October 8, 2015

PHARMACYTE BIOTECH

(OTCQB – PMCB - $0.092)

Near Term Price Target: $0.45
Long Term Price Target: $1.80

Rating: Speculative Buy

PHARMACYTE BIOTECH, INC.
On The Road to Our $0.45 Near Term Price Target

Rob Goldman
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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 10/7/15	$0.092
52 Week High – Low	$0.27 - $0.069
Est. Shares Outstanding	743.4M
Market Capitalization	$68.4M
3 Mo Avg. Vol.	1,676,000
Exchange	OTCQB

COMPANY INFORMATION

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INVESTMENT HIGHLIGHTS

PharmaCyte Biotech is an innovative biotechnology company whose delivery platform could emerge as the preferred combination therapy for different types of cancer and the go-to therapy for the treatment of diabetes. Each of these categories represents billions of dollars in market opportunity.

Building on the strength of its novel platform, *Cell-in-a-Box*®, PMCB could soon announce it has been awarded Orphan Drug Status in Europe for its pancreatic cancer treatment, which follows last year's similar designation in the U.S. This award would be the first of several key catalyst-driving milestones over the next few quarters.

PMCB is in the middle/late innings of its preparation to initiate a highly anticipated Phase 2b clinical trial, whose launch should serve as major valuation boost to its stock. This multi-site trial will combine *Cell-in-a-Box*® with a low dose of ifosfamide, in an effort to treat patients with locally, advanced pancreatic cancer.

In addition to its recent tests and prospective trials to treat other forms of cancer, early 2015 studies suggest that PharmaCyte Biotech's *Cell-in-a-Box*® platform could be considered the Holy Grail of treatment for diabetes. Directly or indirectly affecting millions, progress on this front should eventually be far more lucrative than even its anti-cancer efforts and take PMCB to our long term price target.

Caution: Huge upside ahead as these shares appear greatly undervalued and grossly overlooked. PMCB trades at a significant discount to our Pancreatic Cancer Peer Group. Development progress culminating in the commencement of the Phase 2b should sharply raise the value of this news-driven stock to our near term target, thus narrowing the peer group discount. We rate these shares Speculative Buy with a near term price target of $0.45 and a long term target price of $1.80.

PHARMACYTE BIOTECH: AT A GLANCE

- PMCB owns exclusive rights to a delivery platform that could emerge as the first universal therapy and treatment of choice for multiple cancers and diabetes, potentially worth billions in annual sales down the road. PMCB was granted the coveted Orphan Drug designation by the FDA for its pancreatic cancer treatment, which is used as a combination therapy with ifosfamide.
- Favorable legacy and updated results from early to mid-stage pancreatic cancer clinical trials will be followed by the commencement of a Phase 2b clinical trial in 1Q 2016.
- Management is in the midst of preparing to launch the multi-site Phase 2b trial, and preclinical trials to treat the accumulation of ascites related to abdominal cancers using the Company's platform technology are ongoing, thanks in part to one of the leading authorities on pancreatic cancer, Dr. Daniel Von Hoff.
- Studies are underway that will ultimately help affirm the Company's thesis that the *Cell-in-a-Box*® technology could revolutionize diabetes treatment, and lead toward future, diabetes-centric clinical trials.
- Management is actively engaged in pursuing the use of compounds from the Cannabis plant (known as "cannabinoids") in combination with its *Cell-in-a-Box*® platform technology to treat deadly cancers where there are no substantially effective treatments on the market.
- With multiple shots on goal we believe that PMCB's stock is overlooked and undervalued, relative to its peer groups. Plus, the shares represent a tremendous value and opportunity as they were caught up in the recent industry-wide biotech stock sell-off.

Today, the primary driver of these shares is related to clinical development progress on the oncology treatment side of PharmaCyte Biotech's business. These events will be followed by clinical development progress on the diabetes side. As a result, this report provides an overview of PharmaCyte Biotech's efforts in treating cancer, diabetes, the associated milestones, and the Company's valuation.

