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Due Diligence Report: Game Changing Contract Pushes Price Ahead

Summary

Mediwound Ltd., Incorporated on January 27, 2000, is a biopharmaceutical company focused on developing, manufacturing and commercializing products in the fields of severe burns, chronic and other hard-to-heal wounds, connective tissue disorders and others. The Company's biopharmaceutical product, NexoBrid, received marketing authorization from the European Union agency (EMA) for removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns, also referred to as severe burns. It has launched NexoBrid in Europe and Israel and established a commercial organization for the marketing, sales and distribution of NexoBrid. It also initiated a European pediatric study to broaden the approved indication of NexoBrid and plan to initiate the United States Phase III pivotal study. NexoBrid is a topically-applied product that removes eschar in four hours without harming the surrounding healthy tissues.

The removal of eschar is a procedure also known as debridement. Debridement is a critical first step in the healing of severe burns and chronic and other hard-to-heal wounds. Under existing standard of care (SOC), burn eschar may be removed either by employing certain existing topical agents that have been found to be minimally effective or that take a longer period of time to work, or by resorting to non-selective surgery, which is traumatic and may result in loss of blood and viable tissue. NexoBrid has been investigated across 15 countries and four continents in Six Phase II and Phase III clinical studies. Trial 1 evaluated the safety and efficacy of NexoBrid in hospitalized subjects between 0.5 and 82 years of age with severe burns of up to 67% Total body surface area (TBSA). Trial 2 evaluated the efficacy and safety of three doses of NexoBrid; 20 hospitalized adult subjects, with severe burns of 1-15% TBSA were randomized and provided a one, two or four gram dose of NexoBrid powder per 20 grams of a sterile gel substance, or Gel Vehicle.

The study confirmed that the use of two grams of NexoBrid mixed with 20 grams of Gel Vehicle per 100 square centimeters was a safe and effective dose. Trial 3 evaluated the safety and enzymatic eschar removal efficacy of NexoBrid. A total of 140 hospitalized adult subjects, with severe burns ranging from 2-15% TBSA, were randomized in a 2:1:1 ratio to NexoBrid, Gel Vehicle and SOC treatment. The trial results showed that NexoBrid was a fast and effective enzymatic debriding agent, combining the advantage of early eschar removal with reduced surgical burden. Trial 4 evaluated the safety and exploratory efficacy of NexoBrid in comparison to the Gel Vehicle and SOC in hospitalized adult subjects, with severe burns ranging from 1-5% TBSA. There were 30 hospitalized subjects randomized and provided NexoBrid, the Gel Vehicle or SOC treatment. Trial 5 evaluated the safety and efficacy of NexoBrid. The study was a prospective, controlled, two-arm, parallel, open-label, randomized, multi-center design. It included 182 enrolled patients, between the ages of four and 55, who were hospitalized with severe burn wounds covering from 5-30% TBSA. Trial 6 assessed long-term scar formation and quality of life in adults and children who received NexoBrid or SOC during the Phase III clinical study. The results confirmed that based on the Midwestern Vascular Surgical Society (MVSS) the quality of scars was comparable between the patients who received NexoBrid and those who were treated with SOC.

Mediwound Ltd. has a current market capitalization of $136.08 M with 21.81 M outstanding shares. Its daily average volume traded is 17,235 shares.

Key Indicators (Q1 2015)

Shares Outstanding	21.81 M
Revenue (FY 2014)	0.17 M
Gross Profit	-0.67 M
Net Loss (basic/diluted)	-4.13 M
Cash and Short-term Inv	55.23 M
Total Debt	Nil

Performance (6 months)

Recent News and Analysis:

The Company recently announced that the U.S. Biomedical Advanced Research and Development Authority (BARDA) have awarded the Company a contract valued at up to $112 million. The contract is for the advancement of the development and manufacturing, as well as the procurement of NexoBrid(R), the Company's proprietary pharmaceutical product for enzymatic removal of eschar in adults with deep-partial and full-thickness thermal burns, as a medical countermeasure as part of BARDA preparedness for mass casualty events. The five-year base contract includes $24 million of funding to support development activities to complete the U.S. Food and Drug Administration (FDA) approval process for NexoBrid for use in thermal burn injuries, as well as $16 million for procurement of NexoBrid, which is contingent upon FDA Emergency Use Authorization (EUA) and/or FDA marketing authorization for NexoBrid. In addition, the contract includes options for further funding of up to $22 million for expanding NexoBrid's indications and of up to $50 million for additional procurement of NexoBrid.

Mediwound has been on analysts' minds for some time now, with early signs of movement coming from Zack's Research in late August of 2015. The stock showed slight upward moves and was predicted to move higher in the coming weeks. With the recent announcement of the $112 million contract with BARDA and aid in obtaining FDA approval for NexoBrid, the company has made a massive move in its revenue projection for 2016. From a mere $0.17 million to $112 million over 5 years, the company has been given an opportunity to move up the big leagues.

Conclusions:

Mediwound and its team certainly feel as though their hard work is paying off. From a company that only just started generating revenue in 2014 (annually just a quarter of a million) has seen itself grow overnight after landing this contract with BARDA. Many other benefits come with this contract including additional funding for development of the product and additional procurement. Investors are certainly active in with this ticker and should continue to improve liquidity with further developments resulting from this game changing contract.

Sources:

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