

Aegis Capital 2014 Healthcare & Technology Conference

September 11, 2014



# **Forward** Looking Statements

The following discussion, in addition to the other information contained in this presentation, should be considered carefully in evaluating our prospects. This presentation (including without limitation the following factors that may affect operating results) contains forward-looking statements regarding us and our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such words are intended to identify forward-looking statements, but are not the exclusive means of identifying forward-looking statements in this presentation. Additionally, statements concerning future matters such as revenue projections, projected profitability, growth strategies, possible changes in legislation and other statements regarding matters that are not historical are forward-looking statements.

Forward-looking statements in this presentation reflect the good faith judgment of our management and the statements are based on facts and factors as we currently know them. Forward-looking statements are subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, but are not limited to, those discussed in this presentation. Readers are urged not to place undue reliance on these forward-looking statements which speak only as of the date of this presentation. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this presentation.

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## **About** VolitionRx

### **WHO WE ARE**

- US OTC-quoted company (VNRX)
- Lab and head office in Namur, Belgium, Europe

### WHAT WE DO

 Diagnostics company developing blood tests for cancers, beginning with colorectal cancer (CRC)

### **HOW WE DO IT**

- 4,800-individual clinical trial in Denmark (analysis underway)
- 14,000-individual prospective screening trial in Denmark (collection underway)
- Apply for CE Mark regulatory approval to sell products in Europe
- Negotiate CLIA lab sales in US
- Apply for FDA approval to commercialize products in US
- Strong IP protection 8 patent families in US, Europe & worldwide

### **FUNDING**

- ≈\$12M equity funding (mainly founders/angels)
- \$1.75M Walloon regional funding
- Comparable companies' market caps
  - Epigenomics \$61m
  - Exact Sciences \$1.8bn





# **Seasoned** Leadership Team

#### **MANAGEMENT**

## President & CEO, Cameron Reynolds MBA

- 20+ years entrepreneurial executive expertise; strong experience in management, structuring and strategic planning of start-up companies
- Previous appointments with Integrated Coffee Technologies; Probio, Inc.; Mining House Limited

### **CFO & Treasurer, Mike O'Connell**

- Held roles as Financial Director or CFO for a number of private to public companies including Systems Integrator Pacific Group PLC and InsightSoftware.com
- Educated at Imperial College London before qualifying as a Chartered Accountant with Ernst and Young in London

## CMO & Head of US Operations, Jason Terrell MD

- Currently owns and operates multiple diagnostic laboratories in Texas within the Any Lab Test Now franchise
- Since 2011, has been Medical Director of CDEX Inc, a US listed company developing drug validation technology, serving on Board since 2013
- Education: Hardin-Simmons University, University of Texas at Houston Medical School and affiliate MD Anderson

## Corporate Secretary, Rod Rootsaert LLB

- 10+ years in providing corporate, legal and administrative services to start-ups
- Has served as a director of Mining House Ltd since 2007; previous appointments with Magellan Copper and Gold Plc.,
   Delta Pacific Mining Plc.

## Sales & Marketing Director, Thomas Bygott

- 15+ years experience in sales and marketing for technology companies.
- Previous appointments with AWA (Australia), Genevra Technology (UK), Wellcome Trust Sanger Institute, Active Motif
- Currently a member of the Board of Governors of Cambridge University Hospitals NHS Trust



# **Seasoned** Leadership Team

#### **SCIENTIFIC EXECUTIVES**

## CSO, Belgian Volition, Jake Micallef PhD MBA

- 20+ years in R&D and management of early stage biotech companies
- Previous appointment with World Health Organization, developed diagnostic products in reproductive health and cancer; started Immunometrics Ltd.
- Co-founded Gene Expression Technologies, played a major role in procuring GeneICE technology contract with Bayer Pharma.
- Served as Technical Officer for ValiRx, in-licensed the Hypergenomics and Nucleosomics technologies and cofounded ValiBio SA., which is now Belgian Volition SA
- Education: King's College London (BSc; PhD); St Thomas' Hospital Medical School, London (MSc); and Imperial College Management School (MBA)

