

Making Protein Drugs Even Better

Snapshot

Fall 2010

PROLOR Biotech, Inc. (NYSE Amex: PBTH) is a publicly traded biopharmaceutical company applying its patented technology to develop proprietary, longer-acting versions of therapeutic proteins that require frequent injections. The company focuses on approved protein drugs with established safety and efficacy, an annual market estimated at more than \$50 billion. PROLOR's core technology, discovered by researchers at Washington University, is based on a naturally occurring short amino acid sequence, the Carboxyl Terminal Peptide (CTP). When attached to a therapeutic protein, CTP significantly extends the length of time the protein remains active in the body. PROLOR is currently developing **biobetter**, CTP-modified versions of **human growth hormone, interferon beta, EPO, factor VII and GLP-1**. The drug candidates developed to date have demonstrated excellent safety, significantly longer duration of effect and comparative biological efficacy in animal studies. A Phase II clinical trial of hGH-CTP is ongoing. **Merck**, which has rights to apply the CTP technology to four endocrine proteins, has validated the technology's clinical potential. **Merck** announced on January 28, 2010 that it has received marketing authorization in Europe for its CTP-modified follicle-stimulating hormone (FSH-CTP, named ELONVA®) product – showing that a single injection of FSH-CTP provided the same clinical effect as 7 daily injections of standard FSH. PROLOR's leadership team includes CEO Abraham Havron, who has extensive experience developing protein therapeutics, including Merck Serono's MS drug Rebif, and Chairman and major investor Dr. Phillip Frost, a biopharma entrepreneur best known for his business and financial success in founding, building and selling Key Pharmaceuticals and IVAX Corporation, and currently Chairman of Teva.

Key Points

- **Pipeline** – PROLOR has initiated development of five products using its long acting CTP therapeutic protein platform – **human growth hormone (hGH), interferon-β (IFN-β), erythropoietin (EPO), Factor VII, and glucagon-like peptide-1 (GLP-1)**. These candidates target an existing combined annual market of \$15 to \$20 billion.
- **Validation/Clinical Maturity** – **Merck** announced on January 28, 2010 that it has received marketing authorization in Europe for its CTP-modified follicle-stimulating hormone (FSH-CTP, named ELONVA®) product. A **single injection of FSH-CTP has the same biological effect as 7 daily doses of standard FSH administered over the course of a week**. Previous Phase I, II & III trials also demonstrated that attaching CTP did not affect the therapeutic activity of FSH or cause a negative immune system response in patients.
- **Technology** – CTP is a naturally occurring peptide that evolved in the human body to provide long durability to a certain human protein. It was identified by researchers at Washington University in St. Louis and exclusively licensed to PROLOR for all proteins and peptides except for the four endocrine proteins that are licensed to Merck. PROLOR believes that CTP has the potential to enhance the durability of many protein drugs. To date the technology appears to be safe and effective in extending the duration of all proteins tested. It is manufactured using standard industrial biotech processes.
- **Clinical Data** – In Phase I, a single injection of **hGH-CTP** has shown the potential to replace 14 daily injections of commercial hGH. All safety and tolerability endpoints were met for all participants at all doses. hGH-CTP is currently in Phase II clinical trial.
- **Preclinical Data** – **EPO-CTP** has demonstrated a 33% increase in durability and biological effect over Amgen's Aranesp®. A **single injection of IFN-β-CTP has shown the potential for once every 2-week administration**, compared with the **2-3 times per week** administration required for some commercial forms of IFN-β.
- **Milestones** – Within the next 12 months, PROLOR intends to achieve the following milestones: Report results of hGH-CTP Phase I; Proceed into Phase II clinical trials for hGH-CTP and move forward with its other drug candidates; and Complete one out-licensing partnership agreement.
- **Management** – Company CEO Dr. Abraham Havron was one of the lead developers of Merck Serono's \$1.3 billion MS drug, Rebif® as well as BioTechnology General's hGH drug BioTropin® and hepatitis B vaccine Bio-Hep-B™. President Shai Novik was Chief Operating Officer and head of strategic planning of THCG, Inc., a technology and life sciences investment firm that is a portfolio company of private equity firm Greenwich Street Capital Partners L.P. He holds an MBA with Distinction, from Cornell. Chairman and major shareholder Dr. Phillip Frost was the former Chairman and CEO of IVAX Corp. and holds leadership positions in a number of major biopharmaceutical and financial institutions.
- **Financial Position** – PROLOR completed \$24.4 million stock offering on March 2010.
- **Analyst Coverage** – Andrew Vaino, Ph.D., Roth Capital; Nancy Hull, Ladenburg Thalmann.

This executive overview contains forward-looking statements, including statements regarding the results of current studies and pre-clinical experiments and the effectiveness of PROLOR Biotech's long-acting protein programs and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that forward-looking statements involve risks and uncertainties that may affect PROLOR Biotech's business and prospects, including the risks that PROLOR Biotech may not succeed in developing any commercial products, and that ongoing studies may not continue to show substantial or any activity; and other risks and uncertainties that may cause results to differ materially from those set forth in the forward-looking statements. In addition to the risk factors set forth above, investors should consider the economic, competitive, governmental, technological and other factors discussed in PROLOR Biotech's filings with the Securities and Exchange Commission.