

# Strategic Partners



BIONICA was originally founded in 1980, and effectuated its move from Australia to Sacramento, CA under the new ownership of Mr. Gregory Gilbert. BIONICA and Gregory Gilbert (“Licensors”) have “Licensed” the BIONICA pump technology under an “EXCLUSIVE LICENSING AGREEMENT” to CAT Clinic, LLC, founded by Mr. Gregory Gilbert and Associates in 2002, as the “Licensee” of the “Bionica Pump Technology” for Cellular Activation Therapy (CAT) Clinics. In October of 2007, CAT Clinics, LLC, entered into a “Stock Exchange” Agreement and “Licensing” agreement with VitalCare Technology Enterprises. Further, Mr. Gregory Gilbert, CEO of CAT Clinics, LLC and Founder of BIONICA International became the VP of Research and Development and a member of VitalCare Technology’s Board of Directors, to assist with the overall direction of the Company. BIONICA International, Inc. and Mr. Gregory Gilbert are the “exclusive” owners of both the U.S. Patents as well as the FDA approval for the BIONICA pump (iCAT infusion pump; aka: Micro pump) through the acquisition completed in 2005 from AMSys Corporation and Connecticut Innovations, Inc., which includes the T. Aoki Patents, along with the extensive intellectual and proprietary property (data) used in building the equipment, and lastly, the algorithms used in the micro-chip technology which analyzes a patient’s blood sugar level and end-tidal CO<sub>2</sub> levels in “real time” in order to calculate and deliver exact pulsatile dosages of insulin intravenously during each iCAT therapy session.

The iCAT infusion device (the “BIONICA” pump) has been continuously in use in a few hospitals as well as “Licensed” CAT Clinics, plus there are a few patients who’ve been clinically managed in the homecare setting now for over 25 years, with not one documented adverse reaction or complication to date. Patients who’ve been treated with the pump using iCAT therapy have ranged from age seven (7) upwards of eighty (80) years of age, pregnant mothers and breast feeding mothers as well. This is a perfect safety record, unheard of in the medical industry, which is due, in part, to the expert engineering of the patented internal pump mechanism. This total avoidance of mechanical and software failures, limited moving parts and the lack of any recalls, show that the BIONICA pump platform is extremely stable and dependable, critical to this group of patients. The BIONICA Pump system is also uniquely suitable for the new fluid micrometer pre-filled insulin cartridge system, a modification that will allow greater accuracy as well as a bi-directional pumping mechanism, giving healthcare providers a means to sample the patient’s blood for biological measurements of their blood sugar (glucose) level, as they receive their iCAT therapy, again, an industry first. Having a proprietary cartridge technology, bi-directional capability, with superior accuracy and performance allows the Company to deliver pre-filled disposable cartridges direct to the consumer. And with the planned next generation homecare pump, it will allow for the integration of a glucose sensor, to make the home therapy easy, safe, affordable, with the

ability for remote monitoring of all homecare patients.

As of 2007, a little over \$14 million dollars has been raised through private “angel” investors for iCAT therapy research and development. The majority of the capital was used in research, therapeutic protocol development, product design, FDA approval and operational costs. Additional capital was spent on administrative and legal work for obtaining U.S. and Foreign Patents, insurance approvals and reimbursement, developing the training programs and quality assurance standards in addition to R&D for the homecare pump, for homecare iCAT therapy.

**Intellectual property protection for the Company’s license through CAT Clinics, LLC and BIONICA International, Inc. is divided into the following:**

**Patent Protection:** Generally the Company is protected by a complete set of US Patents which cover the use of iCAT for several reasons. First, these patents are pending in all PTO countries, and are being applied for in non-treaty countries on a country by country basis, and include inventions, improvements, and techniques as they relate to the US patents, US patents pending and patents pending in PTO countries, used for the delivery of insulin for the treatment of diabetes, which includes US Patent Number 6,565,535 (2003) under USFDA # 3004435660 / BIONICA and EU # CE0470; US Patent Applications for Quantitative Chronological Medical Infusion Device, Serial No 10/834.466 filed April 2004 and August 2004, with Patent Convention Treaty elections, by Gregory Ford Gilbert to include any and all improvements thereto developed, whether patentable or not, which may now or may hereafter develop; the Development Purchase Agreement by BIONICA International, Inc. and Connecticut Innovations Inc. includes all Aoki Patents and other intellectual property as described herein. A complete list of issued, pending and intended patents can be provided with a signed “Non-disclosure Agreement”.

**Infusion Device (BIONICA Pump) Technology Patents for iCAT Therapy:**

- (a) Quantitative Chronological Medical Infusion Device  
Serial # 10/834.466
- (b) US Patent 6565535 (2003)
- (c) USFDA # 3004435660 / BIONICA
- (d) European Union # CE0470

**Treatment Patents for Each Organ System Using iCAT Therapy:**

- (a) **US Patent 6579531** (2001; Aoki) Method for treating heart disease and cardiovascular disease in diabetic and non-diabetic patients using pulsed dose intravenous insulin therapy.
- (b) **US Patent 6582716** (2003; Aoki) Method for treating wounds, promoting healing and avoiding amputations in

diabetic and non-diabetic patients using pulsed dose intravenous insulin therapy.

