Introduction and Product Overview

Section 1: Business Presentation
Section 2: Oxbridge Research Report
Section 3: Products Overview
Business Presentation

Section 1
Overview of Our Technology

PBI’s Sequential Dialysis Methodology is a novel approach that eliminates the molecules and proteins from the body that cause disease. By having this process occur in a device outside the body, targeting the cause rather than the effect of a disease, side effects are severely reduced, if not completely eliminated. Current medical research suggests that variations of this methodology can be used for a range of purposes—including reducing the effects of Traumatic Brain Injury, preventing cancer metastasis, and slowing the neuropathological changes caused by Alzheimer’s disease.
Sequential Dialysis

*Sequential-Dialysis Technique* is a methodology for the removal of molecules which are harmful and responsible for causing diseases.

- Fluids are temporarily removed from the body using a typical dialysis method.
- PBI drug therapy is added outside the body, which attaches itself directly to, and only to, the undesirable molecules.
- Target compounds are removed prior to returning the fluid to the body.

Premier Biomedical continues its development of specialized and direct removal of harmful molecules produced in excess by the human body.
Patented method for the removal of specific and unique molecules utilizing antibody antigens as a target attraction

For neurological conditions (diseases or concussions) cerebrospinal brain fluid is removed from the body and sequentially dialyzed.
Sequential Dialysis

*Sequential-Dialysis Technique* is a methodology for the removal of molecules which are harmful and responsible for causing diseases.

- Extracorporeal (outside the body) process to prevent the severe side effects which are normally encountered with other treatments
- The methodology can be used for:
  - The prevention of cancer metastasis
  - Reducing the effects of Traumatic Brain Injuries
  - Eliminating the neuropathological changes created by Alzheimer's Disease.
  - Preventing the death of anterior motor neurons in ALS
  - Eradicating the causations of Infectious Diseases

The methodology involved in this technique is largely unexplored and has the opportunity to create a huge market share within a $2 trillion industry.
The PBI Business model

A collaborative approach

Step 1: Coordinate our IP with the lab services of a large research based university (UTEP’s $45 million lab) agreement established – April 2012

Step 2: Add the Department of Defense (DOD) with their large, unequalled power of advanced model creation and clinical testing – June 2013

Step 3: Increase collaboration with various organizations, non-profits, sports leagues, etc. – On-going

Step 4: Expand internationally through alliances with leading regional pharmaceutical companies throughout Asia, Europe and South America.– Launching

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"After a more than two-year association with Army Medicine, I cannot even begin to convey the incredible potential of this huge organization, some of which borders on science fiction capabilities. I truly believe that the Department of Defense, in conjunction with Premier, has the power to defeat suicidal depression, cancer, Alzheimer's Disease, and multiple sclerosis."  

Mitchell S. Felder, M.D. (April 2013)
Business Plan Strategy

• Build patentable Sequential Dialysis machines at UTEP. *In-process.*
• Build patentable antigen-dispersing canisters into the Sequential Dialysis™ Machine. *In-process.*
• Initiate FDA application submission. *In-process.*
• Approach potential manufacturing and marketing pharmaceutical partners. *In-process.*
Premier Biomedical Inc.
Breast Cancer Treatment Progress

Day 15 (Treatment Day 10)

Control
Chemotherapy
PBI Treatment – Cancer immunotherapy

Day 24 (Treatment day 19)

Control
Chemotherapy
PBI Treatment - Cancer immunotherapy

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Ebola Treatment Development Status

• Provisional patent application filed
• Treatment cartridge initial design complete
• Cartridge prototype fabrication planned
• Initial submission made to FDA
• Currently in 4th round of discussions with the FDA
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Section 2: Oxbridge Research Report
Company Description

Premier Biomedical, Inc. is a research-based company that has acquired exclusive licenses for patent-pending medications and medical procedures to develop cures for a significant number of the most debilitating and often fatal illnesses: ALS, Traumatic Brain Injury, Multiple Sclerosis, Clinical Depression, Alzheimer’s Disease, Blood Sepsis, and Cancer. The company is in the process of developing targeted medicines and procedures and will prove out their superior efficacy in addressing these diseases and others through laboratory, hospital, and actual patient applications. At the anticipated successful conclusion of the clinical trials, contact will be established with the leading worldwide pharmaceutical firms to establish the right to market and distribute Premier Biomedical’s technology products and procedures.

Analyst Background

Jeffrey Song has over 10 years of investment banking, private equity, and public equity investing experience including 3 years of investment banking at Goldman Sachs, 4 years at a private equity firm, and 4 years as the investment manager for private family wealth. Mr. Song started his career at Goldman Sachs where he spent 3 years as a financial analyst in their mergers & acquisitions and private equity groups covering a broad range of industries and closing 8 transactions with a total value of over $6 billion. He then spent 4 years as a senior associate at Friedman, Fleischer, & Lowe, a $1 billion SF-based private equity firm where he focused on leverage buyouts and growth equity investments in middle market companies. After working briefly at Gandhara Capital, a $2 billion equity hedge fund in Hong Kong, Mr. Song spent 4 years as the investment manager for private family wealth. Most recently, he was the consulting CFO and founder of two early stage internet startup ventures and provides ongoing consulting to startups across a variety of industries. Mr. Song graduated from Stanford University with a Bachelors degree in Industrial Engineering.
EXECUTIVE SUMMARY

- Premier Biomedical is a research-based company that intends to discover and develop medical treatments targeting the treatment of: Alzheimer’s Disease, Multiple Sclerosis, ALS, Fibromyalgia, Traumatic Brain Injury, Blood Sepsis, and Cancer

- The Company’s proprietary Sequential Dialysis Technique is a methodology that physically removes the pathophysiologic basis of the disease, eliminating it without dangerous side effects
  - Superior to current treatments which eliminate the presence of most illnesses but often with catastrophic or even fatal side effects
  - Targets cancer, Alzheimer’s disease, Multiple Sclerosis, ALS, blood sepsis, and Traumatic Brain Injury – collectively over $700 billion market opportunity

- Developed a proprietary drug candidate Feldetrex as a potential treatment for Fibromyalgia, and neuropathic pain
  - Expected to deliver significant relief to patients, while presenting fewer side effects than other alternate medications
  - The Company was recently granted a US patent for this drug candidate
  - The annual market size of all proposed market segments for Feldetrex is over $20 billion

- The Company has established two outstanding research partnerships with the University of Texas, El Paso (UTEP) and the Department of Defense
  - Leverage the substantial infrastructure and resourced capacity of these organizations to perform experimentation and to engage in product development in an inexpensive and efficient manner
  - Positive results in animal testing for the immune system manipulation treatment of cancer

- Strong management team and advisors with extensive experience and contacts in the medical/pharmaceutical fields as well as a demonstrated track record of launching new business ventures in a competitive environment

Investment Thesis

Premier Biomedical ("PBI" or the “Company”) presents an opportunity to invest in a promising early stage research and development company which has developed proprietary medical treatments for a large number of the most fatal illnesses including Alzheimer’s Disease, Multiple Sclerosis, ALS, Fibromyalgia, Traumatic Brain Injury, Blood Sepsis, and Cancer. The Company has developed a proprietary Sequential Dialysis Technique which is a methodology that is
largely unexplored and has been described by scientists as the “wild west” of modern medicine. This methodology targets cancer, Multiple Sclerosis, Alzheimer’s disease, strokes and Traumatic Brain Injury which collectively represent a huge market opportunity of over $700 billion. The Company also developed a proprietary drug candidate Feldetrex, with one US patent, for the potential treatment of Fibromyalgia, and neuropathic pain. The annual size of this market is $4.7 billion as recorded by the leading pharmaceutical company in this market.

