Venture Capital

Kromotech, Inc. – A Venture Capital Assessment

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Introduction

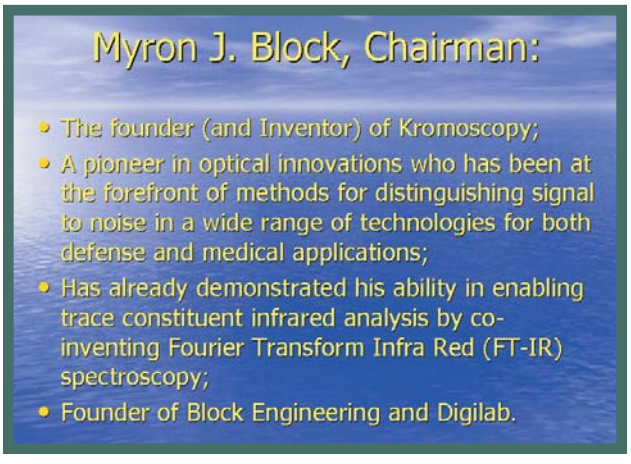
Specialty Pharmaceuticals has continued to be an area of great interest to the traditional investment community. Often equated to late-stage compounds that are in-licensed and advanced by an organization without a research drug development infrastructure, the breadth of coverage suggested by these organizations has historically stayed clear from the medical device and diagnostic sectors. As the practice of medicine continues to evolve, we are witnessing a greater interest by the major multinationals in developing a franchise around a particular disease, as opposed to focusing singularly on diagnosis or treatment. Forming a franchise around a disease incorporates products that participate in either diagnosis, management and/or monitoring, and treatment. Given that Specialty Pharma may ultimately enter into a relationship with a major multinational that will potentially leverage a compound not only for its treatment potential, but also for its role as one component of a franchise, it is important to understand the drivers behind the non-therapeutic contributory elements. To this end, we have decided to focus on a technology that has the clear potential to participate in a franchise for a disease recognized by many as one of our major medical hurdles.

"Translational Franchise" as a Model for Venture Capital Consideration

The concept of a franchise within a particular disease has often been utilized to refer to "captive market" positioning, often a particular drug or a proprietary medical device or diagnostic that has successfully positioned itself as the undeniable leader. A disease franchise is very different from what is seen with the more traditional use of the franchise concept, as we see with many of today's businesses within this category, which follow a predefined way of administration, marketing, and operations. We believe that the strategy of capturing market share for a particular disease by controlling diagnosis through therapy is novel. While it makes complete sense to develop a disease franchise as we are now defining the concept, certain diseases are more appropriate for implementing this strategy. One additional element of what we describe further as a valuable strategy is provided by the use of non-invasive methodology.

Our goal in this article is to elucidate and define a medical marketing strategy providing a unique value and opportunity for capitalization, maximized by non-invasive elements all the way from initial diagnosis through therapy, focused on a particular disease.

The concept and practice of "translational medicine" has evolved extensively throughout the past 5 years, wherein a basic discovery from the laboratory becomes applicable to the diagnosis, treatment, or prevention of a specific disease. Many major universities' medical centers and hospitals now have separate divisions focused on translational medicine. We are introducing the concept of



a "translational franchise" to focus on a multinational strategy addressing (continuous) diagnosis, monitoring, and treatment of a single disease. Participation in, and control of, a translational franchise correlates directly to the valuation process of its contributory elements.

Diabetes is the ideal disease to test this model, given the constant and continual requirement for monitoring and treatment. Many technologies have been advanced for the non-invasive measurement of glucose, but have failed. Similarly, only recently has there been progress in the non-invasive administration of insulin. There remains great concern regarding the quantity of insulin administered non-invasively, and the actual amount absorbed into the blood. In order for the non-invasive delivery of insulin to provide maximal benefit for the patient, a continuous non-invasive feedback of glucose levels would be extraordinarily helpful. All of the arguments regarding minimally invasive glucose measuring have done little to allay the legitimate concerns of the diabetic who has grown tired of promises of "needle-free" and marginal improvement with invasive modalities.

