PHARMACYTE BIOTECH, INC.

Pancreatic Cancer Treatment Approval Odds Just Moved Higher

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PHARMACYTE BIOTECH, INC. (OTCQB – PMCB – $0.106)	
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 10/23/15	$0.106
52 Week High – Low	$0.27 - $0.069
Est. Shares Outstanding	743.4M
Market Capitalization	$78.8M
3 Mo Avg. Vol.	1, 755,000
Exchange	OTCQB

COMPANY INFORMATION

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INVESTMENT HIGHLIGHTS

Conclusion: Major industry and company news released last week came as very pleasant surprises and take our sentiment regarding the potential of FDA approval for PharmaCyte's pancreatic cancer treatment up a few notches. Therefore, **we believe the near term valuation of these shares should be provided the first of several boosts** heading into the trial launch next year.

Pancreatic Cancer Treatment Peer Receives FDA Approval. Merrimack Pharmaceuticals (NASDAQ – MACK) was awarded FDA approval last week for its treatment designed for patients with metastatic pancreatic cancer. Considering its poor side effect profile and only incrementally positive median survival rate, we believe that the bar has been lowered by the FDA for priority approval of pancreatic cancer therapies which serves as a huge positive for PMCB timing-wise as well.

Hall of Fame CROs and oncologists collaborated on future PMCB trial design and protocols. PMCB announced that the design of the trial was a collaborative effort that included TD2, America's premier Contract Research Organization specializing in oncology (founded by the renowned Dr. Daniel Van Hoff), and other leading oncologists. TD2 will conduct the trial, which will occur in the U.S. enabling swift patient enrollment and should be viewed as a big positive by investors.

New Positioning Enhances Potential Approval Odds. In our view, the MACK approval coupled with PMCB's trial positioning as an expansion of the current standard of care, or consolidation therapy for certain patients, have just upped the ante on the platform's potential success. Thus, we rate these shares Speculative Buy and reiterate our near term price target of $0.45 and a long term target price of $1.80.

PANCREATIC CANCER TRIAL DESIGN AND PROTOCOLS

For months, investors have been waiting with baited breath for management to provide details regarding its planned human clinical trial to treat patients with advanced pancreatic cancer using its signature live-cell encapsulation technology, *Cell-in-a-Box*® with low-doses of ifosfamide chemotherapy. With its two releases of last week, management outlined very specific information that should imbue investors with even greater confidence in the trial's outcome than ever before.

The Players

The design of the trial was a true collaborative effort. The parties included PharmaCyte, Translational Drug Development (TD2), America's premier Contract Research Organization (CRO) specializing in oncology, founded by celebrated oncologist Dr. Daniel Van Hoff, world renowned oncologists Dr. Mathias Löhr of the famed Karolinska Institute in Stockholm and the Chairman of PharmaCyte's Scientific Advisory Board, and Dr. Manuel Hidalgo, Director of Clinical Research at the Spanish National Cancer Research Center and a member of PharmaCyte's Scientific Advisory Board.

TD2 and Clinical Network Services (CNS), recently voted Australia's "best" CRO, will work together conducting the clinical trial. TD2 has assumed the lead role and will be responsible for clinical development plans, program analysis, medical writing, clinical management and database development. PharmaCyte Biotech plans to conduct its pancreatic cancer trial in the U.S., with additional study sites in Europe and Australia. TD2 will conduct the clinical trial in the United States and CNS will conduct the clinical trial in Europe and Australia, in alliance with TD2.

Our Take: This is a great move as the Company should be able to enroll patients at a relatively rapid pace—and certainly a faster one than abroad. Moreover, it will be easier to manage than one overseas. What cannot be overlooked is the weight and authority carried by these well-regarded CRO and oncology partners. They have provided the Company with unique insight and experience into what it takes to initiate and execute a pancreatic cancer therapy trial that has the best possible chance for success. Therefore, their inclusion in the trial design and management process should be viewed as a meaningful positive by investors and even the FDA.

