# Kromotech Inc. Public Offering

October 2006

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# Kromoscopy: A non-invasive diagnostic platform technology

- While there have been many different approaches attempted for using infra-red spectroscopy for noninvasive purposes, almost all have failed due to the limiting noise originating in the human sample.
- Those attempts at non-invasive analysis of glucose, for example, were thwarted by the inability to rule out noise effects due to temporal, spatial and spectral heterogeneity arising from differences in fat content, tissue density, tissue thickness, blood distribution and motion, and pigmentation.

### What Differentiates Kromoscopy?

- The scientists at Kromotech have invented ways to increase sensitivity and also to suppress this "noise."
- This is the basis of the IP of the company, and its superiority in comparison to all other competitive products for sample noise limited measurement.
- The company believes that the claims of the patent portfolio include every optical method using water as an internal reference for *in vivo* solute measurement.

### What Makes Kromotech an IPO Candidate?

 What is most appealing about Kromoscopy is its diverse potential to the medical, infield, and industrial markets.

 Kromoscopy allows for a broad range of non-invasive measurements in diagnostic healthcare, industrial processing, and homeland security. Kromoscopy in Nature



# A Sampling of Potential Applications

Non-Invasive Assays - [e.g., glucose, hematocrit, hydration, cancer detection, etc.] Process Control Tagless Binding Assays - [e.g., DNA and Immunoassay] • CW Agent and Pollution Detection - Remote and In Situ Spatial/Spectral Imaging

# Kromoscopy Opportunity Matrix

	Market Potential	Technical Feasibility	Regulatory	Partner	Priority
Glucose Monitor	Highest	High	Required	Needed	Highest
Process Control	Moderate	Very High	Not Required	Wilks	High
CW Agent/ Pollution	Moderate	Very High	Not Required	Wilks	High
Hematocrit	Moderate	Very High	Required	Needed	Moderate
Tagless Binding Assays	Large	High	Not Required	Needed	Moderate
Cancer Detection	Moderate	Moderate	Required	Needed	Moderate
Spatial/ Spectral Imaging	Small	Moderate	Needed for Medical; Not Needed for Industrial	Needed	Lowest

### Glucose Monitoring Market: Present and Future

- Kromotech's primary area of concentration is the rapidly growing and highly lucrative \$15 billion glucose monitoring market.
- Non-invasive glucose monitoring for home use is the largest user market for the 30 million people afflicted with diabetes in the United States.
- Estimates are that diabetes will continue to grow at 15-20% primarily due to life style changes, and our aging population.
- This growth represents a potential market in the United States of \$36-40 billion dollars and an inflicted population of 80 million people.
- Current estimates are that 200,000 million people worldwide are afflicted by diabetes today.

### Diabetes Testing Market Glucose Monitoring



## Kromoscopy Market Diabetes Segment



## Kromotech Inc. Patents 1994 - 1997



# Kromotech Inc. Patents 1998-2001



# Kromotech Inc. Patents 2002-2006



## **Regulatory Approvals**

- Bio-Investigations Ltd. will serve in a project management role for clinical trials, with the utilization of external CROs and or data management organizations.
- Quintiles, Covance, Parexel, and Client Associated Businesses, Inc. have been targeted and advanced for their respective CRO and data management capabilities.
  PMA (Premarket approval) applications or 510(k) (with clinical) submissions will dictate key elements in manufacturing of the Kromoscope.
- Historical approval of a glucose monitor and insulin pump, in 2003, as a "combination product" sets a precedent for Kromoscopy's unique consideration by the FDA.

# "Second Opinion" TM\*

- A technical concept and marketing tool enabled by Kromoscopy, and responsive to the rigors of the FDA process.
- Affords a potential relaxation of FDA requirements.

 Provides critical feedback for reliable and timely insulin delivery decisions.

\* (Def.) "Second Opinion" – The availability of a simultaneous and independent measurement of blood glucose at another site.

## **Combination Product**

- Defined by the FDA as "a product comprised 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.\*
- This convergence poses special challenges, including intellectual property relationships, management responsibility, regulatory review, product ownership, and physician referral patterns.\*
- 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 as a component within a combination product.

\* Source: "Marketing Combination Products," MX, September/October 2006

### Development Plan - Step I

Next-generation Kromoscope for in vivo Glucose Quantitation

- Instrument Construction and in vitro System Qualification
  - Complete design for 7-channel instrument with transmixion sampling
    - Mechanical and optical components
    - Opto-electronic and electronic components
  - Acquire purchased parts, construct other parts, and assemble
    - Includes 3 additional HP 3458 (leased or purchased)
    - Specify and acquire additional optical filters (co-ordinate with part 2)
  - Upgrade data acquisition software to 7-channel capability
  - Begin upgrade of data analysis software
  - In vitro qualification of system Kolor-blind system (matching filters)
  - Refine analysis software and instrument performance as needed
  - Complete qualification of Kolor-blind system
    - Measurement of noise levels
    - Comparison with prior Kromoscopic systems
  - In vitro qualification of Kolor-sensitive system
  - Refine analysis software and instrument performance as needed
  - Complete qualification of Kolor-sensitive system
    - Measurement of noise levels
    - Concentration-equivalent variance estimates
    - Comparison with prior Kromoscopic systems

Milestone: In vitro instrument variance does not limit performance of new instrument in vivo