CANCER: A PRIMER

Over the past several decades, cancer screening and prevention have been huge tools in the cancer fight, but there is still no single approved treatment that could be considered the "holy grail." In fact, there are multiple approaches to cancer treatment that may be a part of radiation or chemotherapy. The American Cancer Society highlights the most common approaches in practice and under development, today. These include immunotherapy and targeted therapy.

"Doctors use chemotherapy to kill cancer cells. The term chemotherapy refers to the use of drugs to kill cancer cells. Usually, the drugs are given into a vein (or IV) or they're taken by mouth. Chemo drugs then travel through the body in the bloodstream, reaching cancer cells that may have spread (metastasized) from the tumor to other places in the body."

"**Immunotherapy** is treatment designed to boost the cancer patient's own immune system to help fight the cancer. **Targeted therapy** is treatment that targets the cancer cells and causes less damage to healthy cells…".

Some of these approaches, especially targeted therapy, can combine treatment methods in order to stop cancer cells from spreading, promote cell death, kill cells, etc. While some cancers are treatable and carry favorable survivability rates, in other cases, therapies have been designed to incrementally raise survival rates

and increase the quality of life, in untreatable or terminal patients. Some of the companies that have developed such treatments have received Federal Drug Administration (FDA) approval for their treatments. However, since the current overall relative state of cancer treatment is poor, there are hundreds of ongoing and pending trials whose objectives are to move along the developmental path to ultimately obtain FDA approval to use their therapy for treatment.

If successful, we believe that PMCB could emerge as the universal therapy or "go-to" treatment for multiple cancers.

Pancreatic Cancer-The Unmet Need

There is a highly unmet medical need for all pancreatic cancer patients as survival rates from this disease are consistently the lowest of all solid tumors. Today, the surgical removal of pancreatic cancer tumors followed by chemotherapy tends to prevent relapses in only 20% of all patients. Pancreatic cancer is already one of the leading causes of cancer-related deaths.

The large remaining group of patients whose tumors are inoperable may receive palliative chemotherapy (treatment designed to prolong survival and ease symptoms), but these patients only exhibit survival rates of around 6 months. Recent progress in the chemotherapy of pancreatic cancer has pushed this survival to 10-11 months through the use of either the combination of gemcitabine and Abraxane® or a combination of conventional cancer chemotherapy drugs, known as FOLFIRINOX, that not all patients can reportedly tolerate.

What about patients with locally advanced disease (LAD) whose tumors are inoperable due to overgrowth of the arterial blood vessels? The current practice is to treat these patients using gemcitabine plus Abraxane® or FOLFIRINOX to reduce the size of their tumors to the point where they become operable. However, this chemotherapy only works in about 20% of patients with LAD.

It should be noted that with about 30% of patients that are treated with neoadjuvant chemotherapy, their tumors advance and spread to other organs. This makes their primary pancreatic cancer tumors no longer eligible for curative surgery, and therapy is usually continued as a palliative measure.

However, for the group (about 50%) of patients whose tumors neither progress nor show signs of tumor reduction, there is no effective treatment alternative. For this cadre of patients, a targeted and localized tumor therapy, such as that being developed by PharmaCyte Biotech, could present a welcome therapeutic option.

THE CELL-IN-A-BOX® TECHNOLOGY

Following a series of transactions ending in 2013, PhamaCyte Biotech acquired exclusive, worldwide rights to use a proprietary cellulose-based live-cell encapsulation technology for the development of treatments for all forms of cancer and exclusive, worldwide license to use the same technology to treat diabetes, using the trademarked name for the technology, *Cell-in-a-Box*®. In 2014, the Company also acquired an exclusive, worldwide license to use that same technology in combination with compounds from constituents of *Cannabis* for the development of disease treatments.[1] Multiple animal studies and clinical trials were completed, including a successful Phase I/II clinical trial to treat inoperable pancreatic cancer in the early-2000's.