The Proprietary Platform Technology of Kromoscopy

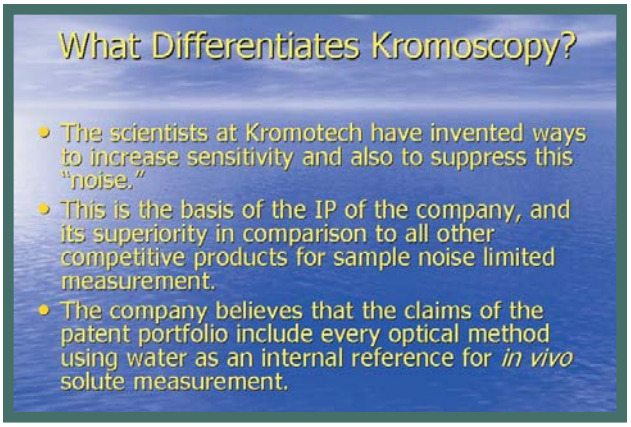
The new world of opportunities in detection and measurement has been opened up by the invention of a proprietary platform technology. Since the dawn of science, a sensor has been used to report unambiguously and independently one piece of information at any instant of time. This is often called an orthogonal measurement code. In nature, however, a different measurement scheme or measurement code is used by virtually all of the senses. This scheme is found in most species. Myron J. Block has called this the *Combinatorial Measurement Code*, or Kromoscopy. Kromoscopy has two advantages over an orthogonal code.

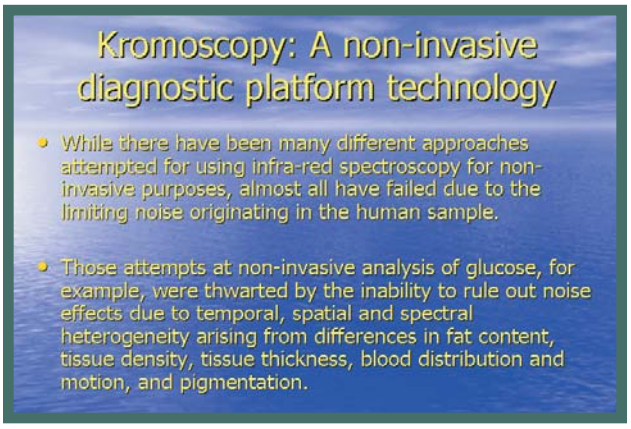
The intrinsic advantage is that measurements can be made beyond the capability of a sensor. We see this, for example, with odors (Linda Buck) for which there is no specific sensor and yet can be detected, or with the millions of colors that may be resolved with just three types of color receptors. The extrinsic advantage of Kromoscopy is that measurements may be made when the desired information is overwhelmed by a larger and variable background. It is this second advantage that Kromotech, Inc. has chosen for its first application of the combinatorial measurement code. The non-invasive measurement of glucose is limited by a noise generated in the sample. The extrinsic advantage of Kromoscopy is clearly needed here.

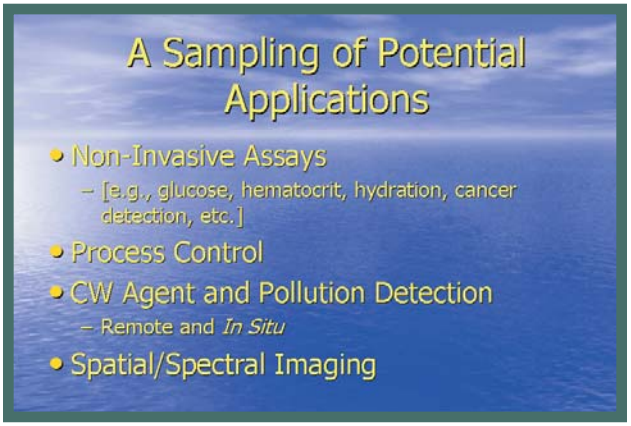
Kromoscopy, simply defined, is a proprietary combinatorial measurement code (not a data processing algorithm) in which different but overlapping simultaneous detection responses perform the measurement. This enhances the performance (eg, sensitivity and specificity) of detectors. In addition, in those measurements in which the limiting noise arises in the sample (eg, *in vivo*), the sample noise is reduced.

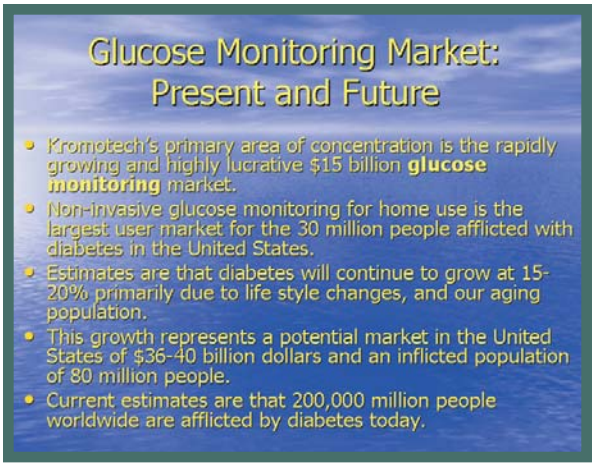
Financing Opportunities for Combination Products, Within Diabetes

Because of its advanced capabilities, Kromoscopy can make available simultaneous and independent measurements of blood glucose at multiple sites, providing a "second