### Development Plan - Step II

Next-generation Kromoscope for in vivo Glucose Quantitation

- In vitro analyte Kolor component measurements for instrument filters (to be performed at Iowa if possible) – to be conducted in parallel with Optix efforts (parts 1 and 3)
  - Restart collaborative effort
  - Measurements of in vitro Kolor directions and magnitudes of water, glucose and temperature to be made on congruent instrument
  - Investigations of effect of blood cell scattering on Kolor directions and magnitudes

 Milestone: Kolor component directions determined for all filters to be used in next-generation Kromoscope for use in determining in vivo Kolor directions

### Development Plan - Step III

Next-generation Kromoscope for in vivo Glucose Quantitation

#### In vivo System Qualification

- Upgrade in vivo data analysis software
- Acquire initial estimates of in vivo variance
- Analyze dominant variance components and remove as justified
- Refine analysis software as needed
- Repeat in vivo variance measurements
- Estimate concentration-equivalent variance levels
- Improve variance levels, software, and estimation procedures as required
  - Include replicates and multiple subjects
  - Monitoring periods as appropriate for market needs

 Milestone: In vivo variance estimates at levels appropriate for glucose monitoring

### Development Plan - Step IV

Next-generation Kromoscope for in vivo Glucose Quantitation

#### Initial Internal Glucose Monitoring Trials

- Establish protocol for glucose monitoring (IRB, etc.)
- Initial monitoring trials
  - Establish variance levels under protocol
  - Quantify correlation to reference measurements
- Refine software, variance measurements, etc. as needed to improve performance
- Repeat as needed to establish desired performance levels

 Milestone: Adequate correlation of Kromoscopic data to reference measurements in small-scale internal trials

### Development Plan - Step V

Next-generation Kromoscope for in vivo Glucose Quantitation

#### Large-Scale External Monitoring Trials

- Repeat smaller scale trials on diabetic and non-diabetic subjects, as defined by project needs
- To be performed under auspices of proposed marketing partner?

Milestone: Proof of feasibility of Kromoscopic glucose monitoring in vivo

### Manufacturing Process

- If a corporate or financing relationship requires Kromotech to be responsible for manufacturing, we will provide a combination of internal manufacturing and outsourcing.
- FDA's potential regulation of the Kromoscope's manufacturing will impact Kromotech's final manufacturing strategy.
- MJ Block, Chairman of Kromotech, Inc., has historical experience (as President of Block Engineering) managing the manufacture of products ranging in size and cost from large FT-IR systems to small inexpensive instruments (e.g., tonometers, for measuring glaucoma on the sclera).

Bernard Gordon, Founder of Analogic Corporation, an *active* member of the Board of Directors of Kromotech, Inc., and considered the "father of analog to digital conversion" for his inventions and contributions to signal translation, medical tomography and other high-precision instrumentation, will be a major contributor to the final manufacturing strategy.

## Light Source



This source plus the "shiny band-aid" is the entire optical and sample holding system of the wearable Kromoscopic sensor.

## Myron J. Block, Chairman:

The founder (and Inventor) of Kromoscopy;

 A pioneer in optical innovations who has been at the forefront of methods for distinguishing signal to noise in a wide range of technologies for both defense and medical applications;

 Has already demonstrated his ability in enabling trace constituent infrared analysis by coinventing Fourier Transform Infra Red (FT-IR) spectroscopy;

Founder of Block Engineering and Digilab.

### Stewart B. Rosenberg, President and CEO:

- President and Founder of Bio-Investigations Ltd., a successful specialized venture capital firm operating since 1987;
- University of CT, University of PA, and WHARTON formal education;
- Established business relationships with global diagnostic multinationals (http://www.bioinvltd.n3.net)

### Frank Rotatori, Chief Financial Officer:

 President and CEO, Kromotech, 2004-2005;
Vice President Sales, Cotelligent, 2001-2002;
Vice President Business Development, President, Healthcare Division, Vice President Europe, Executone Information Systems, Inc., 1987-2000;

Vice President and General Manager, Rolm, an IBM Corporation, 1981-1987;
Owner, Exposition Motors, 1980-1981.

# Major 2006 Developments

- The most recent patent issued, on 31 January 2006, USPTO Patent # 6,992,772. This patent continues to strengthen the IP portfolio, which has grown to approximately 12 key patents.
- The most recent publication, by Mark Arnold and his group, in Analytical Chemistry 2006, 78, 215-223, which provides a critical element in the scientific evidence as to "proof-ofconcept" of Kromoscopy. (*In Vivo* Near-Infrared Spectroscopy of Rat Skin Tissue with Varying Blood Glucose Levels by Jonathon T. Olesberg, Lingzhi Liu, Valerie Van Zee, and Mark A. Arnold.) This paper removes risk to success by providing a critical element in the proof of principle for Kromoscopy for the measurement of *in vivo* blood glucose. Not only is this paper the first credible evidence of spectral determination of in vivo blood glucose, it also quantitates the detection. The advantages of Kromoscopy over spectroscopy are well established. By applying the established Kromoscopic advantages to Arnold's detection level we now have for the first time an analytic scientific proof of principle.

### Next Steps:

Finalize valuation analysis of Kromotech Inc.;

- Fine-tune acceptable involvement of major diagnostic multinationals;
- Select underwriter to work on IPO, from short list of appropriate firms;
- Refine/accept/decline merger interest by profitable analytical instrumentation company(s); and
- Advance qualified participation of top three major therapeutic multinational, toward.....

The development of a \* non-invasive diabetes franchise:

# The future of medicine



# an Opportunity for Kromoscopy.

\*Privileged Communication/Proprietary

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