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Cell-in-a-Box® Technology Platform offering hope in the treatment of Pancreatic Cancer, Breast Cancer, Malignant Ascites Fluid and Diabetes

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"We believe we are in the midst of making medical history in the way solid tumors are treated. We also believe that we have an opportunity to provide a treatment for malignant ascites, where none has previously existed, and to our knowledge no one is working on. Then, of course, we are tackling the largest healthcare problem in the world with our novel platform technology."- Kenneth L. Waggoner, JD, CEO

CEOCFO: ***Mr. Waggoner, would you tell us about how you came to be with PharmaCyte and how long you have been with the company?***
Mr. Waggoner: I was working for a startup company when one of the Board members of the Company, known then as Nuvilex, asked me to join the Company to reorganize it and advance its technology in the field of cancer and diabetes. At the time, it was a nutraceutical company that was trying to change into a pure biotech play. He knew my background in business and law well and that the job required both skill sets. He called in January of 2012 the first time. I was engaged fulfilling an obligation to another startup company and passed on this opportunity at that time. Every-six-months he would call. In August of 2013 he made a final plea. It just happened to be a time when I had decided to go back into the practice of law for a major law firm. This time, I looked closely at the technology that he had been so excited about on every call. At that time, the Company had a platform technology for the treatment of cancer and diabetes, but the technology was not being advanced. After looking at the technology more carefully, I ran it by one of my former law partners who also runs a biotech company. He said that if the technology proves to be what it appears to be, this could make medical history and

that I should join the Company, because of my background in management and law. I came on board in September of 2013 as a consultant, and then in late 2013 took over as CEO and President. Not long thereafter, I took on the responsibility of being General Counsel as well.

CEOCFO: ***Would you tell us about your role as CEO?***
Mr. Waggoner: It is a defined role. I am CEO, president and general counsel. I establish the goals and strategies for the Company. Together with Dr. Gerald W. Crabtree, we implement them with help from professional colleagues who work with us as consultants and as part of our management team. We have orchestrated what has become a worldwide organization with some of the best and brightest physicians and scientists around the globe. We took a relatively small company and have achieved some rather remarkable things with it in a very brief period for a biotech company. We are poised to inaugurate our platform technology in the U.S. and Europe in the field of cancer. We call the platform technology, "Cell-in-a-Box®." We are about to introduce it to the United States the very first time. The technology was actively being developed in the late 1990s through the mid-2000s. It was picked up by the Company in early 2011, but not much happened between then and when I joined the Company.

CEOCFO: ***Dr. Crabtree, would you tell us about your role and how long you have been with PharmaCyte?***
Dr. Crabtree: I have been in the cancer drug development and treatment development area, since graduate school back in the late 1960s. I have been around the block a few times. I spent fifteen years at Brown University on the faculty there. About half the time at Brown I spent most of my time in Roger Williams Cancer Center, which was associated with Brown University. I was fortunate to be working with one of the best oncologists of that time. We developed several drugs to early stages of development. We did early clinical trials on several of them. One of these agents ultimately became a fully functional drug in terms of sales for a well-known pharmaceutical company. Following that, I spent six years in southern California running the Department of Molecular Pharmacology for ICN Pharmaceuticals, Inc., where we examined the anti-tumor and anti-viral activity of a variety of compounds that were produced by the company's medicinal chemists. Then in 1990, I was recruited by Bristol-Myers Squibb to establish a department of Project Planning and Management for oncology and immunology. Personally, I was tasked with coordinating the development of three different drugs. By far the most important of these was a drug called Taxol®, which is pretty well known in the cancer business. It was recognized as the most important cancer drug developed during the 1990s and it ultimately made Bristol-Myers Squibb $15-17 billion, I believe. Following that, I left Bristol-Myers Squibb in 1996 or early 1997 and did a lot of consulting with various biotech companies and helped them in the project management area to develop their products. In the year 2000, I joined a biotech company in Cambridge, Massachusetts called ETEX Corporation as VP of R&D for the oncology part of their company. ETEX was actually a medical device company that wanted to use their main product, which was a form of calcium phosphate, as a depot to enable the controlled release of cancer drugs. That was very popular area for study at that time. When I left there in about 2005, I consulted with another biotech company that was working on a traditional Chinese medicine formulation to assist in the chemotherapy of colorectal cancer initially. Later, that same formulation was used in trials for primary liver cancer as well as pancreatic cancer. I joined what was then Nuvilex in 2011. When I first joined, we had not yet acquired the Cell-in-a-Box technology that Ken mentioned earlier. We soon did acquire it, and I have been with the Company ever since. This technology is so different from anything else that I have been exposed to in the cancer field and I have heard the same thing from a lot of prominent oncologists. The use of the Cell-in-a-Box encapsulation technology together with a cancer prodrug is a brand-new way to look at the treatment of solid tumors. Solid tumors are the tough ones to treat. For leukemias, we have treatments, some of which are very good, but solid tumors are still a problem. The reason is that it is hard to get a high enough concentration of an effective drug to the tumor so that it will destroy the tumor cells and not have side-effects that make its use impossible.