The Company has developed an aggressive timetable to advance the development of these breakthrough technologies through laboratory, hospital, and clinical trials. PBI has a management team with extensive experience and contacts in the medical/pharmaceutical fields as well as a demonstrated track record of launching new business ventures in a competitive environment. The team’s extensive contacts in the medical/pharmaceutical industries will ensure that new developments will achieve maximum visibility and exposure to the market.

The Company’s proprietary core technology involving Sequential Dialysis Technique aims to physically remove the pathophysiologic basis of the disease, thus eliminating it without dangerous side effects. A significant disappointment in the practice of modern medicine is that the capabilities do not exist to eliminate the presence of most illnesses and the process of treatment often comes with dangerous side effects. PBI’s approach is superior to current approaches in efficacy by eliminating the diseased cells and their life force entirely without damaging healthy nearby cells in the process. In successful animal trials conducted at the University of Texas, El Paso (UTEP), the efficacy of using antibodies against disease antigens was demonstrated in duplicated mouse tests in which the company’s antibody process vastly outperformed conventional chemotherapy. The Company is also planning to initiate a future patient clinical trial for the Sequential Dialysis Technique with its research partners.

PBI’s patented candidate drug Feldetrex consists of a unique combination of FDA approved medications which the Company believes will provide relief of symptoms and far fewer side effects than current medications for the treatment of Fibromyalgia and neuropathic pain. The Company is planning clinical trials for Feldetrex versus the leading pain relieving medication with annual sales of nearly $5 billion.

PBI has established two strong research partnerships with the University of Texas, El Paso (UTEP) and the Department of Defense. These partnerships allow the Company to maintain a lean cost structure and leverage the substantial infrastructure and resourced capacity of these organizations to perform experimentation and to engage in product development in an inexpensive and efficient manner. These partnerships have already yielded successful benefits for the Company through positive results in animal testing for treatment of breast cancer and preliminary work towards clinical trials of the Sequential Dialysis Technique to treat PTSD/Traumatic Brain Injury. To overcome the significant obstacles inherent to the development of the Sequential Dialysis Technique, PBI is seeking to partner with additional prestigious institutions and pharmaceutical companies with the substantial infrastructure and resourced capacity to perform experimentation and to engage in product development with the intent of negotiating a possible sale, or licensing of rights to the medications and technologies.

The diseases and illnesses that the Company’s medications and technologies targets represent a wide variety of often fatal diseases which currently have no cures or significant treatments. These include cancer, Alzheimer’s disease, Multiple Sclerosis, ALS, Fibromyalgia, Traumatic Brain Injury, and blood sepsis. The aggregate annual market opportunity is large and growing at over $700 billion. Capturing a small fraction of this market opportunity over time still represents a significant revenue opportunity for the Company over the long term.
Industry Overview

PBI’s focus is to discover and develop medical treatments for the following diseases and illnesses:

Cancer

Cancer is a class of diseases in which a group of cells display 1) uncontrolled growth beyond the normal limits of cell reproduction, 2) invasion and destruction of adjacent tissues, and sometimes 3) metastasis or spread to other locations in the body via lymph or blood. These three properties of malignant cancers differentiate them from benign tumors which are self-limited and do not invade or metastasize. Most cancers form a tumor, but some, like leukemia, do not. Cancer may affect people at all ages but the risk for most varieties increases with age. In the US, cancer accounts for nearly 1 in 4 deaths making it the second most common cause of death. According to the American Cancer Society about 585,720 Americans will die of cancer this year, making the death toll a staggering 1,600 people per day. Globally and on average, 7.5 million people die of cancer every year. There are about 14.5 million people living with cancer in the United States. The National Institute of Health estimates the 2009 direct medical costs of cancer were $86.6 billion.

Nearly all cancers are caused by abnormalities in the genetic material of the transformed cells. These abnormalities may be due to the effect of carcinogens, such as tobacco smoke, chemicals, or infectious agents. Other cancer-promoting genetic abnormalities may be randomly acquired through errors in DNA replication, or are inherited, and thus are present in all cells from birth. The heritability of cancers is usually affected by complex interactions between carcinogens and the host’s genome. New aspects of the genetics of cancer pathogenesis, such as DNA methylation and microRNAs are increasingly recognized as important.

The leading types of cancer for males include lung, prostate, and colon/rectum cancers accounting for approximately 44% of cancer deaths in 2010. The leading types of cancer for females include lung, breast, and colon/rectum cancers accounting for approximately 50% of cancer deaths in 2010.

Cancer can be treated by surgery, chemotherapy, immunotherapy, monoclonal antibody therapy, or other methods. The choice of therapy depends upon the location and grade of the tumor and the stage of the disease, as well as the general state of the patient. A number of experimental cancer treatments are also under development. Complete removal of the cancer without damage to the rest of the body is the goal of treatment. Sometimes this can be accomplished by surgery, but the propensity of cancers to invade adjacent cells or to spread to distant sites by metastasis often limits its effectiveness. The effectiveness of chemotherapy is often limited by toxicity to the other tissues in the body. Radiation damages normal tissue.

Potential for Sequential Dialysis Technique

PBI intends to develop a methodology for treating cancer which is completely different from the standard treatments of chemotherapy and radiation therapy that are now being used. Due to the fact that all presently known treatments directly inject chemotherapeutic agents into the
body of a patients and/or directly irradiate the patient, there is a very high level of adverse side
effects, such as kidney failure, encephalopathy, neuropathy, heart toxicity, and other severe
morbidities. The Company intends to develop its intellectual property applications for utilizing a
proprietary methodology in which the cancer patient’s blood or other bodily fluids is utilized to
remove metastatic cancer cells or other disease causing antigens, or their life force elements.
This is accomplished by sequentially dialyzing the patient’s blood or other bodily fluids extra-
corporeally. The method will utilize designer antibodies to physically remove the
pathophysiologic basis of the disease. In cancer treatment, there will be the physical
attachment and then physical removal of metastasizing cancer cells. To date there has been no
specific clinical evidence to support a conclusion that this treatment is effective for premetastatic
or metastatic cancers. PBI hopes to demonstrate this in future lab and animal
experimentations. Through this process, the cancer can be targeted through a number of
innovative techniques developed by the Company.

