

**NuVue Therapeutics, Inc.**

[www.NuVueTherapeutics.com](http://www.NuVueTherapeutics.com)

**Industry:** Biotech and Medical Device Industry

**Management Team:**

Roger S. Kolasinski, Chairman /CEO  
Mark Ehlert, Corporate Development, Board Member  
Dr. Anne Rose, ViCRO, FDA Advisor  
Mr. Elliot Cole, Esq., Patton Boggs, Board Member  
Patrick LePivert, MD, PhD, VP R&D, Chief Medical Officer, Board Member  
Dennis Morrison, PhD, MS, BPS, VP R&D, Microencapsulation  
Mr. Jim Kulinski – Director of Sales  
Mr. Robert Pfefferkorn – Director of Marketing  
Chief Financial Officer, TBD

**Revenues: projected**

2008 R&D only  
2009 800 K  
2010 8.5 M  
2012 103.2M  
2013 206.5M

**Current Debt:**

Founder: 1M loan-three year note  
Line Of Credit: N/A

**Previous Investment:**

Founder: 5.0M  
Other Round: 2.0M (Family and Friends)  
Structure: C Corp.

**Financing Sought:**

\$15 Million with 3 tranches of 5.0 M each. Over a period of 1.5 years - Upon reaching specific benchmarks: share price negotiable

**Use of Funds:**

- Complete 510(k) and conduct product launch of enhanced visualization biopsy needles (Product 1);
- Complete design, conduct trials and obtain 510(k) for microencapsulated biopsy tissue markers (Product 2);
- Complete design, conduct trials and obtain NDA and 510(k) for CryoChemoAblation cancer treatment (Product 3).
- Build organizational infrastructure, R&D, patents, legal, and operational & manufacturing

**Business Description:**

**Business Description:** NuVue Therapeutics, Inc., (NuVue) is a privately held, Biotechnology Driven/ Medical Device Company founded to address and solve unmet medical needs in oncology through minimally-invasive, image-guided, site-specific diagnostics and therapeutics for soft-tissue cancers. NuVue has created a completely new and innovative way to treat soft tissue cancers with its recently developed and patented therapeutic “Site-Specific Regimen of Cancer Therapy”.

**Company Background:** In 1971, the Company’s founder, Roger Kolasinski, founded Kol Bio-Medical Instruments, Inc., a highly successful medical specialty distribution company reaching sales of some \$45 million per year. [See www.kolbio.com.] In the mid 1990’s, due to family, he realized the amount of individual patient debilitation that was created by the use of radiation and systemic methods of cancer chemotherapy. In 1999, Mr. Kolasinski formed NuVue (initially named Critical Care Innovations, Inc.), and set about strategically acquiring specific technologies with certain inherent characteristics, metabolically which he believed, when integrated, would create a completely new and innovative way of treating soft tissue cancers, ridding the patient of most, if not all, therapeutic side effects.

**Technologies/Special Know-How:** Some four years were spent in looking for three specific technologies that when integrated would hopefully create this new and innovative proprietary Technology Platform for the treatment of soft tissue cancers. NuVue™ can now say that it has prevailed with the creation of its “Site-Specific Regimen of Cancer Therapies”. Through the integration of these specific technologies, Oncology will avail itself to having a completely new, *less toxic*, set of proprietary therapeutic methods, processes and interventional devices in which to treat cancer patients with pinpoint accuracy. With this less toxic “Regimen of Therapy” allowing for the preservation of the patient’s Immune system, the Company is now poised to capture rapid market penetration, upon its commercialization. Because of the creation of multiple clinical solutions, via this focal “Regimen”, Oncology will now have the ability to overcome many of the significant unmet clinical needs present in today’s radiation and systemic methods of therapy, ultimately insuring better patient outcomes. NuVue’s combined and innovative Site-Specific Regimen, with its proprietary therapeutic approach is expected to become a valuable adjuvant and/or alternative to simple conventional tumor mass de-bulking or to local, regional or systemic palliative therapies.

**Consumables:** The Company has deployed its integrated technologies into three product Systems, to be introduced in a phased-in go-to-market strategy: (1) *Biopsy Needles with Enhanced Ultrasound Visualization: NuVue ColorMark™ needles* show up brightly under ultrasound for use in fine needle aspiration and core biopsies. These products will meet the demand for minimally invasive biopsies that are accurate enough to avoid the high error rate currently experienced in deep tissue FNAB. They are planned for market introduction, in July /August this year, 2009. (2) *Microencapsulated Tissue Markers: NuVue BrightMark™* long-lasting, biodegradable microencapsulated tissue markers that can be delivered directly into targeted tumors, with no migration within the tissues. These products will be delivered by the Company’s biopsy needles and sold into the same customer base. Projected introduction - six to nine months after NuVue ColorMark™ needles. (3) *Cryo-Chemo Ablation of Tumors:* Ultrasound-directed, site-specific delivery of *NuVueChemo™* microencapsulated chemotherapies into cryothermally sensitized soft tissue cancers via proprietary consumable devices. The system permits accurate, localized delivery of powerful and individualized chemotherapy agents enhanced by *NuVue CryoCool™* cryotherapy, while sparing the immune system. The Company initially will target hard-to-treat indications such as liver and pancreatic cancer, where it has advantages over current, unsatisfactory treatments. Together, these products give the practitioner an integrated set of tools to detect cancer early and treat it with individualized, powerful therapies that are minimally invasive and preserve the patient’s immune system – NuVue’s *Site-Specific Regimen of Cancer Therapy*.