- (c) **US Patent 6613736** (2003; Aoki) Method for treating eye and central nervous system disorders in diabetic and non-diabetic patients using pulsed dose intravenous insulin therapy.
- (d) **US Patent 6613342** (2003; Aoki) Method for treating kidney diseases, specifically arresting the progression of diabetic neuropathy and therefore the risk of developing End Stage Renal Disease in diabetic and non-diabetic patients using pulsed dose intravenous insulin therapy.
- (e) **US Patent 6821527** (2004; Aoki) Update of the previous Patent No. 6613342
- (f) **US Patent 6967191** (2005; Aoki) Update of the previous Patent No. 6613736

Avoiding use of any patented portion(s) of Intercellular Activation Therapy technology will be extremely difficult as any use of the intravenous pulse dose and/or insulin pulse dosing is protected under the technology patents as well as the treatment patents. This protection will extend for both diabetes and non-diabetic medical conditions.

**Pump Business:** Protection from another pump manufacturer who might try to duplicate or reverse engineer another pulsatile intravenous pump to satisfy the requirements of Intercellular Activation Therapy is covered in the current US Patents. Any potential competitor cannot use their pumps for ANY Intercellular Activation Therapy or like therapy application without a review of their product “Label,” which would require FDA approval and necessitate having the iCAT treatment “Logic” programmed into the pump. The iCAT treatment “Logic” is proprietary and confidential. In addition, the proprietary pre-filled cartridge system, which was patented in 2003, is being modified and will have additional US Patent protections.

**Circulating Glucose Measurement Technology:** Further protection for BIONICA’s pump will be extended once the integral sensing mechanism is included for the purpose of measuring real-time circulating blood sugar (glucose) level, using the Patent pending “bi-directional” sampling system designed into the second generation BIONICA pump. An essential part of iCAT therapy is continuous intermittent measuring of circulating blood sugar (glucose) levels while the patient is receiving iCAT therapy, in addition to metabolic measurements of the respiratory quotient. Although blood sugar (glucose) measurements are currently made using the conventional “finger stick” technique, iCAT therapy will begin using its patented sampling technology as a way to make those measurements more accurate without having to prick the patient’s finger several times during each treatment session.



## MedEdCo

MedEdCo, LLC, was Co-founded in 2003 by Melanie Kunz, Director of Clinical Services, based in Phoenix, AZ with a satellite office located in Sacramento, CA. In October of 2007, MedEdCo LLC, entered into a “Stock Exchange” Agreement and “Licensing” agreement with VitalCare Technology Enterprises. Further, Miss Melanie Kunz, Co-founder and Director of Clinical Services became the VP of Clinical Services and a member of VitalCare Technology’s Board of Directors, to assist with the overall direction of the Company. MedEdCo will provide VCTE with the clinical support, professional training and quality assurance services provided for the clinical support and operations of all licensed iCAT Diabetes Centers™, through MedEdCo’s Exclusive Management Services Agreement with CAT Clinics, LLC and BIONICA International, Inc.

MedEdCo is the company that has helped develop a scientific understanding of how the clinical application of iCAT therapy directly influences the body’s natural re-establishment of dormant enzymes within the liver necessary for proper cellular function by properly metabolizing carbohydrates and fat (lipid) metabolism in the proper proportion. It has been shown to do this in all patients treated with iCAT therapy to date. iCAT therapy has, like all new therapies, taken many years to develop, get approval and start the process of becoming accepted by leaders in the medical community.

All diabetics, no matter how healthy they may seem, may have already developed an advanced secondary medical complication or will begin developing a secondary medical complication as a result of their diabetes. Some diabetics develop these secondary medical conditions more quickly than others, based on their diet, exercise and lifestyle, including alcohol and tobacco consumption. Poor metabolism attacks the diabetic at his or her weakest points. There are two different types of diabetic people. Type I Diabetes, “juvenile onset” diabetics (also occurs in adults) fail to produce either enough insulin or none at all. Type II Diabetes, “adult onset” diabetics are able to produce insulin but are slow to release insulin and are therefore considered “insulin resistant”. Both types of diabetes are not just conditions of insufficient insulin; they are diseases of improper cellular metabolism. That is the technical definition of diabetes, a “Disease of Metabolism”.