CEOCFO: ***Why is Cell-in-a-Box so exciting and what is different from what they have been trying to do with cancer? Is this an adjuvant where you will be using it with other cancer drugs or is this a standalone product that could knock out a solid tumor?***
Mr. Waggoner: Cell-in-a-Box is a platform technology we are using for the treatment of cancer and diabetes. We encapsulate genetically modified live cells in small capsules, to treat diseases, which in our case is diabetes and cancer. What we do for cancer is encapsulate live human genetically engineered cells that are capable of converting an inactive chemotherapy drug, or more accurately a prodrug, from its inactive form to its cancer-killing form. In our case, for use against pancreatic cancer, this prodrug is ifosfamide, which is normally activated in the liver. What we do is first encapsulate these prodrug-activating cells and then implant the capsules containing the cells as near to the site of the tumor as possible. Once that is done, we give the patient low doses of ifosfamide intravenously. As the ifosfamide is carried by the blood to where these capsules are sitting near the tumor, it then enters the capsules through slits or pores that allow nutrients and oxygen to enter the capsules and feed the cells inside them. Ifosfamide enters the capsules through these slits as well. When it does, the ifosfamide is converted from its inactive form to its active form. It's as though you have an artificial liver right at the site of the tumor. We get optimal cancer cell-killing effect because the

concentration of the active form of ifosfamide is at its highest as it leaves the capsules. That's remarkable. But what makes it even better is that our treatment results in no treatment-related side effects. For diabetes, we use the same Cell-in-a-Box live cell encapsulation technology, but with a different cell line. For diabetes, we encapsulate cells that have been genetically modified to read your blood glucose levels, produce insulin, store it and then release the insulin when needed by person with diabetes. This cell line was developed by a Professor Ann Simpson and her colleagues at the University of Technology Sydney in Australia. The cells are called Melligen. We plan to encapsulated Melligen cells and implant them in the body to act as a type of bio-artificial pancreas for producing insulin. There is a lot more to what we do, but I think we are best served by talking more about our cancer program because that is the area that is most advanced and is the one that is close to entering into the clinic here in the U.S. and Europe. Gerry will talk about the mechanisms of action and how unique this is from any other way of treating solid tumors, as well as the potential it has for changing the way solid tumors are treated forever.