[1] http://yahoo.brand.edgar-online.com/displayfilinginfo.aspx?FilingID=10563865-1072-89972&type=sect&TabIndex=2&dcn=0001019687-15-000953&nav=1&src=Yahoo

This patented live-cell encapsulation technology enables the targeted placement of almost any cell type into the body after enclosing the cells inside tiny beads about the size of a pinhead. This platform technology does not encapsulate drugs, but live cells. Depending on the cell type placed into the beads, or encapsulated, these cells enable continuous and/or controlled production and release of targeted therapeutic molecules via an innovative delivery system. The capsules enclosing the live cells are made largely from cellulose a bio-inert, non-toxic, biocompatible material that protects the encapsulated cells from attack by the body's defense mechanisms. At the same time, the beads provide a microenvironment that enables encapsulated cells to survive for long periods of time, even when frozen and thawed, which is a major advantage over other encapsulation technologies. There is no other encapsulation technology on the market that has these properties.

By using the technology, it is possible to create small cell-based factories that can be made to 1) convert *inactive* chemotherapy drugs into *active* ones, 2) produce bioactive therapeutic substances, and for numerous other applications. In the case of the drug-converting "factories" and their use in cancer therapy, capsules with the activating cells are placed as close to the site of the tumor as possible to create a continuous high concentration of active cancer fighting molecules and in effect provide a dramatically elevated dose of active drugs right where they're needed, the tumor.[2] This is targeted chemotherapy in every sense of the word.

CURRENT APPROVED TREATMENTS

Gemzar® (also known as gemcitabine), first approved in 1997, is still the only drug approved to date as a single agent for the treatment for advanced pancreatic cancer. According to the American Cancer Society, 49,000 people in the U.S. are diagnosed with pancreatic cancer each year and 41,000 die from the disease.[3] Since the gemcitabine therapy results alone leave a lot to be desired, a drug called Abraxane®, produced and sold by Celgene (NASDAQ – CELG - NR) is now used in combination with gemcitabine. This combination has been the "gold standard" for the treatment of advanced, inoperable pancreatic cancer since its approval by the FDA in 2013. It has been a big seller, with $848 million in total cancer treatment sales in 2014,[4] even though the use of the gemcitabine/Abraxane combination for pancreatic cancer still only increases average survival time of patients with the disease incrementally as compared to gemcitabine alone.

Results from the pivotal Phase 3 study used to obtain regulatory approval of the gemcitabine/Abraxane® combination revealed that 35% people on the combination were alive at the end of the first year compared to only 22% who just underwent treatment with gemcitabine alone. Those were solely on gemcitabine chemotherapy survived for only 6.7 months compared to a median of 8.5 months among those who also took Abraxane®.[5] To put this in perspective, the price tag for Abraxane®, is a hefty $28,000 a year for a small increase in survival rate, which is a main reason why the U.K. has not approved it for reimbursement.[6]

The combination of the Cell-in-a-Box® technology with the anti-cancer drug ifosfamide has been shown in Phase I/II trials conducted in the early 2000s to be effective in treating patients with advanced inoperable

[2] http://www.pharmacytebiotech.com/live-cell-encapsulation/

[3] http://www.cancer.org/cancer/pancreaticcancer/overviewguide/pancreatic-cancer-overview-key-statistics

[4] http://finance.yahoo.com/news/celgene-reports-fourth-quarter-full-123000735.html

[5] http://www.medicalnewstoday.com/articles/255388.php

[6] http://www.firstwordpharma.com/node/1234052#axzz3Utv1TR5I

pancreatic cancer. When the data from those trials were compared with historical data for Gemzar® alone (the only drug approved at the time to treat the disease), the median survival time was increased to about10 months (from 5.7 months for Gemzar®) using the PMCB treatment and the one-year survival rate with treatment (36%) was double that seen with Gemzar® (18%). Tumor sizes were also reduced from 25-50% in 4 out of 14 patients and no serious treatment-related side-effects were experienced using the Cell-in-a-Box® plus ifosfamide combination. This is because only one-third the dose of ifosfamide normally employed in treating other forms of cancer was used in this Phase I/II trial because of the unique nature of the Cell-in-a-Box®-targeted treatment.

