madeleine|pharmaceuticals

A CardioRenal Therapeutics Company

September 2015

Key Success Factors

Madeleine Pharmaceuticals, Inc. ("Madeleine") is a U.S. based biotech firm seeking to develop **Vastiras®** as a leading drug therapy with cardio-renal benefits to be used in hospitalization and post-discharge care, including for heart failure patients.

Overview & Business Description

The genesis of Madeleine began in June 2009 in Australia with Madeleine Pharmaceuticals Pty Ltd. ("Madeleine Pty"). Madeleine Pty was spun out of leading medical company Hospira (NYSE:HSP) which has recently been acquired by Pfizer (NYSE:PFE). Madeleine was incorporated in 2014.

In 2015, Madeleine updated its corporate structure in anticipation of managing and leading the clinical development programs in the U.S. by gaining unencumbered access to the IP in Madeleine Pty. By virtue of its offshore location, Madeleine Pty maintains an Australian presence for Madeleine Inc. for access to regional grants, research expertise and Asian markets among other benefits. Madeleine is supported by an experienced management team, board of directors, and advisors.

Madeleine intends to pursue Food & Drug Administration ("FDA") approval for the manufacturing of **Vastiras®** - formulated to address the recurrence of cardio-renal symptoms in heart failure ("HF") patients prior to and immediately after hospital discharge, which is when they are most vulnerable. Madeleine has the opportunity to position **Vastiras®** as the standard of care that works in concert with other classes of drugs currently at use in the market.

Madeleine will have all the necessary rights to the development and IP protection of **Vastiras®**, for commercialization objectives globally, with a primary focus on the U.S., Americas, and European markets.

Market Opportunity & Product Position

HF Markets are projected at $21.8 billion, providing significant revenue potential for **Vastiras®**. About 20 million people in the U.S and Europe live with heart failure.

HF is the leading cause of re-hospitalization in Medicare beneficiaries over age 55. There is a 30% chance of readmission at 3-6 months, and 20-35% mortality at 1 year after hospitalization.

Hospital treatment and associated costs for HF are at over $20 billion per year, and projected up to $95 billion in 2030 – based on the prevalence of HF to increase by 25% in 2030 [1].

[1] *American Heart Association*

MP3167 will be formulated as **Vastiras®** and **Vastiras®XT** for the vulnerable HF discharge patient as a renal co-therapy, to address renal function and diuretic response in concert with established HF front-line drug therapies. This will support a "continuum of care" beginning at hospitalization and continuing through discharge and compliance at home, in an effort to target lower re-admission rates typical under other HF drugs.

Madeleine is targeting a premium price position, for a solution to reduce a) high re-admission based on accelerated (and potentially premature) discharge and b) passive patient compliance at home.

Using prior research of linear peptides of the pro atrial natriuretic hormone (proANP), Madeleine identified the amino acid sequence 31-67 as a lead candidate for clinical studies:

- **Efficacy & Safety Proven:** Affiliate has sponsored human clinical exposure in over 78 treatments of MP3167
- **Demonstrated cardio-renal benefits for HF patients:**

  a) improved renal function

  b) profound natriuresis and diuresis

  c) preservation and improvement of cardiac performance

  d) no symptomatic hypotension over a range of dosing

  e) a significantly long half-life, and

  f) superior bio-availability when delivered via subcutaneous pump – which combination is not currently available for HF patients in-hospital and at home, from approved drug therapies
- **Proprietary Manufacturing:** Recombinant process for scale, at low cost developed in partnership with Hospira
- **Intellectual Property:** for drug and manufacturing, filings made internationally
- **FDA:** clear path for continued clinical research to support the manufacture and human exposure safety of the peptide to address HF

As MP3167 represents a new drug candidate class with features and benefits for improved cardio-renal function currently not available in the HF markets, the Company is proceeding with plans to drive MP3167 into a U.S. FDA approved phase II trials over the next 24 months:

- ✓ First-in-Patient Phase IIa
- ✓ Renal Hemodynamics Proof of Concept (POC) Phase II