The extra-corporeal sequential methodology for cancer treatment has an enormous potentiality
for decreasing the side effects of chemotherapy and radiation treatment in cancer patients. This
methodology may also increase the efficacy of cancer treatment by allowing for much higher
dosages of anti-neoplastic agents to be used through this extra-corporeal methodology. Due to
the fact that this methodology completely avoids exposure of the patient’s body to these anti-
cancer agents, dosages that cannot be normally tolerated can now be utilized in fighting the
cancer.

Alzheimer’s Disease

Alzheimer’s disease is a dementing illness, which induces a progressive impairment of
intellectual functioning, including a loss of short term memory. There is also a progressive
impairment in executive functioning with occasional psychiatric manifestations such as
depression and delirium. Delirium is characterized by an acute confusion. Oftentimes patients
have language impairment and apraxia – an inability to perform previously learned tasks.
Patients also oftentimes show agnosia, an inability to recognize objects, and patients have a
loss of visual-spatial abilities, for example becoming lost in familiar surroundings. Occasionally
hallucinations occur in severe forms of Alzheimer’s disease.

Alzheimer’s disease comes from neuropathic changes in the brain which includes the
accumulation of neurofibrillary tangles and amyloid plaques in the cortex of the brain.
Neurofibrillary tangles are composed of Tau proteins, which are deposited within the neurons of
the brain. Thus, Tau proteins are the causation of Alzheimer’s disease and other Tauopathies
such as Pick’s Disease, Tuberous Sclerosis and certain forms of Parkinson’s disease.

The report “Changing the Trajectory of Alzheimer’s Disease” by the Alzheimer’s Association
examining the current trajectory of Alzheimer’s disease shows that the number of Americans
age 65 and older who have Alzheimer’s disease will increase from 5.1 million in 2010 to 13.5
million by mid-century. The report shows that “in the absence of disease-modifying treatments,
the cumulative cost of care for people with Alzheimer’s from 2010 to 2050 will exceed $20
trillion, in today’s dollars. Total costs of care for individuals with Alzheimer’s disease by all
payers will soar from $172 billion in 2010 to more than $1 trillion in 2050.” During this time, the
Medicare costs for Alzheimer’s disease will soar 600% to $627 billion and the Medicaid costs of
Alzheimer’s disease will soar 400% to $178 billion.
Presently, there is no cure for Alzheimer’s disease. Treatments exist but only target the symptoms of Alzheimer’s disease without targeting the underlying progression of the disease. Consequently, the projected future life span of an individual diagnosed with the disease is 5 to 7 years.

Potential for Sequential Dialysis Technique

The Company believes that its proprietary Sequential Dialysis Technique can be used to prevent the onset of Alzheimer’s disease. This would be done by removing the proteins believed responsible for the pathologic changes in the brain, namely the protein Tau, thus, preventing the cause of the neuropathic changes that cause Alzheimer’s disease. The Tau protein will be removed from the cerebral spinal fluid in which it resides utilizing a designer antibody (an antibody genetically engineered for a specific purpose) which will allow for the efficacious removal of the protein. PBI hopes to demonstrate this in future lab and animal experiments. The Company believes that its Sequential Dialysis Technique can also be used in this fashion to treat Traumatic Brain Injury.

ALS

Amyotrophic Lateral Sclerosis (ALS) is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. While the cause of ALS is uncertain, the process of ALS is known to occur as motor neurons in affected patients progressively degenerate until death. As motor neurons degenerate, they can no longer send impulses to muscle fibers that normally result in muscle movement. Eventually, the motor neurons die and the ability of the brain to initiate and control muscle movements is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease become totally paralyzed.

ALS has been frequently referred to as Lou Gehrig’s disease, after the famous New York Yankees baseball player diagnosed with the disease in 1939. Annually, about 5,600 people are diagnosed with ALS in the United States. The projected future life span of a diagnosed patient is two to five years. It is projected that of the current US population, 300,000 people will die of ALS before a cure is found.

The financial cost to families of persons with ALS is exceedingly high. In the advanced stages, care can cost up to $200,000 a year. Entire savings of relatives of patients are quickly depleted because of the extraordinary cost involved in the care of ALS patients.

This past summer, through the viral media sensation of the ALS Ice Bucket Challenge which attracted celebrities, professional athletes, and entertainers, a huge spotlight was shown on this terrible disease. Through the generous outpouring of support from people all over the world, in a span of a few weeks, the ALS Association received over $115 million in donations. The unprecedented awareness around ALS from the Ice Bucket Challenge is expected to continue to fuel future support to find treatments and a cure for the disease.

There is currently no cure or treatment that halts or reverses ALS. However, there is one FDA approved drug, Riluzole, which modestly slows the progression of ALS.

Potential for Sequential Dialysis Technique
Numerous medical studies have proven that the causation of ALS is an over excitation of the anterior motor neurons in the spinal cord. PBI’s Sequential Dialysis Technique method may have the potential to remove those excitatory neural transmitters that cause the death of those cells. The method will utilize designer antibodies to physically remove excitatory neurotransmitters such as glutamate from cerebrospinal fluid. The Company hopes to demonstrate this methodology in future lab and animal experiments.

**Blood Sepsis and Viremia**

Blood Sepsis, also known as Blood Poisoning, is an infection of the blood stream. Sepsis is caused when toxin releasing bacteria, such as Staphylococcus, enter the blood. Blood Sepsis is a particularly devastating disease due to the domino-effect of organ shutdown which causes multiple organ failure. Blood Sepsis causes a whole body inflammatory state called Systemic Inflammatory Response Syndrome. Blood Sepsis first results in the shutdown of kidneys, thus patients require dialysis immediately to prevent death. As the disease progresses, vital signs collapse – the foremost of these being blood pressure. Subsequently, symptoms of Sepsis include elevated temperature, elevated heart rate, respiratory collapse, further organ failures, altered mental states and cardiac failure. Septicemia is a major cause of death in the US and puts people in the intensive care unit at a very high rate. Only about 1-2% of all hospitalizations in the US are attributed to Septicemia, though Septicemia accounts for as much as 25% of bed-utilization in intensive care units.