For a second Phase II trial more recently led by the same principal investigator as the previous trial, results were published in the medical journal *Pharmaceutics*. [7] In total, 27 patients with advanced, inoperable pancreatic cancer have been treated with the Cell-in-a-Box®/ifosfamide combination – 14 in the Phase I/II clinical trial and 13 in the second Phase II clinical trial. For the second Phase II trial, the dose of ifosfamide was double that used in the Phase I/II trial. Surprisingly, doubling the dose of ifosfamide did not increase the antitumor effectiveness of the treatment but it substantially increased the severity of the side effects associated with treatment. Therefore, the combination of Cell-in-a-Box® and one-third of the "normal" dose of ifosfamide will likely be used for future clinical trials.

PHASE 2B TRIAL: WHAT'S NEW AND WHAT'S PENDING

A number of steps must be completed prior to the commencement of a clinical trial. Based upon recent news, we infer that the Company is in the middle innings of the preparation for its Phase IIb clinical trial in pancreatic cancer. To date, management has selected a CRO (Clinical Research Organization), and significant progress has been made on a cGMP (Good Manufacturing Practices-compliant) facility in Singapore for the encapsulation of the genetically modified human cells using the Cell-in-a-Box® technology. Plus, the Company has hired industry-leading firms to assist with the Investigational New Drug (IND) application, the chemistry, manufacturing controls section of that application, for radiology imaging that will be needed for its upcoming clinical trial and successfully recruited oncology all-stars to join the PharmaCyte Biotech advisory board.

Serving as catalysts to boost the shares, the most important next steps include:

- Inspection of the encapsulation facility to ensure cGMP compliance
- Finalizing members of the IND (Dream) team to aid in the last few steps which include:
    - Selection of trial study sites
    - Trial protocol and design
    - Pre-IND meeting with FDA
    - IND application filing.
    - FDA approval to move forward.
    - Encapsulation of cells for the trial.
    - Enrolling patients to the trial.

Separately, securing the Orphan Drug Designation in Europe for the PMCB pancreatic is a major coup in our view, and follows the award of a similar designation in the U.S. last year. With the Orphan Designation, PharmaCyte Biotech will be provided 10 years of marketing exclusivity throughout Europe for its pancreatic cancer treatment.

[7] http://www.pharmacytebiotech.com/nuvilex-announces-publication-combined-results-initial-phase-12-clinical-trial-second-phase-2-clinical-trial-cell-boxr-plus-ifosfamide-combination-patients-advan/

PharmaCyte Biotech's CRO in Australia and Europe will finalize the documents required for submission and final consideration, to the EMA. Once the European Commission has approved the documents, PharmaCyte Biotech will make an announcement.

OTHER PMCB TRIALS AND STUDIES

Translational Drug Development (TD2), whose Chief Development Officer is Dr. Daniel Van Hoff, is arguably the leading authority on pancreatic cancer. In recent months, TD2 has been conducting preclinical studies to determine the ability of *Cell-in-a-Box*® plus low-doses of ifosfamide combination to delay the accumulation of malignant ascites fluid produced by abdominal cancers. The accumulation of this fluid that occurs in those with pancreatic as well as other abdominal cancers can be very problematic. It is painful when it occurs, and the gross swelling of the abdomen that it causes can be very problematic for patients because it can cause breathing difficulties and may result in new malignant tumors being formed. Therefore, this fluid must be removed on a regular periodic basis; this is a difficult process for the oncologists, is painful for the patients and can be quite expensive. There is currently no effective treatment for malignant ascites accumulation. Initial preclinical studies (in the U.S) of the *Cell-in-a-Box*® plus ifosfamide combination, indicated that it might be effective in reducing the rate of accumulation of ascites fluid. These preclinical studies could lead to a future clinical trial that may show that this combination is an effective treatment that can slow down the accumulation of malignant ascites fluid. Given the TD2 relationship, the launch of a Phase 1 trial in 2016 could be in the cards.

