunity into the U.S. market.

Over the past five years, the market size and competitive landscape for the first therapy suite has increased with the addition of multiple therapies of various dosage strengths and formula types. The non-tablet market has grown due to its ability to provide a more accessible drug formulation and thus steal share from the tablet therapy market. However, the non-tablet market remains a small fraction of the size of the tablet market. The target company currently has two therapies in the non-tablet market and a double strength (DS) version of their therapy in the pipeline. The DS therapy was developed as a defensive strategy to combat the increase in competition in the non-tablet market.

Clarkston included the DS therapy in its evaluation as part of the overall commercial viability of the therapy suite. Through our due diligence, Clarkston confirmed the acquiring company's investment thesis for the first therapy suite and discovered conflicting evidence to the investment thesis for the second therapy suite. Furthermore, we helped set realistic expectations on the timeline for the FDA's approval of the DS therapy. Ultimately, our due diligence work provided the guidance and comfort the client needed in determining the acquisition of the therapies.

Life Sciences Case Study

PROJECT OVERVIEW



INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Generic liquid
pharmaceuticals

PRIMARY OBJECTIVES:

- Evaluated a multi-therapy IP asset acquisition within the pharmaceutical space.
- Performed commercial due diligence to understand the competitiveness of market and market viability of the current therapies and DS therapy as well as determine the size and growth potential of the non-tablet therapy market over the next five years.
- Created a financial model to evaluate Low, Likely, and Lights Out future state projections.
- Performed a high-level operational due diligence of the target's supply chain, third-party logistics, and third-party manufacturing to evaluate potential red flags.
- Completed quality due diligence to assess the conformity of the company against FDA requirements and quality standards.
- Addressed regulatory concerns regarding the likelihood and timelines of FDA approval for the target company's DS therapy.

RESOLUTION:

- Interviewed the leadership team of the target company to gain an understanding of the company's history, current sales strategy, customer targets, therapy coverage, supply chain structure, regulatory setbacks, and the launch strategy for the DS therapy.
- Interviewed industry SMEs to gain a third-party perspective on the pricing and sales structure of the target company's therapies.
- Leveraged Clarkston expertise to provide insight on the timeliness of the FDA approval for the DS therapy.
- Utilized a physician research survey to assess the competitiveness of the DS therapy based on certain attributes and prescribing behaviors.
- Independently created a financial model, inclusive of the DS therapy, in which our Low scenario validated their investment thesis and identified upsides for future market growth.

KEY BENEFITS:

- Gained confidence in the investment in the first therapy suite, which has potential upside over a five-year period.
- Ascertained insight that the non-tablet market is stealing market shares from the tablet market and is projected to continue to expand over the next five years.
- Provided conflicting evidence for the second therapy's investment thesis due to market saturation.
- Obtained a realistic timeline for the FDA's approval of the new DS therapy which helped adjust the launch projections accordingly.
- Informed on ways to improve future processes and procedures based on actionable quality and compliance recommendations.

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