Goals and Endpoints

The overall goal of the trial is to determine whether PharmaCyte's pancreatic cancer treatment (*Cell-in-a-Box*® + low-dose ifosfamide chemotherapy) can satisfy a critical unmet medical need by acting as a consolidation therapy for patients who no longer respond to the combination of nab-paclitaxel (*Abraxane*®) + gemcitabine – currently the "gold standard" for the treatment of pancreatic cancer. Currently, treatments for this group of patients are only marginally effective. The trial will compare the efficacy of PharmaCyte's pancreatic cancer treatment "head-to-head" using several criteria with one of the commonly used treatments for these patients - the combination of the cancer drug capecitabine (*Xeloda*®) + x-radiation. Capecitabine, which can be given orally, is a "prodrug" form of the widely used chemotherapeutic agent 5-fluorouracil (5-FU) that is given intravenously.

The primary endpoints will essentially mirror some of the primary endpoints of other treatments that have received FDA approval, such as Abraxane®. These include *progression-free survival (PFS)* and the *side effects* experienced from the combination treatment that occurs in the patients. PFS is the time that elapses from the first day of treatment until the disease gets worse and will be measured and determined at 6 and 12 months. The occurrence of any side effects will be monitored throughout the trial.

The trial design also includes a series of secondary endpoints. These include:

- Onset of pain and need for pain medications
- Whether inoperable tumors become operable as a result of treatment;
- Change in tumor size; and
- Patient overall quality of life during the treatment.

It is important to note that for purposes of this trial, not all pancreatic cancer patients are eligible to participate. Eligible patients accepted into the trial must have pancreatic cancer that is inoperable, but that has not yet spread from the pancreas where it first started to another place in the body (metastatic cancer). Patients must also have tumors that are no longer responsive to the combination chemotherapy treatment of *Abraxane*® + gemcitabine and that have been on the treatment for a period of between 4-6 months.

Patients will be divided into two groups. Group One will be treated with PharmaCyte's pancreatic cancer treatment. The patients in Group Two will receive treatment with the combination of capecitabine + x-radiation.

Our Take: We have always assumed that PharmaCyte's pancreatic cancer treatment (*Cell-in-a-Box*® + low-dose ifosfamide chemotherapy) might go head-to-head against the gold standard (Abraxane® + gemcitabine) as its primary goal, or at the least, as a secondary marker. Clearly, the Company's clinical trial design team is smarter than we are judging by the subtle wording in the trial design description. In this trial, the Company's treatment is being positioned as an expansion of the current gold standard of care or as a consolidation therapy, rather than a front-line therapy. In our view, this new positioning may prove to be the single most important cog in the trial's success. After all, too often these trials fail due to poor design, endpoint, and protocol planning, rather than treatment efficacy, resulting in companies repeating the same trial twice, with new goals.

In PharmaCyte's case, we believe that by being positioned as the next or last stage therapy for the difficult patient treatment group may be the fastest route to approval, as there is no truly effective therapy for patients at this stage that can materially extend survival rates and improve their quality of life. As a consolidation therapy PharmaCyte plays to the strengths of the *Cell-in-a-Box*® + low-dose ifosfamide chemotherapy, given the very strong one-year survival rates and no side effects in its first clinical trial. Plus, we would not be surprised to see the PMCB combination therapy measure very favorably with the comparator arm of capecitabine + x-radiation.

We should note that while the compilation and measurements of the upcoming trial's primary endpoints on their own and versus the comparator arm are the single most important data, if certain secondary endpoint data, such as tumor shrinkage prove encouraging, they could have a materially favorable impact on a trial's outcome.

MERRIMAC(K) AND THE MONITOR

Civil War buffs will recall that the Monitor and the Merrimac were engaged in the first "Battle of the Ironclad Ships" in 1862. While not head-to-head competitors, Merrimack Pharmaceuticals and PharmaCyte may eventually be referred to in the same breath as these two venerable warships.