MedEdCo’s Clinical Specialists and medical researchers began to realize that metabolic dysfunction is the core of the Diabetic’s problem which led researchers to develop the theory behind the iCAT therapy solution. The method of intravenous administration of insulin, coupled with carbohydrate loading was developed to restore proper liver stimulation and enzyme release, so that body-wide metabolic functions returned to normal. MedEdCo’s proprietary treatment method utilizes the FDA approved and U.S. Patented BIONICA pulsatile insulin pump with its proprietary software program

(algorithm) along with a proper oral administration of carbohydrates (dietary food intake) has become the new emerging standard of care for the treatment of Diabetes. Using this specially formulated therapeutic protocol to administer insulin intravenously with the BIONICA Pump, researchers were able to re-establish the patient's ability to metabolize glucose as the body intended and further demonstrated restoration of normal cellular metabolism in all of the diabetic patients treated. This had never been achieved in the normal subcutaneous insulin injections, nor was it consistent with pulsatile insulin therapy using micro-dosing without ongoing metabolic measurements throughout the therapy session.

MedEdCo, along with its corroborative partners, have documented the following; i) that iCAT therapy can stop, reverse or at a minimum stabilize secondary medical complications of diabetes; ii) every patient to date, begins feeling positive results within days to a few weeks of their initial iCAT therapy session; and iii) there have been no failures, "negative" outcomes, complications or adverse effects from iCAT therapy to date. iCAT therapy has been in continuous use for over 25 years, with approximately 100,000 therapy sessions and with a statistically significant number of documented patient's cases, and has performed without any reduction of effectiveness or negative side effects being reported. Furthermore, there is no indication that any patient has demonstrated a lack of response to iCAT therapy. To the contrary, iCAT therapy has proven greater effectiveness with prolonged use. The following institutions have been engaged in research of Cellular Activation Therapy (iCAT) including: University of California, Harvard (Joslin Diabetes Center), Mayo Clinic, Scripps Clinic, University of Arizona, Temple University, University of Maryland, Donnellson (HCA Tennessee) and other institutions have documented iCAT therapy benefits. Independent investigators have published their peer reviewed articles documenting iCAT's beneficial effects using several different names of their own, including CIIT (Chronic Intermittent Intravenous Insulin Therapy), PIVIT (Pulsatile Intravenous Insulin Therapy), Hepatic Activation, and iCAT depending upon the reviewer's terminology. All of these terms related solely to the Company's iCAT Therapy Program. (Copies of the peer reviewed articles and information are included and made a part of this business plan.)

MedEdCo's role will be to provide the professional training, certification and quality assurance support services for all licensed iCAT Diabetes Centers™. MedEdCo, LLC has developed all of the iCAT educational products, training materials, quality assurance standards, clinical oversight methodologies and has assembled world re-known physicians and clinical specialists as its Medical Advisory Board members. In addition, it will be MedEdCo's corporate responsibility to "Certify" all licensed iCAT Diabetes Centers and/or Affiliate Centers and their healthcare providers. iCAT Educational products and services include the following:

**Training for Doctors, Nurses, and Medical Technicians:** iCAT textbooks, videotapes and clinical training manuals have been prepared by MedEdCo, and will be provided to all "Certified" licensed iCAT Diabetes Centers and/or Affiliate Centers and "Certified" healthcare staff engaged in patient care. Additional iCAT educational products and materials will be available in a limited format for the general public at a

nominal cost and offered online.

**Patient training:** A series of specialized iCAT educational products have been prepared for diabetic patients who've completed their initial iCAT therapy at a "Certified" licensed iCAT Diabetes Center and/or Affiliate Center, achieving a normalized metabolism with stabilization of their blood sugar (glucose) levels, stabilization and/or reversal of their secondary medical complication and are now ready to transition into a homecare self-administered iCAT program. VCTE, working together with MedEdCo, will have to establish a training/patient education fee, which will be billed either to the patient or their insurance company for this service. Each patient, family member and caregiver who completes the iCAT homecare training program will be registered into the iCAT database and receive a Certificate of completion from MedEdCo's iCAT Certified Trainer.

**Billing procedures:** VCTE, with the assistance of MedEdCo, has a standardized billing procedure and list of accepted billing codes for both Hospital (UB92) and Physician's Office based (CPT Codes) iCAT Center operations. It is anticipated that there will be an eventual standardized billing code created specifically for iCAT therapy, once Medicare approval is established at the conclusion of Medicare's longitudinal study.

**General Educational Materials.:** General iCAT educational materials, for the public and referring physicians outside the US market, will be translated into the appropriate languages, from approved master doc files that now exist. All iCAT materials and translations will be regulated and approved for use by MedEdCo, LLC, CAT Clinics, LLC and VCTE.

**Medical Advisory board:** The Medical Advisory Board, established thru VitalCare's affiliation with MedEdCo, LLC Management Services includes:

- Philip Levy, MD
- Michel Pinget, MD
- Marc Sandberg, MD
- John Garbaciak, MD
- Marc Rose, MD
- Nardo Zaias, MD
- Kathy Gregory, MD
- Jack Sipperley, MD

**We anticipate several additional appointments in the future.**