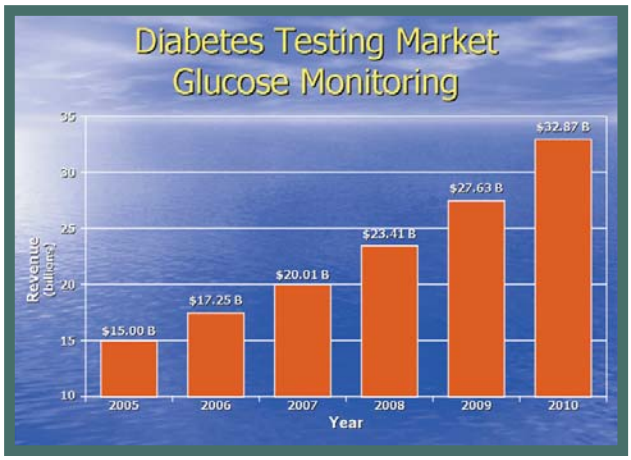
opinion." Second opinion enhances reliability far beyond the capability of single diagnostic tests. Because a Kromoscope provides for measurements in the blood and not in the interstitial fluid, reproducible measurements are available at multiple sites. This unique feature of Kromoscopy is further supportive of participation in a translational franchise, as it provides critical feedback for reliable and timely insulin delivery.

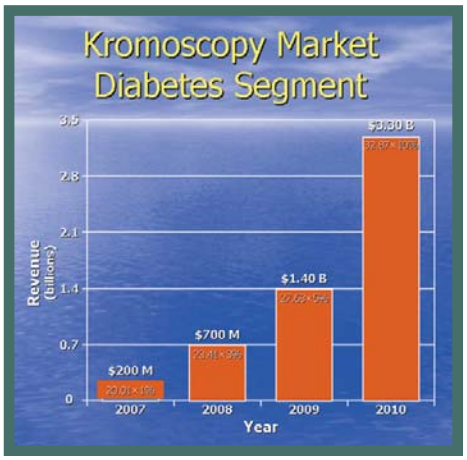
Diabetes is uniquely positioned to gain the attention of many therapeutic multinational companies, toward a point earlier in the development of the disease. Many of the drugs presently being utilized to treat patients with diabetes are now being evaluated for their role in helping to prevent the disease in those who are at risk. The potential role of Kromoscopy as a participatory screening agent for prediabetics, within a total comprehensive diabetes' disease franchise, allows it to play in the diabetes-prevention market. According to *The Wall Street Journal* (October 13, 2006), the market for a diabetes-prevention drug could potentially be as large as $15 billion per year, according to some analysts, addressing an estimated 54 million individuals in the United States alone. Kromoscopy may clearly be the leading player in this market, fueled by its' non-invasive diagnostic capability. This is clearly an additional market to the already well-established and quantified diabetes' market.

A contributory development to enhancing Kromoscopy value, which has occurred in the product development arena and been both endorsed and supported by the FDA, has been the concept of "combination products." Defined by the FDA as "a product composed of any combination of a drug and device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product," products can range from the simple, such as a syringe prefilled with a drug or biologic, to the more complex, such as a drug-coated stent (*Marketing Combination Products*, MX, September/October 2006). The concept of combination product was not established for the uniqueness of Kromoscopy, which may require special attention, as occurred with the first consideration to combination products. Potential partnering of Kromoscopy with non-invasive insulin delivery pharmaceutical companies will be one factor in the ultimate FDA filing route, and submission of the Kromoscope potentially as a component within a combination product. It is unclear how the Office of Combination Products (OCP), established by the FDA in 2002 to oversee the regulatory process for such products, will treat a non-invasive diagnostic product with trend-setting continuous feedback to a therapeutic product receiving drug delivery information. Investor value here must pay careful attention to not only the non-invasive attribute of Kromoscopy, but the ability of this technology to provide continuous feedback.

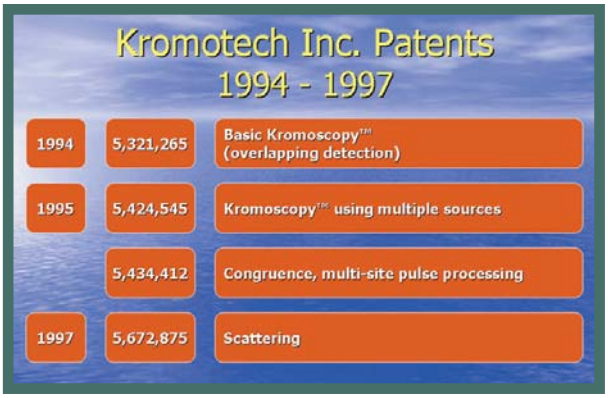
Capitalizing on a "Second Opinion"