The traditional therapy of Blood Sepsis relies on intravenous treatment using multiple antibiotics. However, in intensive care units, even with today’s treatment, approximately 35% of patients with severe sepsis and 60% of patients with septic shock die within 30 days. Septicemia is of particular concern because of the exceedingly high cost of treatment for Septicemia patients. A typical stay in the intensive care unit costs $10,000 per day with testing. Consequently, the treatment of Blood Sepsis is one of the most costly expenditures for hospitals in America.

**Potential for Sequential Dialysis Technique**

PBI hopes to conquer Blood Sepsis and Viremia (a disease having symptoms similar to Sepsis but caused by virus) by using its proprietary Sequential Dialysis Technique. If proven successful, this technique would dialyze the toxin producing bacteria out of the blood by using antibodies, thus saving countless lives while also providing significant cost savings by hospitals around the country. The method will utilize designer antibodies to physically remove the toxin producing bacteria out of the blood. The designer antibodies will attach to the toxin producing bacteria or virus, and then the antibody-antigen compound will be efficaciously dialyzed out of the blood extracorporeally. The Company hopes to demonstrate this methodology in future lab and animal experiments.

**Multiple Sclerosis**

Multiple Sclerosis (MS) is a devastating inflammatory neurologic disease in which white matter, known as myelin, is damaged – causing episodic or neurological symptoms. The destruction of myelin inhibits communications between the nerves in the brain. Symptoms of MS include extreme fatigue, numbness, weakness, difficulty with eyesight, spasticity, speech problems, and
problems with coordination. MS has its greatest incidence in young adults and patients are usually diagnosed at less than 55 year of age at the onset of the illness. The cause of MS is unknown, although the disease is believed to be an autoimmune problem triggered by a virus – meaning that the patient’s immune cells attach and destroy the patient’s myelin. In the United States, there are approximately 400,000 patients diagnosed with MS and approximately 200 new patients diagnosed every week. Globally, MS is believed to effect 2.1 million people.

“ABC” drugs Avonex, Beta-Seron, Copaxone are used to treat MS but have been shown to barely beat out placebos in efficacy and are not approved in England for government subsidy. Another treatment of MS is high dose steroids, though this treatment simply decreases symptoms without curing MS.

Potential for **Feldetrex**

PBI’s proprietary **Feldetrex** candidate drug will not compete with typical treatment methods for MS, but rather, is simply an add-on drug to increase the effectiveness of treatment.

**Fibromyalgia**

Fibromyalgia is a common illness affecting approximately 2% of the general population, most commonly amongst women 20 to 50 years of age. Approximately, five million Americans suffer from the debilitating illness. The cause of Fibromyalgia is officially unknown and diagnosis of Fibromyalgia is a “diagnosis of exclusion” – meaning that Fibromyalgia is diagnosed as an illness after Rheumatoid Arthritis and Lupus have been ruled out with a blood test. Patients with Fibromyalgia suffer from debilitating fatigue, numbness, headaches, and chronic widespread musculoskeletal pain with multiple tender points. Fibromyalgia is a chronic condition lasting 6 months to many years. Patients commonly complain of chronic aching, pain, stiffness, sleep difficulty, headaches, and irritable bowel syndrome. Consequently, approximately 25% of patients with Fibromyalgia are work disabled. The direct and indirect costs of Fibromyalgia are, on average, $5,945 per patient.

Lyrica (Pregabalin), Cymbalta (Duloxetine) and Savella (Milnacipran) are the only FDA approved medications for the treatment of Fibromyalgia. However, often times these drugs have side effects of dizziness, drowsiness, dry mouth, and blurred vision. Rarely, these drugs have been reported to cause suicidal ideation or severe agitation.

Potential for **Feldetrex**

PBI’s proprietary **Feldetrex** candidate drug is intended as an alternative to currently approved drugs for the treatment of Fibromyalgia and neuropathic pain with few, if any, negative side effects.

**Traumatic Brain Injury**

Traumatic Brain Injury (TBI) occurs when an external force traumatically injures the brain. TBI is a major cause of death and disability worldwide, especially in children and young adults. Causes of TBI include falls, vehicle accidents, and violence. Three separate processes of TBI work to injure the brain: 1) bruising/bleeding, 2) tearing, and 3) swelling. Brain trauma can be caused by a direct impact or by acceleration alone. In addition to the damage caused at the
moment of injury, brain trauma causes “secondary injury”, a variety of events that take place in the minutes and days following the injury. These processes, which include alterations in the cerebral blood flow and the pressure within the skull contribute substantially to the damage from the initial injury.

Each year, an estimated two million TBI-related deaths, hospitalizations, and emergency department visits occur in the United States. Of these patients, 56,000 die and 300,000 are hospitalized. The present treatment methodology for TBI is centered on the treatment of symptoms. There are currently no treatments that target the underlying pathology of TBI. Current medications used to treat TBI, such as narcotics and antidepressants, have many side effects including addiction, arrhythmia, liver, and kidney damage, abdominal problems, nausea, and vomiting.

Over the last couple of years, there has been significant increased awareness and focus on TBI as former players in the NFL sued the NFL alleging that it had hidden the dangers of concussions from them. Last year, the NFL agreed to establish a pool of $675 million to cover injuries and diseases linked to head trauma that the players sustained during their careers, which was later deemed insufficient and made an open-ended commitment to pay cash rewards. The NFL, which for years had disputed evidence that its players had a high rate of severe brain damage, recently reported that it expects nearly a third of retired players to develop long-term cognitive problems and that the conditions are likely to emerge at “notably younger ages” than in the general population. The statements were the league’s most unvarnished admission to date that NFL players sustain severe brain injuries at a far higher rate than the general population and appear to confirm that playing football increases the risk of neurological conditions such as TBI. Further, new data from the nation’s largest brain bank focused on TBI has found evidence of a degenerative brain disease in 76 of the 79 former NFL players examined.

**Potential for Feldetrex**

PBI’s proprietary Feldetrex candidate drug has a mechanism of action via a manipulation of central nervous system neurotransmitters, which involves the cerebral cortex, limbic system, and spinothalamic tracts. Feldetrex utilizes a low dosage of Naltrexone, which has been shown in multiple medical articles in the medical literature, to increase endogenous enkephalins. The Company has not independently conducted medical or laboratory tests to show the mechanism of action of this medication. Further experimentation involving the Company’s core technology to physically remove the pathophysiologic basis of disease may provide a role for this technology to treat these injuries.

