

NuVue Therapeutics, Inc.

www.nuvuetherapeutics.com

Industry: Drug/Medical Device
Oncology Markets

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
Director of Marketing, TBD
Chief Financial Officer, TBD

Revenues: projected

2009 R&D only
2010 1.0 M
2011 8.5 M
2012 103.2M
2013 206.5M

Current Debt:

Founder: 600K loan-three year note- and /or Stock
Line Of Credit: N/A

Previous Investment:

Founders: 4.5.0M
Other Round: 2.5.0M
(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: NuVue Therapeutics, Inc., (NuVue) is a privately held Drug/Medical Device Company founded to address and solve the unmet clinical needs in treating soft tissue and deep lesion cancers. With the development of NuVue’s array of cost effective, image-guided Tissue Acquisition and Interventional Site-Specific Drug Delivery Systems, along with its Targeted ChemoAblative Anti-Vascular Regimens of Cancer therapy, NuVue has created a completely new and innovative way to treat these cancerous tumors.

Company Background/ Technologies/Special Know-How: 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. In the mid 1990’s, due to family, he realized the amount of individual patient debilitation that was created by the use of many systemic methods of cancer chemotherapy. In 1999, Mr. Kolasinski formed NuVue (initially named Critical Care Innovations, Inc.), and set about strategically acquiring three specific technologies over a four year period that he believed would have certain inherent biologic characteristics, metabolically, and when integrated, would create a completely new and innovative way of treating soft tissue cancers: A Totally New Regimen of Therapy which inherently preserved a cancer Patient’s Immune System, due to its lessened levels of toxicity, No Hair Loss, No Vomiting, and all of the other vial side effects associated with what’s considered standard Systemic Chemotherapies. NuVue™ can now say that it has prevailed with the creation of its “Site-Specific Anti-Vascular 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.

Through the development and use of its array of image-guided, interventional, site-specific fluid delivery systems, NuVue has now created a completely new and innovative way to treat soft tissue cancers. Used in concert with its newly developed Site-Specific ChemoAblative Therapy for the treatment of all soft tissue solid tumors, NuVue has now finished development of its new cryothermally assisted Cancer Chemoablative Therapeutic alternative. When this new method of therapy is combined with the Company’s proprietary ultrasound visualized, interventional, cryothermal devices, selected full therapeutic doses of different types of formulated drugs can be delivered with pinpoint precision, directly within the tumor tissues. These proprietary methods and devices insure the accurate and predictable diffusion of such doses of drug (s), while they are being held and retained for prolonged chemotherapeutic purposes within such targeted tissues. NuVue, with its newly developed needle-like devices, and regimen of therapies can now target a tumor’s specific vascular network and finally is be able to overcome all of the typical deficiencies of Chemoablative Therapies, as being used today. With the use of its handheld interventional devices, in concert with its Anti-Vascular Cancer Regimen successful therapeutic implementation and superior patient outcomes are achieved. The Company is now poised to capture rapid market penetration, upon its commercialization. NuVue’s combined and innovative methods and regimen of therapies, with its proprietary therapeutic approach is expected to become a valuable neo-adjuvant or adjuvant alternative therapy 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 the first qtr of year 2010, post funding. (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™). (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 Anti-Vascular 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 Site-Specific 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 Anti-Vascular Regimen of Cancer Therapy* demonstrate superior and 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 35 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 minimum of 180 years of 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, an acquisition and merger is what is the most accepted exit strategy. With management's past experience with mergers/acquisitions, because of the size of the opportunity, it regards the occurrence of an M&A as most 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", and proprietary delivery Devices, which fit perfectly within the Managed Healthcare Environment as it exists today. Down the line, no matter what ever happens, NuVue's products will inherently fit perfectly into any system of Health Care created by our Congress. This is due to NuVue's understanding of the market and do to our innovative presents of mind and what will be continued to be developed in the future: taking into account such things as safety, efficacy, cost, and the inherent ease of implementation of it products into the largest segment of the Heath Care Field, that of the Primary Physician Based Healthcare.

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 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 investments - upon exit, probably through a merger-acquisition

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