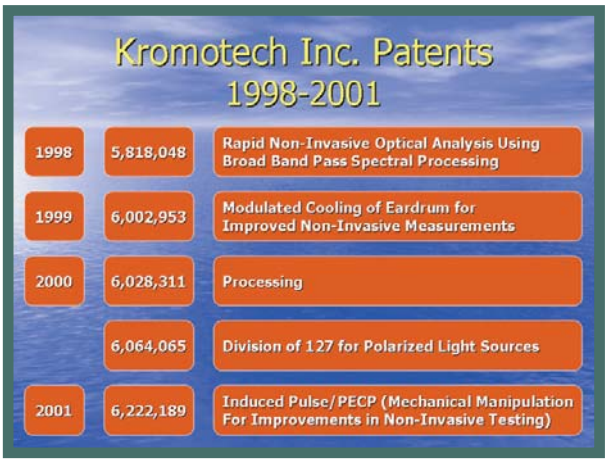
We started our discussion of Kromoscopy with an appreciation of the fundamental significance of this new measurement code, and it is to this central theme that we wish to return, now relating this point to another industry that has significantly changed. While spectroscopy is an orthogonal measurement code similar in principle to a digital camera where each picture element of the scene has its own pixel, we cannot guarantee that the Kromoscopic measurement code will be as widespread and successful an instrument method as the orthogonal code. In nature, the Kromoscopic code is a much more successful and widespread sensory code than the orthogonal code. Following the analogy of the historical early cameras and their eventual role in medicine, one only needs to look at the "earlier adopters" of digital photography versus those who adopted late, and how the players in that industry were impacted. An entire industry evolved, including not only the modifications to the hand-held camera, but also the implications and opportunities for the major medical

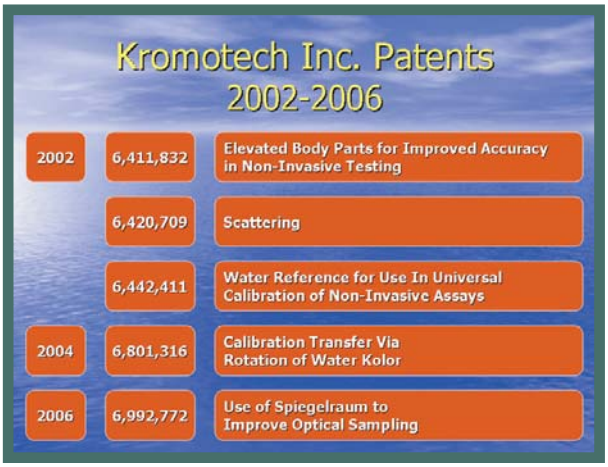




imaging instrumentation companies, including those in the business of nuclear magnetic resonance, positron emission tomography, computerized axial tomography, and others. There were winners and losers based on how quickly and effectively participants could recognize trends and/or market needs, and adopt to change. The progress in photography and the role of the camera within that industry are a very good analogy to Kromoscopy because it is a basic tool used in the simplest of settings, to capture nature, yet spans to a major role in the most complex medical cases, requiring definitive diagnoses. Kromoscopy has a superiority in the detection and measurement of a trace amount of a known substance embedded in and swamped by a spectroscopically unmanageable background. We concur with the inventor of the technology that Kromoscopy will eventually dominate in the medical, military, and industrial IR applications, while spectroscopy will continue to dominate in the laboratory and in research.







What is obvious to us is that there remains a definitive need for a non-invasive diagnostic technology to play a major role in not only glucose measurement but also to unquestionably participate in diabetes management. While there are many diagnostic "technologic tools" that are used with diabetes patients, they are singularly focused on glucose measurement and do not actively contribute to the continuous management of the entire disease. Kromoscopy's unique ability to provide a "Second Opinion" non-invasively provides the patient with a level of comfort unrealized to date. As a proprietary platform technology with a fence of approximately 12 issued method patents, Kromoscopy is uniquely poised to become the key contributory contender within a diabetes translational franchise. ■

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Mr. Stewart Rosenberg is President and Founder of Bio-Investigations Ltd. A venture capital firm heavily focused in the fields of human, veterinary, and agricultural healthcare, Bio-Investigations Ltd. maintains relationships with universities and corporations worldwide. The firm often takes positions in innovative technologies in the form of exclusive options or worldwide licenses, as well as corporate equity participation. As a result, Mr. Rosenberg and/or Bio-Investigations Ltd. may hold a residual financial interest in some of the companies referenced in this article. With undergraduate and graduate degrees in business and science from The University of Connecticut, the University of Pennsylvania, and Wharton, he has served in an advisory capacity to many of the major multinational diagnostic and pharmaceutical companies. He can be reached at bioinv1@aol.com. He would like to thank M.J. Block, Chairman, Kromotech, Inc., for his technical contributions and William Rosenberg, Vice-President-Information Technology for his graphic contributions.