**Competition**

PBI’s business is conducted in an intensely competitive and often highly regulated market. Its treatments face competition in the form of branded drugs, generic drugs and the currently practiced treatments for MS, Blood Sepsis, and Cancer. The principal forms of competition include efficacy, safety, ease of use, and cost effectiveness. Where possible, companies compete on the basis of the unique features of their products, such as greater efficacy, better patient ease of use or fewer side effects. A lower overall cost of therapy is also an important factor. Products that demonstrate fewer therapeutic advantages must compete for inclusion
based primarily on price. Though the means of competition vary among product categories, demonstrating the value of PBI’s medications and procedures will be a critical factor for the Company’s success. Competitors include worldwide research-based drug companies, smaller research companies with more limited therapeutic focus, and generic drug manufacturers. PBI competes with other companies that manufacture and sell products that treat similar diseases as its major medications and procedures.
Premier Biomedical is a research-based company that intends to discover and develop medical treatments for humans, specifically targeting the treatment of:

- Alzheimer’s Disease (AD)
- Multiple Sclerosis (MS)
- Amyotrophic Lateral Sclerosis (ALS/Lou Gehrig’s Disease)
- Fibromyalgia
- Traumatic Brain Injury (TBI)
- Blood Sepsis and Viremia
- Cancer

The Company has a two-fold corporate focus:

1. Target Alzheimer’s disease, ALS, Blood Sepsis, Leukemia, and other life-threatening cancers, MS and Traumatic Brain Injury by developing a proprietary Sequential Dialysis Technique. The methodology involved in this technique is largely unexplored and has been described by scientists as the “wild west” of modern medicine. Consequently, first entry into the therapeutics market for medications that work against cancer, MS, Alzheimer’s disease, strokes and TBI carries significant obstacles before reaching the opportunities of a $700 billion industry.

2. Development of a proprietary drug candidate Feldetrex, a potential treatment for Fibromyalgia, and neuropathic pain. The formulation used in Feldetrex will be individually tailored to the various illnesses targeted, with each formulation being given a unique proprietary brand name. The annual market for all proposed Feldetrex market segments is over $20 billion.

The Company has developed an aggressive timetable to advance the development of these breakthrough technologies through laboratory, hospital, and clinical trials. The Company has a management team with extensive experience and contacts in the medical/pharmaceutical fields as well as a demonstrated track record of launching new business ventures in a competitive environment. The team’s extensive contacts in the medical/pharmaceutical industries will ensure that new developments will achieve maximum visibility and exposure to the market. To overcome the significant obstacles inherent to the development of the Sequential Dialysis Technique and Feldetrex candidate drug, PBI is seeking to partner with prestigious institutions and pharmaceutical companies with the substantial infrastructure and resourced capacity to perform experimentation and to engage in product development in an inexpensive and efficient manner.

**Felder Doctrine – Sequential Dialysis Technique**

The Company is currently working to bring to market potential treatments for its targeted diseases using its proprietary “Felder Doctrine” or Sequential Dialysis Technique. Developed by inventor and PBI Chairman of the Board Dr. Mitchell S. Felder, the Felder Doctrine aims to physically remove the pathophysiologic basis of the disease, thus eliminating it without
dangerous side effects. A significant disappointment in the practice of modern medicine is that the capabilities do exist to eliminate the presence of most illnesses, including life-threatening diseases such as AIDS and cancer, but with a caveat that the process of treatment comes with catastrophic side effects that can and often do kill the patient.

In the proprietary Sequential Dialysis Technique designer antibodies can be created which target specific disease-related antigens. By introducing these antibodies extra-corporeally (outside the body) in specific concentration into the blood (or other bodily fluids), they will target and attach themselves to the disease cells, or the life force that the disease needs to survive. The sequestered components and any substances introduced during the treatment are then filtered out of the bodily fluid through a sequential dialysis process prior to being returned to the patient. The result is a “starving” of the disease of the life force needed to survive, at which point the disease cells will die without introducing any chemicals or procedures into the body of the patient. This is a truly unique and innovative method for alleviating disease. This methodology can be used for the prevention of cancer metastasis, for directly attacking the causation of intractable seizures, for preventing the death of anterior motor neurons in ALS, for preventing the cause of the neuropathological changes in Alzheimer’s disease and TBI and for eradicating the causations of infectious diseases, and the like.

This approach differs from traditional medicine which typically adds much weaker and less effective substances into the body in an effort to inhibit disease-related processes. Further, conventional methods can target only one single antigen, thus allowing other antigens to survive treatment and enabling the disease to progress, or worse, damage or kill “good” cells along with the disease. PBI aims for far greater efficacy by eliminating multiple target antigens simultaneously, and only those targets. An example of the efficacy of the approach was proven out in 2 rounds of mice tests conducted at the University of Texas, El Paso (UTEP). In that study, the PBI treatment methodology vastly outperformed conventional chemotherapy. The results of these studies were presented at the American Association for Cancer Research Conference in San Diego in April 2014. UTEP researchers are working to identify unique antibodies which can be used in similar tests on higher order mammals and clinical trials on human subjects. It is believed that the removal of the disease molecules and/or the disease “life force” molecules from body fluids will eliminate diseases such as Cancer and Clinical Depression, both of which rely on these related molecular compounds to survive and spread.

**Feldetrex**

PBI’s work on the treatment of Fibromyalgia has yielded a patent on a unique combination of FDA approved medications which the Company believes will provide relief of symptoms far fewer side effects than the currently most prescribed drug for this condition, Lyrica, which posts $4.7 billion in annual sales and will soon run out of patent protection. While this deviates from the basic principle of the Felder Doctrine, and more closely conforms to conventional medicine, the Company believes that the candidate drug *Feldetrex* will deliver significant relief to patients, while presenting fewer side effects. PBI is in the process of preparing an application to the FDA for approval of *Feldetrex*, while at the same time investigating partners in Malaysia to assist with certification, clinical trials, manufacture and marketing there.

Although it consists of a combination of generic medications, PBI has proprietary rights to its *Feldetrex* candidate drug. In this way, *Feldetrex* is similar to Viagra which was a proprietary cardiac drug prior to its current use and ownership by Pfizer. Consequently, the Company was recently granted a patent for its *Feldetrex* candidate drug. *Feldetrex* may serve as an additional
medication utilized by physicians for the treatment of Fibromyalgia, and neuropathy, and is designed to decrease symptomatology in those conditions.

*Feldetrex* utilizes a low dosage of Naltrexone which has been shown in multiple medical articles, in the medical literature, to increase endogenous enkephalins (which function as neurotransmitters that inhibit neurotransmitters in the pathway for pain perception, thereby reducing the emotional as well as the physical impact of pain). The Company has not independently conducted medical or laboratory tests to show the mechanism of action of this medication. While Naltrexone in high dosages acts as an opioid antagonist, it inhibits opiate receptors. Naltrexone in low dosages causes a compensatory upregulation (increase in number of receptors) of native endorphins and enkephalins, which last beyond the effects of the Naltrexone itself. The Company believes that this means, that a daily dose of low dose Naltrexone can be used to chronically increase endorphin and enkaphalin levels. By utilizing a low dosage, Naltrexone has a unique ability to increase enkephalins and other neurotransmitters in the brainstem of patients.