CEOCFO: ***Will you also tell us what causes the cell death in the cancer?***
Dr. Crabtree: Let me take a step back. One of the big things that people in cancer treatment have tried to do for many years is develop what are known as targeted therapies for specific solid tumors. All types of cancer are not the same and they all have to be treated differently. There are certain cases where targeted chemotherapies have been developed. A prime example of that is a drug called Herceptin® that was originally developed by Genentech, but is now owned by Roche. Herceptin is directed to a specific population of cells in breast cancer patients with genetically inherited disease; not in all breast cancer patients, but in about 20-25% of them. This drug is so target-oriented that it goes to those cancer cells that have increased ability to react to Herceptin, binds to them and stops their growth. That is an example of targeted chemotherapy. I look at this chemotherapy that we have that uses Cell-in-a-Box, as being a targeted chemotherapy as well. The difference is that what we are doing is planting a target very close to the tumor and then a prodrug is given that hits that target and then this prodrug is activated or converted into its cancer-killing form right near the tumor. The drug we use in our pancreatic cancer work is ifosfamide, an old drug that has been around for a long time, and it has been widely used for different cancers. It is, by itself, active against pancreatic cancer; however, the doses that you need to give to get any positive anticancer activity are so high that very serious and even deadly side-effects can occur. Again, what we at PharmaCyte do is take Cell-in-a-Box capsules that contain cells that are genetically engineered to contain an enzyme that converts the ifosfamide into its cancer-killing form. During this conversion, ifosfamide is metabolized into two different substances and one of them is the cancer-killing form of the drug. If you had cancer cells in a Petri dish and you put ifosfamide in there by itself, probably nothing would happen. The cancer cells would just grow happily and reproduce. What we are doing really is setting up a little ifosfamide-activation factory very close to the site of the tumor itself. Once the ifosfamide prodrug gets into the Cell-in-a-Box capsules, it is converted into the active form of this drug which then kills the cells of the pancreatic cancer. This is an amazing thing to me because I have never seen anything like it. The whole premise is different from what normal cancer chemotherapeutic people like me have been used to. We are used to searching for and discovering drugs from all different sources or making drugs and testing them and trying to find something that is effective against the tumor and does not kill the patient. This way, because we are putting an artificial liver or a little ifosfamide activation factory right next to the tumor, we are able to use a low concentration of the cancer drug, essentially one-third of the normal dose of ifosfamide, when we give the drug after the capsules are implanted. This is enough to kill a significant percentage of the cancer cells in the pancreatic cancer. That is the advantage of this technology as I see it. However, its use is not limited to pancreatic cancer. We could use it for other types of solid tumors. In fact, we have preclinical data from a study of breast cancer in dogs, but we do not use Ifosfamide in this case. We use the exact same capsules with the exact same cells inside them as for pancreatic cancer, but here we use a different drug called cyclophosphamide. This drug is well known and used in a variety of combination chemotherapies for breast cancer. It is a sister drug to ifosfamide. Like ifosfamide, it is inactive in its own right and must be activated. Normally, as for ifosfamide, that activation occurs in the liver but in our case we are putting the activation factory close to the tumor. In the clinical dog study, these were dogs that had spontaneously occurring mammary tumors so they are a perfect model for human breast cancer. What we did in this case was implant groups of the Cell-in-a-Box capsules at several locations around the tumor itself and then gave cyclophosphamide and got remarkable anti-tumor effects.

CEOCFO: ***You also mentioned diabetes, how does this Cell-in-a-Box relate in trying to treat or cure diabetes?***
Dr. Crabtree: For diabetes, we use the same Cell-in-a-Box encapsulation process. The difference is the cell type that we are encapsulating. These capsules are perfect spheres. They are about 0.7 millimeters in diameter. They are not microscopic, but they are quite small. Each capsule, in the case of pancreatic cancer, holds about 10 thousand cells. In the case of diabetes, we are using a totally different cell line that was developed in Australia. The cell line is a genetically altered form of a human liver cell. This cell line is called Melligen and has been designed to produce, store, and release insulin on demand. For people that have Type I diabetes, their pancreas cannot produce insulin because the insulin-producing cells have been destroyed by the individual's own immune system. Insulin is only produced in the pancreas

under normal conditions. Insulin helps the glucose in the blood get from the blood fluid to the inside of cells in the body. It helps the glucose cross cell membranes to get inside the cells. You want that because glucose is a major source of energy for most types of cells in the body. With type II diabetics, of whom I am one, the pancreas can produce insulin but usually not enough of it to control the blood glucose level. If Type II diabetes is caught early enough, you can control it by diet and exercise. Then later it evolves to where you can control it by anti-diabetes medications and that is where I am now. Eventually these two ways of controlling blood glucose levels are no longer effective and the only treatment for Type II diabetes then is insulin injections by needle or pumps or insulin pens. That is what happens with Type I diabetics all of their lives every day. Their lives are a mess because they have to worry about constantly monitoring their diets and blood glucose levels otherwise their diabetes can kill them. Diabetes is notorious for four areas of damage. These areas are damage to the eyes, known as retinopathy and I have lost partial sight in one of my eyes because of it, then another common result of diabetes is what is called peripheral neuropathy that causes severe pain in the feet and I have that as well. Neuropathy can ultimately result in limb amputations. Diabetes can also affect the cardiac system and one can die from a heart attack and it can also destroy kidney function.

CEOCFO: Is your therapy something that they would do and it would change the whole thing or is it a therapy like the insulin which would need to be taken on a regular basis?