In July 2014, in the medical journal PLOS ONE, the Company announced that very encouraging results obtained in a veterinary Phase I/II trial in dogs bearing spontaneously occurring mammary cancers. This is a good animal model for breast cancer in humans. The major difference between this veterinary trial and the previous Phase I/II trial in pancreatic cancer was that in the former, the treatment consisted of the combination of *Cell-in-a-Box*® capsules plus the cancer drug cyclophosphamide wheras in the latter, *Cell-in-a-Box*® plus ifosfamide was used. However, since both cyclophosphamide and ifosfamide are "sister" drugs and are converted to their cancer-killing forms in the same way, the same type of encapsulated cells were used in both the pancreatic and mammary cancer studies. As in the human pancreatic cancer trials, the capsules were well tolerated in the mammary cancer trials, with no major safety issues. Importantly, significantly greater degrees of tumor shrinkage were observed in those dogs treated with encapsulated cells in combination with cyclophosphamide versus those dogs receiving cyclophosphamide alone. Therefore, it is evident that the results of this animal trial could lead to a future successful human breast cancer clinical trial that utilizes the *Cell-in-a-Box*® live-cell encapsulation platform.

Considering that Celgene's Abraxane® was initially approved for breast cancer and then pancreatic cancer, there may be a relationship between efficacy of treatments for the two cancers. Prevention and treatment of breast cancer that is diagnosed in 200,000+ women and kills over 40,000 in the U.S. alone each year is now a multi-billion dollar industry unto itself, highlighted by mammograms, other tests, involvement of multiple non-profit organizations, etc.[8] Moreover, breast cancer appears to be affecting younger and younger women each year. As a result, when firms gain even modest success in their quest for ever more effective treatment for breast cancer, their stocks enjoy huge gains because of the market size and high profile of the disease. Therefore, progress in this treatment category could potentially prove to be worth substantial sales with potential human clinical trials in the exploratory stage.

[8] http://www.breastcancer.org/symptoms/understand_bc/statistics

DIABETES

As noted above, PMCB acquired the exclusive worldwide rights to use the cellulose-based live-cell encapsulation technology for the development of treatments for diabetes. **This treatment category represents an even larger opportunity for the company than its current cancer treatment initiatives, as there is no cure for diabetes and the current insulin replacement technologies certainly leave much room for improvement, as anyone with insulin-dependent diabetes will attest.**

According to a report by Transparency Market Research, entitled 'Global Diabetes Devices Market and Diabetes Drugs Market – Industry Scenario, Trends, Analysis, Size, Share and Forecast, 2011 - 2018,' the global diabetes market for therapeutic devices and drugs is expected to reach US $114.3 billion by 2018. After all, diabetes kills more Americans than AIDS and breast cancer combined.

Since the year 2000, efforts have been made to develop treatments for Type 1 diabetes that do not involve multiple daily injections of insulin to control the blood sugar levels of individuals suffering from this disease including the use of encapsulation techniques. However, the success of these approaches is somewhat limited because the encapsulation material used in such studies is often alginate, a derivative of seaweed. Compared to PharmaCyte Biotech's cellulose-based capsules, alginate-based capsules have a rather limited lifetime in the body and need to be replaced, and the insulin-producing capacity of the islet cells within such capsules is difficult to maintain. In addition, the use and/or supply of human or pig islet, cells which are responsible for producing insulin, can be very problematic.

PharmaCyte Biotech has approached these problems by deciding to use the Cell-in-a-Box® technology to encapsulate insulin-producing cells that are not pancreatic islet cells but rather genetically engineered human cells. For PharmaCyte Biotech's initial efforts to develop a treatment for Type 1 diabetes, it has obtained the rights to a human, new, non-pancreatic, insulin-producing cell line derived from human liver cells; this cell line is known as Melligen cells.

The developer of the cells, who serves as a member of PMCB's international Diabetes Consortium, published an article in the scientific journal *Molecular Therapy*[i] illustrating that tests on diabetic mice with transplanted Melligen cells demonstrated an ability to reverse Type 1 diabetes (T1D). 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, which is where PMCB comes in. The Melligen cell line, when combined with *Cell-in-a-Box*® encapsulation, could ultimately become a treatment that has clear advantages over current insulin injection and pump therapies for Type 1 diabetes. Therefore, the PMCB *Cell-in-a-Box*® -based treatment system approach could potentially replace these therapies.