The Company’s cost-effective, customized solution for soft-tissue tumor treatments offers the clinician the ability to develop and design individualized regimens of interventional ablative therapies. The encapsulation of multiple and varied cytotoxic drugs within a single microcapsule creates a systematic way of individualizing a patient’s chemotherapeutic regimen. More effective direct and site-specific interventional therapies delivered using highly accurate real-time image-guidance lessens the need for repeated high volume systemic chemotherapy. NuVue’s pre-clinical studies with its *Site-Specific Regimen of Cancer Therapy* demonstrate measurably improved clinical outcomes with far less morbidity, while ensuring lessened levels of toxicity.

**Markets:** The Company’s products address a potential U.S. market of \$18.2 billion and globally some \$40 billion. (See Business Plan) Analysts have estimated that the diagnostic markets are growing at 4.5% to 5.0% per year and the therapeutic drug delivery markets at 18.3 to 24% per year. On a worldwide basis, the market opportunity is estimated by the World Health Organization to be double the size of the U.S.

**Distribution Channels:** NuVue intends to market its products to both the domestic and international healthcare markets through highly experienced specialty distributor organizations. Each organization will operate under an exclusive distribution agreement, with NuVue overseeing and measuring their efforts through its internal sales management structure. The company will employ dedicated clinical specialists to assist the distributors' sales personnel in the field. This arrangement will provide the Company with the opportunity to become directly identified with each customer account as they adopt NuVue's technologies.

**Competition:** NuVue competes with device companies such as C.R. Bard, Boston Scientific, Sanarus, and SenoRx for some portion of its technologies. However, none of these companies offers the full complement of therapies that NuVue's Site-Specific Regimen of Cancer Therapy provides; hence, the Company does not have a full competitor, and maintains significant competitive advantage. The Company purchased or licensed 32 patents, and has applied for five new patents covering the integration of its technologies, hence, protecting its newly developed proprietary platform of technologies. In addition to its patent protection, the Company has erected barriers to entry including the development of a proprietary line / system of consumables to insure the exact positioning and controlled release of its imageable microencapsulated drugs, cryothermal enhancement devices, and biopsy-site biodegradable marker systems.

**Management:** Roger Kolasinski serves as the Company's Chairman and CEO. A graduate of Michigan State University (1968) with a B.S. degree in microbiology, he began his career in the field of genetic research in the Microbiology Department at the University of Connecticut. He then moved into specialty medical equipment sales, and in 1971 founded Kol Bio-Medical Instruments, Inc. (See Company Background, above.) Mr. Kolasinski has remained active with Michigan State, serving on the Dean's Board of Advisors of the University's College of Natural Science. Mr. Kolasinski has assembled a proven team with significant start-up, research and development, manufacturing and entrepreneurial experience in the life sciences. The management team includes the inventors of the NASA microencapsulation technology (Dennis Morrison, Ph.D.) and the cryothermal technologies (Patrick Le Pivert, Ph.D., M.D.).

**Financial Projections:** The Company projects breaking even in the 1st Quarter of Year 3 and does not anticipate the need for additional outside financing. It expects to record revenues of \$30.5 million in Year 3 and \$206.5 million in Year 5; with 78.0% and 74.7 % gross margins, and EBIDTA of \$3.4 million and \$112.9 million, respectively.

**Exit Strategy:** In the medical diagnostics and therapeutics industry, acquisitions and mergers and/or IPOs are accepted exit strategies. With management's past experience with mergers/acquisitions and IPOs, it regards such an occurrence as likely, and anticipates that such opportunities might occur after the third year. **Outlook:** The Company believes that it will realize success through the acceptance of its newly developed "Site-specific Regimen of Cancer Therapies", which fit perfectly within the Managed Healthcare Environment as it exists today.

**The Company's newly developed Method's of Therapy" serve as a strong market differentiator and will ensure a significant recurring revenue stream and bottom line profits for the company's shareholders. Why NuVue Therapeutics, Inc.?**

- Robust, integrated technology platform capable of supporting multiple products, Strong management and manufacturing teams with technical infrastructure including technology inventors, first products, July 2009
- Many unmet clinical needs finally resolved! Only through the implementation of NuVue's Regimen of Therapy, with integrated minimally invasive disposables having the staying power sufficient to attract industry buyers
- Strong enterprise value with multiple on investment - upon exit through probable merger-acquisition

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