PBI has exclusive license to 2 United States Patents, and 1 European PCT, plus 20 provisional US patents applications, in the areas of cancer, TBI, blood sepsis, MS, et al. All patent applications have been filed by Marv, LLC and Altman, LLC. The owner of Marv, LLC and Altman, LLC is Dr. Mitchell S. Felder, the Chairman of Premier Biomedical and Chairman of the Scientific Advisory Board of Premier Biomedical.

PBI has existing business relationships with the University of Texas at El Paso (UTEP) and the Department of Defense:

*University of Texas, El Paso Agreement*

In May 2012, entered into a Collaborative Agreement with the University of Texas, El Paso (UTEP). Pursuant to the terms of the Agreement, will work jointly with the University to develop a series of research and development programs around its sequential dialysis technology in the areas of Alzheimer’s disease, TBI, chronic pain syndrome, fibromyalgia, MS, ALS, blood sepsis, cancer, heart attacks and strokes. The programs will utilize the facilities at one or more of the University of Texas’ campuses. PBI will pay the University’s actual overhead for the projects, plus a negotiated facility and administration overhead expense, and 10% of all gross revenue associated with the sale, license, and/or royalties of all products and treatment procedure directly affiliated with programs. PBI will retain 90% revenue generated from products and treatments arising from the underlying technology. Intellectual property jointly invented and developed as a result of the projects will be owned jointly by the University and the Company. The agreement has an initial term of 5 years and is renewable upon mutual agreement of the parties.

In April, researchers at UTEP presented positive results from its duplicated testing on mice at the American Association for Cancer Research meeting in San Diego. The results showed statistically significant improvements in the survival and prevention of breast cancer in mice treated with its anti-breast cancer treatment versus chemotherapy-only and non-treated groups. These results were a major step forward in the goal of preventing breast cancer metastasis and defeating cancer in a completely non-toxic manner by utilizing the body’s own immune system.
US Army CRADA

After a three year vetting process by the Department of Defense (DoD), in June 2013 PBI entered into a Cooperative Research and Development Agreement (CRADA) with the DoD for performing medical research, development, testing and evaluation for the treatment of Traumatic Brain Injury and Suicide Ideation - more specifically targeting the prevention of suicidal ideation and clinical depression, and to assist in the creation of antibodies in order to obtain a decrease in the neuropathologic findings in traumatic brain injury. Initial studies are being conducted at the William Beaumont Army Medical Center at Fort Bliss in El Paso, Texas. PBI’s obligation under the CRADA, in addition to providing the basis for the study, is to cover approximately $10,000 in costs while the US Army will provide equipment, material and services. The CRADA can be terminated by either party pursuant to 30 days notice or work will cease upon completion of the study, exhaustion of funds, termination, or July 2016, whichever occurs first. The Company has initial authorization to file patent applications on all inventions jointly developed during the term of the CRADA. Additional follow-on CRADA’s are planned for other diseases and medical conditions in the future. This agreement leverages and significantly increases the Company’s technical capabilities by establishing procedures and venues for animal and clinical testing, provides protection against theft of intellectual property, and allows rapid FDA approval of procedures and medications.

The William Beaumont Army Medical Center has scheduled a submission of test protocol to their internal regulatory board for a double blind clinical trial of Feldetrex versus the leading pain relieving medication, Lyrica. A positive clinical result could result in a substantial boost to the Company’s finances. The Feldetrex clinical trial will be followed by a second clinical trial of the Sequential Dialysis Technique to remove the malevolent molecular compounds from the cerebral spinal fluid of individual soldiers. These heroes suffer from PTSD/Traumatic Brian Injury leading to clinical depression and suicide/homicide ideation. The Veterans Administration estimates that one active-duty soldier per day commits suicide from this disorder.

Development Plans

The Company does not have the financial ability to conduct the necessary clinical trials for FDA approval of the Feldetrex product candidate. PBI intends to enter into agreements with larger pharmaceutical companies as collaboration partners, in part to help cover the cost of such processes. At the conclusion of the studies involving Feldetrex, the Company plans to publish the results in established medical journals and subsequently contact the large pharmaceutical firms for a possible sale or license of the rights to conduct clinical trials, manufacture, and distribute Feldetrex.

Laboratory tests were initiated to prove the cancer-fighting technology in late 2012. In 2013, the Company completed two breast oncology studies to test the effectiveness of a treatment proposed by PBI on small mice populations. The Company plans to undertake additional studies at a university/hospital over the next several months. The Company estimates the cost of each of these studies to be between $300,000 and $500,000 including actual testing with cancer patients, to be funded with the Company’s current access to additional capital. At the anticipated successful conclusion of these studies, the Company plans to contact the large pharmaceutical/medical devices firms, such as Johnson and Johnson, Boston Scientific, Medtronic, Pfizer, and Eli Lilly, to attempt to negotiate a partnership and/or sale of the technology.
Currently, two clinical trials are soon to be underway – one on the candidate drug Feldetrex that should be approved by the FDA for distribution and the second clinical trial on the Sequential Dialysis Technique. If the second clinical (patient) trial is successful of the core technology in solving the DoD’s number one health concern, it is likely that the DoD will exert pressure on the FDA to approve procedure for immediate application.

**Research and Development**

The Company plans to conduct research internally and may also through contracts with third parties, through collaborations with universities and biotechnology companies and in cooperation with pharmaceutical firms. The Company may also seek out promising compounds and innovative technologies developed by third parties to incorporate into its discovery or development methods and procedures or projects, as well as its future product lines, through acquisition, licensing or other arrangements.

In addition to discovering and developing new products, methods and procedures of treatment and treatments, the Company expects its research operations to add value to its existing products and methods and procedures of treatment in development by improving their effectiveness and by discovering new uses for them.

**Marketing**

Currently, the Company manages its marketing responsibilities internally. PBI intends to seek a partnership with and/or sale of our product candidates/technologies to large pharmaceutical and/or medical devices firms. These firms have the ability to effectively promote our product candidates to healthcare providers and patients. Through their marketing organizations, they can explain the approved uses, benefits and risks of our product candidates to healthcare providers, such as doctors, nurse practitioners, physician assistants, pharmacists, hospitals, Pharmacy Benefit Managers, Managed Care Organizations, employers and government agencies. They also market directly to people to have meaningful conversations with their doctors. In addition, they sponsor general advertising to educate the public on disease awareness, important public health issues, and patient assistance programs.

The large pharmaceutical devices firms principally sell their products to wholesalers, but they also sell directly to retailers, hospitals, clinics, government agencies and pharmacies and also work with MCOs, PBMs, employers and other appropriate healthcare providers to assist them with disease management, patient education and other tools that help their medical treatment routines.