The next step is to engage *in vivo* studies using *Cell-in-a-Box*® to confirm the Melligen line's viability after encapsulation, and other parameters related to its insulin production. Once confirmed, the next stage would be to initiate Phase I human clinical trials, which will be watched very closely by doctors and patients alike.

RISKS

As is the case with most mid-stage biotechs, the major risks to these shares include delays in launching of trials and studies and access to capital to commence and conduct these trials. Of course, poor results from trials are the greatest overall risk to these shares and other biotech stocks. However, given the results thus far, major additions in leadership and validation of the technology mitigate many of these risks. Plus, we believe management does indeed have access to the capital necessary to conduct near term trials because of these strengths. Risks associated with PMCB trading as a non-NASDAQ security can include liquidity and

other related issues such as greater than average volatility. All of these risks are typical of firms PMCB's size and standing.

VALUATION AND CONCLUSION

In our view, based upon the valuations of the peer group below, and PMCB's current standing, PMCB's shares are undervalued. As evidenced by the market caps of the companies in the table below, publicly traded biotechs tend to trade based upon milestone developmental events and size of the market opportunity, with tens of millions or even hundreds of millions in market cap associated with various stages. Plus, certain approaches can be valued greater than others. Given its combination targeted therapy with unique encapsulation technology that activates chemotherapy drugs into their cancer killing form and the potential of its use as a universal therapy in the health care fields biggest treatment markets, PMCB has more in its corner than higher valuation peers, yet trades at a huge discount. Moreover, PMCB's combo therapy has demonstrated clinical trial success in treating the most locally advanced forms of the disease, whereas for the most part, all but Threshold Pharma (NASDAQ – THLD – NR) have designed approaches to serve as first-line-of defense or a mid-stage therapy, a lower hanging fruit than the PMCB target market, which is inherently more valuable.

Table I. Pharmacyte Biotech Mid Stage Pancreatic Cancer Peer Group

Small Cap Companies

Company Name	Stock Symbol	Price (10/1/15)	Mkt Cap (mil)	% from Hi	Current Clinical Stage	Treatment Approach
Halozyme Therapeutics	HALO	$13.43	$1,680	47%	Phase 2	Targeted Inhibitor
Merrimack Pharma	MACK	$8.51	$950	39%	NDA Prep	Encapsulation
NewLink Genetics	NLNK	$35.84	$1,000	39%	Phase 3	Immunotherapy
Rexahn Pharma	RNN	$0.52	$94	46%	Phase I	Targeted Inhibitor
Threshold Pharma	THLD	$4.07	$290	23%	Phase 3	Targeted prodrug
Average			*$803*	*39%*		
PharmaCyte Biotech	***PMCB***	***$0.09***	***$66***	**67%**	***Phase 2***	***Targeted, encap, prodrug***
Celgene	*CELG*	*$108.17*	*$85,000*	23%	*Approved*	*Chemotherapy*

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

Judging by these figures, a case could be made that PMCB should at least trade around two-thirds of THLD's valuation once the Phase 2b trial commences, with increases in market value occurring with the closing of each major milestone (i.e., cGMP approval, Pre-IND meeting, IND filing).

Given the huge market opportunity for the lucrative diabetes treatment segment, we believe that even before Phase 2b interim results are released, a successful Phase 1 diabetes trial could be the driver to take PMCB toward our $1.80 long term target, given the unique approach, and high valuations among peers..

The bottom line? The very nature of the *Cell-in-a-Box*®-based disease treatments and their therapeutic indications are unique relative to existing therapies. Such treatments may ultimately be used to treat multiple forms of cancer and diabetes. Therefore, we may be witnessing the dawn of new therapies for these diseases.

RECENT TRADING HISTORY FOR PHARMACYTE BIOTECH, INC.

(Source: www.BarChart.com)

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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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