Just last week, Merrimack Pharmaceutical's (NASDAQ – MACK) *ONIVYDE* has been approved by the U.S. Food and Drug Administration (FDA) in combination with fluorouracil (5-FU) and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. With this approval, *ONIVYDE* in combination with 5-FU and leucovorin becomes the first and only FDA-approved treatment option for patients in this setting.

There are approximately 49,000 patients diagnosed with pancreatic cancer each year in the United States, the overwhelming majority of who have adenocarcinoma. Most patients receive gemcitabine-based therapy during either adjuvant/neoadjuvant treatment for locally advanced disease or during first- or second-line therapy for metastatic disease, but are left with no standard of care therapy upon progression. *ONIVYDE* in combination with 5-FU and leucovorin is now approved for these patients whose disease has progressed following gemcitabine-based therapy.

While Merrimack's treatment is to be used with patients suffering from metastatic cancer and PharmaCyte is targeting the use of its treatment for patients suffering from locally advanced pancreatic cancer, there are a number of similarities between the two firms. First, both companies received an Orphan Drug Designation relatively early. Second, both are using a form of encapsulation in its treatment. MACK uses a novel encapsulation of irinotecan in a liposomal formulation and PharmaCyte uses a proprietary cellulose-based live cell encapsulation technology. Third, both firms (have or are) using their treatment in combination with a chemotherapeutic agent.

Table I. Merrimack vs. PharmaCyte Biotech

Company	Stock Symbol	Therapy	Treatment Category	Treatment Approach
Merrimack Pharma	MACK	Combo w/ fluorouracil and leucovorin	Patients w/metastatic adenocarcinoma of pancreas after disease progression following gemcitabine-based therapy	Encapsulation
PharmaCyte Biotech	PMCB	Cell-in-a-Box® + low-dose ifosfamide chemotherapy	A consolidation therapy for (non-metastaic cancer) patients no longer responding to Abraxane® + gemcitabine	*Targeted, encapulation, prodrug*

Sources: www.Yahoo!Finance.com, Company websites, Goldman Small Cap Research

Interestingly, MACK received a FDA Priority Review and 10 months later was awarded approval as a treatment following disease progression which follows gemcitabine-therapy. Similarly, PharmaCyte's proposed trial

design calls for use with patients with tumors that are no longer responsive to the combination chemotherapy treatment of *Abraxane*® + gemcitabine and that have been on the treatment for a period of between 4-6 months. The MACK combination therapy includes the use of fluorouracil (5-FU) and leucovorin while the PharmaCyte trial's comparator arm features Capecitabine, which can be given orally, is a "prodrug" form of the widely used chemotherapeutic agent 5-fluorouracil (5-FU) that is given intravenously.

It is important to note that while encapsulation, later stage treatment, and combination therapies are both part of these companies' approaches, there is one huge difference in their profiles, (aside from metastatic versus locally advanced cancer): **SIDE EFFECTS**.

The MACK-approved drug carries a "box-label" warning that the drug could cause severe of life-threatening neutropenia (abnormally low white blood cell count) and sepsis. Plus, *ONIVYDE* can cause severe or life-threatening diarrhea. Conversely, the PharmaCyte side effect profile was excellent in its first clinical trial using one-third the dose of ifosfamide. There were no meaningful side effects in patients receiving PharmaCyte's pancreatic cancer treatment.

Clearly, with such a poor side effect profile, and what could be considered only an incrementally more positive median survival rate, the FDA appears to have lowered the bar for approval of later stage pancreatic cancer treatments. This is great news for PharmaCyte's odds of approval in our view, as we could envision a similar type of approval for PharmaCyte (consolidation therapy but for locally advanced cancer) following a priority review---without the warning label. After all, we expect future results to be similar to the effectiveness and low side effect profile of its encapsulation therapy recorded in a previous trial. Moreover, with some analysts forecasting $1 billion or more in sales in a few years for MACK, PharmaCyte could approach similar top-line figures, upon approval.

RECENT TRADING HISTORY FOR PHARMACYTE BIOTECH, INC.

(Source: www.Stockta.com)

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*.

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