

### PHARMACYTE BIOTECH, INC. Major Diabetes Breakthrough Sets Stage for Human Clinical Trials

Rob Goldman April 15, 2015

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### PHARMACYTE BIOTECH, INC. (OTCQB - PMCB - \$0.154)

NT Price Target: \$0.45, LT Price Target \$1.80 Rating: Speculative Buy

#### **COMPANY SNAPSHOT**

PharmaCyte Biotech is a clinical stage biotechnology company focused on developing and preparing to commercialize treatments for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as Cell-in-a-Box®. This unique and patented technology will be used as a platform upon which treatments for several types of cancer, including advanced, inoperable pancreatic cancer, and diabetes are being built.

#### **KEY STATISTICS**

Price as of 4/14/15	\$0.154
52 Week High – Low	\$0.493 - \$0.095
Est. Shares Outstanding	707.8M
Market Capitalization	\$109M
3 Mo Avg. Vol.	2,762,000
Exchange	OTCQB

#### COMPANY INFORMATION

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#### **KEY TAKEAWAYS**

#### **Major Diabetes Treatment Breakthrough**

A member of PMCB's international Diabetes Consortium, who, along with her team, developed a new, insulin-producing cell line from human liver cells (Melligen), published an article in the scientific journal *Molecular Therapy* illustrating that tests on diabetic mice with transplanted Melligen cells demonstrated an ability to reverse Type 1 diabetes (T1D).

#### Cell-in-a-Box® One Step from Diabetes Phase I Trial

The article noted that in order for the cells to be effective in treating humans with T1D, they must be protected from the body's immune system after introduction. The next step is to engage *in vivo* studies using Cell-in-a-Box® to confirm the Melligen line's viability after encapsulation, as well as other parameters related to its insulin production. Once confirmed, the next stage would be to initiate Phase I human clinical trials.

#### Melligen/Cell-in-a-Box: Diabetes Game-Changer

This recent study notes that the Melligen cell line, when combined with encapsulation, has clear advantages over current insulin injection and pump therapies for Type 1 diabetes. Therefore, the PMCB delivery system approach could potentially replace these therapies.

#### The Diabetes Treatment Numbers Are Staggering

According to Diabetes.org, \$176 billion is spent annually in the U.S. on direct costs attributable to diagnosed diabetes and 1 in 10 health care dollars is spent treating diabetes and its complications. And, diabetes kills more Americans than AIDS and breast cancer combined.

#### **Major Valuation Upgrade Ahead**

Given the diabetes market size, once the next study is completed and a Phase I trial protocol design is underway, PMCB stock could rise by 25-50%, as the technology's effectiveness and flexibility would take center stage. We rate these shares Speculative Buy.



#### **MELLIGEN STUDY HIGHLIGHTS**

As outlined in the article, Type 1 diabetes is caused by the autoimmune destruction of insulin-producing pancreatic  $\beta$ -cells. Current treatment requires daily injections of insulin to control blood glucose levels or transplantation of insulin-secreting tissue. As an alternative to the transplantation of islets, a human liver cell line (Melligen) was genetically engineered to reverse type 1 diabetes (T1D). Numerous tests were completed during the various stages of the development process and studies were carried out to show that Melligen cells secreted insulin in response to physiological concentrations of glucose (blood sugar). Furthermore, when Melligen cells were transplanted into diabetic mice whose immune systems were essentially not functioning, the blood glucose levels of the mice became normal. This observation illustrates that Melligen cells can reverse the diabetic condition.

According to the article, Melligen has meaningful advantages over the current therapies but will require encapsulation in order to truly effective and protected from the body's immune system:

"The utilization of Melligen cells or other nonpancreatic artificial  $\beta$ -cells as a cure for T1D will have an advantage over current insulin therapy regimes, in that the new technology will avoid the autoimmune process and mimic the natural physiological secretion of insulin from the pancreas, delivering the insulin first to the liver and then to the peripheral tissue in response to a glucose load, whereas the insulin delivered by injections or pumps reaches the peripheral tissue first and not the portal circulation. This should both reduce complications by reducing glucose excursions and narrowing the range of glucose concentrations tissues such as the eyes and kidneys are exposed to. This technology would also have the advantage over studies that deliver  $\beta$ -cell transcription factors to the liver, avoiding the need for the use of viral vectors and issues such as exocrine differentiation of liver tissue resulting in hepatitis-like syndromes and abnormal glucose tolerance seen in a number of studies."

The study described the "successful generation of an artificial  $\beta$ -cell line, which, <u>if encapsulated to avoid allograft rejection, may offer a clinically applicable cure for T1D</u>." Melligen cells have already been successfully encapsulated using the Cell-in-a-Box<sup>(R)</sup> process and experiments are already underway.

Armed with these valuable study results, management will likely take steps that will ultimately lead to the initiation of human clinical trials which, in turn, will serve to substantially raise the company's value and its profile. PMCB is clearly not a "one-trick pony" and now has multiple shots on goal with the rights to use the cellulose-based live-cell encapsulation technology in developing treatments for both diabetes and cancer.

<sup>1</sup> http://www.nature.com/articles/mtm201511



#### RECENT TRADING HISTORY FOR PHARMACYTE BIOTECH, INC.

(Source: www.BarChart.com)



## Investment and Company Research Opportunity Research COMPANY UPDATE

#### **SENIOR ANALYST: ROBERT GOLDMAN**

Rob Goldman founded Goldman Small Cap Research in 2009 and has over 20 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

#### **Analyst Certification**

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