Mr. Waggoner: Again, we have a platform technology called Cell-in-a-Box, and it can also be used in treatment of diabetes. We have the exclusive worldwide license to the cell line that Dr. Crabtree mentioned, called Melligen. We plan to encapsulate those cells and then implant them in a diabetic patient to produce, store and release insulin when needed. We already know that when these cells were implanted into diabetic mice with deficient immune systems, the animals' diabetic condition was reversed. A peer-reviewed scientific paper published several months ago on the Melligen cells and their ability to reverse the diabetic condition provides the particulars. Again, our plan is to encapsulate the Melligen cells using the Cell-in-a-Box technology and then implant them in the body to act as a type of bio-artificial pancreas for use against Type I diabetes, and as Gerry is, insulin dependent Type II diabetes. Anybody who needs insulin, whether the person has Type I or insulin-dependent Type II diabetes, could have their problem solved if our therapy works as planned. We do not know how long the encapsulated cells will remain in the capsules without the capsules breaking down. But, we know from earlier studies in humans with pancreatic cancer that the capsules do not break down for at least two years; this was for the entire life of some patients in the earlier clinical trials in pancreatic cancer. But until further studies are completed, we won't know exactly how long they will stay in a body before they have to be replaced. The concept of using the Cell-in-a-Box technology with insulin-producing cells has already been proven successful in an earlier preclinical study using diabetic rats. It was a preclinical proof of principle study of the production and use of a stable bio-artificial pancreas by using these Cell-in-a-Box capsules. What happened in that study was that pig pancreatic islet cells, which are insulin-producing cells, were encapsulated and then placed in diabetic rats. As soon as the capsules with the insulin-producing cells were implanted in the diabetic rats, their blood glucose levels normalized and remained normal throughout the study period of about six months. The long-term protective capability of Cell-in-a-Box capsules was shown for the duration of the study. The live cells inside them could not be damaged by the body's immune system. So that is how we plan to use the Cell-in-a-Box technology for diabetes. You mentioned how diabetes is a serious disease. In our view it is the number-one health problem in the world. It is an epidemic globally, because 422 million people have diabetes, which is 314 million more than in 1980. Approximately 8.5% of adults worldwide have the disease. More than $920 billion annually is spent treating diabetes and the health related affects that are caused by diabetes. About 10% of every healthcare dollar in the world is spent on diabetes or related healthcare. Just here in the U.S. we have over 30 million people with diabetes. Annually, $600 million is spent just on the treatment of diabetes alone.

CEOCFO: Would you tell us about the Diabetes Consortium?

Mr. Waggoner: Gerry and I went to Europe when we joined forces and began to move the technology forward. We went to Europe in April of 2014. We planned to go for a week and I stayed for six. We got to know some of the most incredible physicians and scientists working in both pancreatic cancer and in diabetes, particularly the latter. I asked Gerry after having met them, why are these people not working together to address the number one healthcare problem around the globe? Gerry said because they are in these world renowned academic institutions and people like that often do not work together but rather compete with each other. I said that it seemed to me that instead of working in their silos, we should come up with a way for all of these incredible people who are trying to find an effective therapy for Type I and insulin-dependent Type II diabetes to work together collaboratively. I suggested to Gerry that we put together a Diabetes Consortium and have the members collaborate in their efforts to accelerate efforts to find an effective therapy for diabetes. Gerry said it would be great, but was skeptical about the practicalities of putting such a consortium together. Feeling fairly certain we could persuade those with whom we met to join our group, we circled back with all these amazing people and shared our vision. That vision then led to the formation of the Company's international Diabetes Consortium. Some of the scientists were reluctant to join at first, but now they have. We have nineteen members in the Consortium working

collaboratively on multiple research tracks; all of this is coordinated by our Director of Diabetes Program Development, Dr. Eva-Maria Brandtner.

CEOCFO: ***In closing, will you tell us where you are with financing and will you be looking for partners?***
Mr. Waggoner: I did a shareholder call on the 28th of July that can be listened to by anyone interested in where we are with financing. It is the most current update on the state of our affairs as of the 28th of July. We recently filed our annual report on Form 10K. There you will find as much detail as you can possibly imagine about the company. We are always looking for opportunities to finance the activities in which we are engaged. We are in discussions with pharmaceutical companies around the globe. We have financial partners that are helping us fund our activities. Until recently we were using a shelf registration vehicle to fund a lot of our activities. But we are always considering funding opportunities, including grants, partnerships, joint ventures, private placements and so forth.