**Regulation**

The Company expects to be subject to varying degrees of governmental regulation in the United States and any other countries in which its operations are conducted. In the United States, regulation by various federal and state agencies has long been focused primarily on product safety, efficacy, manufacturing, advertising, labeling and safety reporting. The exercise of broad regulatory power by the FDA continues to result in increases in the amounts of testing and documentation required for FDA clearance of new drugs and devices and a corresponding
increase in the expense of product introduction. Likewise, the approval process with the FDA is estimated to take approximately 7 years from the time it is started. Similar trends are also evident in major markets outside of the United States.

Because the Company intends to seek a partnership with and/or sale of its product candidates/technologies to large pharmaceutical and/or medical devices firms, PBI anticipates that a larger pharmaceutical company will undertake to navigate the regulatory pathway, including conducting clinical trials, for a product such as Feldetrex.

The Company’s expertise is in research and early development, not in taking products or processes through the FDA, so the Company has made some significant additions to its Scientific Advisory Board:

- Dr. Patricio Reyes, Chief Medical Officer, NFL Retired Players Association, co-founder, Chief Medical Officer and Chair of the Scientific Advisory Board of Yuma Therapeutics, Inc.; and a pioneer in the fields of Aging, Alzheimer’s disease and other neurodegenerative diseases
- Dr. David Vigerust, former Health Research Scientist with the US Department of Veterans Affairs whose work focuses on virus-innate immune response and the pathogenesis of inflammation in tumorigenesis and neurodegeneration.
- K. Adam Dubov, Esq., is a subject matter expert in regulations and guidance for all articles regulated by the Food & Drug Administration in both U.S. military and civilian applications
- Dr. Mahlet Abera, has extensive expertise with a variety of cellular assays and molecular techniques applied to tumor cell lines and mouse models. She conducted her Ph.D research in the field of Protein Kinase C (PKC) signaling and cancer, focusing on the role of PKCs in the initiation and progression of lung cancer.

The expertise and credentials of these individuals positions PBI well to address the challenges of quickly and efficiently obtaining FDA approval of its technologies, devises and treatments.

**Financing / Funding**

PBI’s financial strategy to date has been a thrifty one focused on maintaining a lean structure and raising capital through a relatively small number of individual investors and only as needed. For those early feasibility explorations, this has been a prudent approach. However, now that feasibility has been established, it is necessary to ramp up research work to develop marketable cures in a shorter timeframe. The management team continues to search for institutional funding sources (banks and venture capital) to fund its necessary next phase rapid growth. In early 2014, the Company secured a commitment from Kodiak Capital Group, LLC to invest up to $5.0 million over time (only $700,000 drawn to date). This agreement allowed the Company to pay off all of its liabilities and is expected to provide necessary funding over the short-term for PBI to achieve its R&D and growth objectives. The Company recently terminated its relationship with Kodiak and continues to pursue funding from public and private investment sources – banks, private investors, government and foundation grants, etc. – including grants and endorsements from NASCAR, the NFL and NFL Players Association, as well as various foundations and associations including the American Cancer Society and government grants (full-time PhD focused on filing grant requests). The Company recently created a video to be
used to solicit NASCAR sponsorship and endorsements for the Company’s program to cure PTSD and is actively networking with the NFL and NCAA organizations to raise awareness of PBI’s technology to aid Traumatic Brain Injury.

**Timeline / Development**

2009 – Dr. Felder develops the theories that make the Felder Doctrine. Patents written and submitted

December 2010 – PBI incorporated in Nevada

December 2010 – Assembled Board of Directors. includes the Doctor, two attorneys, and individuals previously holding officer positions for public companies

January 2011 – Premier Biomedical, Inc. begins process of “going public”

March 2012 – Dr. Mitchell Felder meets with Dr. Robert A. Kirken, Ph.D. Professor and Chair, Department of Biological Sciences at the University of Texas at El Paso (UTEP)

April 2012 – UTEP demonstrates data to support Proof of Concept: Selective Depletion of Small Reactive Molecules

May 2012 – PBI and UTEP sign Collaborative Agreement: Aphaeresis Selective Depletion of Small Reactive Molecules and Pathogens that Involves a Novel Treatment of Brain Injury (TBI), Chronic Pain Syndrome, Fibromyalgia, Multiple Sclerosis, Amyotrophic, Lateral Sclerosis (ALS or Lou Gehrig’s disease), Blood Sepsis, Cancer, Heart Attacks and Strokes.

June 2012 – UTEP presents Scope of Work Agreement for the Pre-clinical Development of Premier Biomedical Therapeutic Strategies

July 2012 – PBI and UTEP sign Scope of Work Agreement. Premier Biomedical, Inc. receives a letter of intent from William Beaumont Army Medical Center (WBAMC) stating their desire to join the consortium with their primary expertise in animal and clinical testing

August 2012 – Mutual Non-Disclosure Agreement with UTEP, PBI, and US Army Clinical Investigation Regulatory Office (CIRO). Premier Biomedical, Inc. begins primary fundraising for laboratory development and clinical testing—targeting private consortiums, institutional funds, grants, strategic partnerships, and philanthropic donations. BIEI opens on OTCBB at $1.01.
January 2014 – Kodiak Capital Group, LLC agrees to invest up to $5,000,000 in common stock over time. As of June 2014, the Company has sold shares in exchange for total proceeds of $700,000 pursuant to this agreement. This agreement was recently terminated.

April 2014 – presented the successful animal experiment results involving a patent-pending breast cancer cure at the peer-reviewed American Association for Cancer Research Symposium in San Diego

June 2014 – US Patent Office granted 2 patents for Feldetrex. Feldetrex consists of only FDA-approved ingredients and should be approved for distribution by the FDA.
Management Team

William A. Hartman (President, CEO)

President and Chief Executive Officer and a member of the Board of Directors. From March 2008 until June 2010, Mr. Hartman was planning the formation of Premier Biomedical, Inc. From October 2006 to March 2008, Mr. Hartman was the Chief Operating Officer of Nanologix, Inc. From July 1991 to July 2000, Mr. Hartman was a Director at TRW Automotive. From 1984 to 1991, Mr. Hartman was Chief Engineer at TRW Automotive and from 1979 to 1984, he was Division Quality Compliance Manager at Ford Motor Company. At TRW Automotive, Mr. Hartman was one of the auto industry pioneers of the concept of grouping related components into systems and modules and shipping just-in-time to the vehicle assembly plants. He founded and headed a separate business group within TRW Automotive with plants in the U.S., Mexico and Europe with combined annual sales of $1.3 Billion. Academic credentials include a BSME degree from Youngstown State University and a MSIA degree (Industrial Administration/Management) from the University of Michigan. Mr. Hartman is acting vice-president of the PBI Cancer division.

Dr. Mitchell S. Felder (Chairman of Board)

Chairman of the Board of Directors, Chairman of the Scientific Advisory Board, and a prolific inventor. He is a Board Certified Neurologist and former CEO, President, Chairman and founder of Infectech and Nanologix. Dr. Felder acquired a B.A. Degree from the University of Pennsylvania in 1975 and a M.D. Degree from the University of Rome, Faculty of Medicine in 1983. Dr. Felder did his residency at Saint Vincent Hospital in New York, New York, where he was chosen to be Chief Resident in Neurology. He has been Board Certified by both the American Academy of Clinical Neurology and the American Board of Psychiatry and Neurology. Dr. Felder is a Clinical Assistant Professor in the Department of Neurology at the Texas Tech University Health Sciences Center. Dr. Felder has authored or co-authored six publications, three studies and has currently 18 issued patents. Dr. Felder was the Acting Chief of the Department of Neurology, Sharon Regional Health System from 1989 until 2001. Dr. Felder served as the Acting Chief of the Department of Neurology at the William Beaumont Army Medical Center in 2011.

Heidi H. Carl (Chief Financial Officer)

Chief Financial Officer and a member of the Board of Directors. From June 2007 to May 2009, Heidi was the Product Development Specialist at General Motors Corporation. From May 2006 to May 2007, Heidi was the Associate Marketing Manager at General Motors Corporation. From May 2003 to May 2006, Heidi was the Marketing Specialist at General Motors Corporation and, from May 1999 to May 2003, Heidi was the District Area Parts Manager over 40 dealerships in three states in the southeast at General Motors Corporation. Academic credentials include a BSBA Degree from Madonna University and an ASBA Degree from Oakland Community College.
Forward-looking statements: The Company's actual results, performance or achievements could differ materially from those expressed in, or implied by, these forward-looking statements, including those described in the Company's Financial Statements, Management Discussion and Analysis and Material Change Reports filed with the United States Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov).

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Current Product Overview

Section 3
Currently Available Drugs/Treatments
Feldetrex® - Fibromyalgia (FM)

Description:
• Medication for treatment of diseases with symptoms which include nerve pain, demylenation, muscle aches and spasms (i.e., fibromyalgia, MS, auto-immune, depression, etc.)

Market & Competition:
• Penn Biotech Group projects FM drug market size to be $2.0 B in 2015 and growing to $3B by 2030
• Lyrica® by Pfizer
  – Patent expires in 2016
• Cymbalta® by Eli Lilly
  – U.S. Patent expired end of 2013
• Savella® by Actavis (Forrest Labs)

Status:
• U.S. Patent issued 4Q14
• Initial submission to FDA 1Q15
  – Awaiting response

Plans/Actions:
• Conduct Clinical Trials outside of US under ICH6 guidelines (reciprocity)
• FDA filings for additional treatment uses
Currently Available Drugs/Treatments
Multiple Sclerosis (MS)

Description:
• Medication for treatment of diseases with symptoms which include nerve pain, demylenation, muscle aches and spasms (i.e., fibromyalgia, MS, auto-immune, depression, etc.)

Market & Competition:
• Affects 400,000 people in the U.S.
• No cure; only symptom mgmt.
• Numerous symptom treatments
• $20B annual drug treatment expenditures in U.S. (2014 est.)

Status:
• Potential extension of Feldetrex® applications under development
• U.S. Patent issued 4Q14

Plans/Actions:
• Submission to FDA in 2015 for treatment of MS
• Clinical trials to be conducted outside of US.
Currently Available Drugs/Treatments
Ebola Sequential Antigen Therapy (ESAT)

Description:
• Device/Treatment for removal of Ebola Hemorrhagic Fever target antigens from patient’s blood.

Market & Competition:
• No FDA approved vaccine or medicine
• Experimental drugs used to treat latest outbreak
  – ZMapp (Mapp Biopharmaceuticals)
  – TKM-Ebola (Tekmira Pharm. Corp.)

Status:
• Provisional Patent filed 4Q14
• Humanitarian Use Fast Track FDA application filed 4Q14
  – Awaiting response
• ESAT Device Prototyped

Plans/Actions:
• HUD’s do not require clinical testing (ethical concerns)
• Refine ESAT design
• File foreign patent applications

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Humanitarian Use Device (HUD) Duchenne Muscular Dystrophy (DMD)

Description:
• Device/Treatment for removal of target disease antigens from patient’s blood.

Market & Competition:
• No known cure
• Treatment costs exceed $23B
  – 1M cases worldwide
  – Less than 4,000 new cases per year in U.S.

Status:
• Humanitarian Use Fast Track FDA application filing 1Q15
• U.S. Patent Application submitted 3Q14

Plans/Actions:
• HUD’s do not require clinical testing (ethical concerns)
• Refine ESAT design
• File foreign patent applications
Humanitarian Use Device (HUD) Neurofibromatosis (NF)

**Description:**
- Device/Treatment for removal of disease target antigens from patient’s blood.

**Market & Competition:**
- No treatments to stop tumor growth
- Affects 100,000 in the U.S.

**Status:**
- U.S. Patent Application submitted 3Q14

**Plans/Actions:**
- Humanitarian Use supplemental filing to follow DMD filing
- HUD’s do not require clinical testing (ethical concerns)
In-Process Drugs/Treatments
Breast Cancer

Description:
• Metronomic anti-CTLA-4 treatment in conjunction with sequential dialysis therapy

Market & Competition:
• ~$20B annual treatment costs
• Penn Biotech Group projects PBI’s market revenue to be $1.9 B
• Kadcyla®; Roche
  – Full treatment course - $94,000
• Herceptin®; Roche
  – $6B in annual sales
• Numerous other drugs to prolong life.

Status:
• Duplicated mouse testing success presented to AACR Conference, April, 2014
• U.S. Provisional Patent Application filed 2Q14

Plans/Actions:
• Improved anti-CTLA-4 drug under development
• Patent application in 2015
• FDA Application in 2015
In-Process Drugs/Treatments
Atherosclerosis

Description:
• Target antigen antibodies in conjunction with sequential dialysis therapy

Market & Competition:
• Currently no cure
• Leading cause of death in U.S.
  – 4.6M people in U.S. actively treating disease
  – Est. 50% (est.) of population affected
• Most prescribed drug treatments
  – Crestor® (AZ); $5.6B sales (WW)
  – Merck products - $4.6B sales
  – Lipitor®, Plavix® et.al off-patent

Status:
• Filed for U.S. Patent 2Q14

Plans/Actions:
• File Supplemental FDA submission after ESAT approval.