Dr. Crabtree: I first would like to say a few words on pancreatic cancer. We are not doing the pancreatic cancer work in a vacuum. We are working with three of the leading pancreatic cancer specialists in the world on our program. They approached us; we did not approach them. This is particularly true in the case of an oncologist named Dr. Daniel D. Von Hoff. He is, to my mind, the world's leading authority in pancreatic cancer. He approached us to get involved with our program. What we are going to do over the next few months is go to the FDA and then start a Phase 2b clinical trial in patients with locally advanced, inoperable pancreatic cancer. There is very little that can be done for these people after they have been treated with first-line therapy. We are going to take these people and use our treatment and compare it to one of the current standards of care for these people, which is not very effective and has toxicity associated with it and see if we can do better for the patients in terms of their quality of life and anti-tumor effectiveness of their treatment and, most importantly, can we shrink their inoperable tumors to where they become operable. If that happens, it is obvious what the overall effect is going to be - you are going to have a significant extension of life. Pancreatic cancer is one of the deadliest forms of cancer known to mankind. By 2020 it is going to be the 2nd most-deadly cancer in the world.

Mr. Waggoner: ***You should mention what happened in the Phase 1/2 trial in terms of that very subject, taking an inoperable tumor to becoming operable!***

Dr. Crabtree: There was a Phase I/II trial done back in early 2000s on a small number of patients with pancreatic cancer in Europe. In this trial using fourteen patients, the patients were very sick and had very advanced disease. They each were given our treatment that used the Cell-in-a-Box live cell encapsulation technology plus the prodrug ifosfamide. The capsules were implanted, and then the patients were treated with only two courses of low-dose (one-third of normal) ifosfamide. Remarkable anti-tumor effects were shown. When the results of the trial were compared to historical data for the only treatment available at the time for pancreatic cancer, a cancer drug called gemcitabine, and the only FDA approved treatment, the median survival time for those patients was almost doubled as was the percentage of one-year survivors. Also, the quality of life of the patients was improved over that previously seen with gemcitabine treatment. Most importantly, in three out of the fourteen patients in that study, their tumors were converted from inoperable to operable. If that happens in this new trial and you can surgically remove the tumors, as mentioned previously, the patients should have a meaningful extension of life. Instead of dying in a year or even less, we do not know how long they would live. Getting an inoperable tumor to become operable is a major goal for our work in pancreatic cancer.

We are also using our cancer therapy to develop a treatment for malignant ascites. Nearly all abominable tumors produce a fluid as they grow called ascites fluid. It is usually malignant and I say that because the fluid produced by those tumors can contain live cancer cells. The fluid excreted by those tumors accumulates in the abdomen. The cancer cells in this fluid can seed and form new tumors distant from the original tumor where the ascites fluid came from. A major problem with the ascites fluid is that it can accumulate quite rapidly. It can cause distention of the abdomen. As it accumulates, it is extremely painful for the patient. In fact, it can be so dangerous as to infiltrate the pleural cavity or impinge on the function of the diaphragm such that breathing difficulties and even death can occur. This malignant fluid must be removed on a regular basis, usually once a month or so. It is a painful procedure. Oncologists do not like doing it and certainly the patients do not like doing it, and it is expensive. There is no treatment for it right now other than surgical removal of the fluid every thirty days or so. Dr. Von Hoff, whom I mentioned earlier, had postulated that our treatment for pancreatic cancer may have an effect on the rate of production and accumulation of this ascites fluid. We have been doing preclinical studies for some time in this area. These preclinical studies are continuing. There is a company called Translational Drug Development, which is a Contract Research Organization that specializes in only the oncology area and in preclinical studies and early to mid-phase clinical trials. Dr. Von Hoff is Chief Development officer at Translational Drug Development, or TD2. These studies are ongoing. If we can find that our treatment works to reduce the rate of malignant ascites fluid accumulation, then, we have another avenue to go down.

CEOCFO: ***Would you tell our readers why they should take an interest in your company?***
Mr. Waggoner: We are excited about everything we are doing. We have a lot on our plate. What we are doing is part of a much bigger picture in terms of treating individuals that so desperately do not have very good alternatives and in many cases no alternatives at all for a successful outcome. We believe we are in the midst of making medical history in the way solid tumors are treated. We also believe that we have an opportunity to provide a treatment for malignant ascites, where none has previously existed, and to our knowledge no one is working on. Then, of course, with diabetes we are tackling the largest healthcare problem in the world with our novel platform technology.

Dr. Crabtree: We do have a lot on our plate but things are moving along quite well. I am excited for both pancreatic cancer and diabetes. Personally, diabetes is a major problem for me and I do not like needles and surely do not want to have to be injected with insulin every day. Just think about what the market is for something like that when you consider there are major big pharma companies that make different forms of insulin or different types of treatments using their form of insulin. If our treatment works as well as we think it will, we could get a lot of noise from those big pharma companies.

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