## **External Collaborations Manager, Mark Eccleston PhD**

- Biotech entrepreneur with 18+ years experience in academia and industry
- Previous appointments with ValiRx Plc.; CEO of Vivamer Ltd.; CSO then consultant to Cambridge Applied Polymers
- Education: University of Aston in Birmingham, UK (Chemistry; PhD in Polymer Chemistry); and Dundee University (MBA)



# **Investment** Highlights

### **LANDSCAPE**

- Blood-based tests are the future of cancer diagnostics higher compliance rates than current tests (colonoscopy and fecal tests)
- Initial CRC target market: 175m in Europe / 95m in USA in recommended screening cohort (aged 50-69)
- Colorectal cancer IVD market to be \$1.6bn worldwide by 2019
  - 94% of which will be fecal tests
  - This does not include \$10bn annual US cost of colonoscopies

#### **VOLITIONRX SOLUTION**

- NuQ<sup>®</sup> diagnostic test leverages proprietary Nucleosomics <sup>®</sup> epigenetic biomarker platform
- Cost effective, scalable and patient- and doctor-friendly test
  - Non-invasive, encourages greater patient compliance
- Analysis underway for 4,800-subject CRC trial
  - Top-line results from initial group of 938 subjects show NuQ<sup>®</sup> test accurately detected colorectal cancer in 84% of subjects<sup>1</sup>
- FDA Panel hearings March 2014 recommended Epigenomics/Exact Sciences CRC tests
  - Established bar for blood test at 78% specificity/68% sensitivity







# Significant Need for Better CRC Diagnostics

## **Current CRC diagnostics:**

- Colonoscopy accurate but invasive and expensive; low compliance
- FIT/FOBT fecal-based tests unpleasant; don't pick up precancerous polyps; compliance problems

## Blood optimal for early diagnosis:

- Fecal test compliance only 30-60%
- Only blood test commonly used (PSA prostate cancer blood test) has high compliance (around 80%) however test is not very accurate (sensitivity 72%)
- 95% of people would rather take a blood test than a colonoscopy<sup>1</sup>

### VolitionRx solution:

 NuQ® test for colorectal cancer shows high accuracy: high sensitivity and specificity



1. 2013 VolitionRx-sponsored survey of 2004 61-100 year olds in the US and UK



# The Market for Colorectal Cancer Tests

432,000

New CRC cases in Europe p/a1

\$1.6bn

IVD screening market for CRC worldwide, by 2019<sup>2</sup>

44%

Market share of IVD CRC screening globally held by 5EU (France, Germany, Italy, Spain, UK)<sup>3</sup>

### **Cancer Statistics**

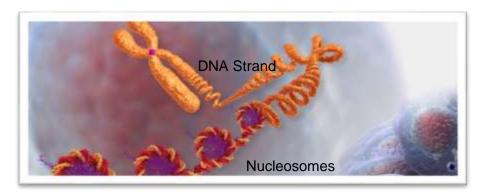
### THE EUROPEAN MARKET FOR CRC

- The European Union (EU) recommends FOBT (fecal) screening for colorectal cancer in all men and women aged 50 to 74<sup>4</sup>
- There are approximately 175m 50-69 year olds in the EU
- 28 member states in EU:
  - 9 have no government screening program
  - 9 have population screening programs (e.g. all citizens between 50 and 74)
  - Further 9 have some form of screening
- Screening rates still low only Germany successfully screens more than 40% of target population<sup>5</sup>
- 1. Health at a Glance: Europe 2012, OECD, [online], Available at: http://www.oecd-ilibrary.org/sites/9789264183896-en/04/04/03/index.html;jsessionid=5or2ma86e64nj.x-oecd-live-01?contentType=&itemId=%2fcontent%2fchapter%2f9789264183896-48-
- en&mimeType=text%2fhtml&containerItemId=%2fcontent%2fserial%2f23056088&accessItemIds=%2fcontent%2fbook%2f9789264183896-en , [accessed 03.06.2014]

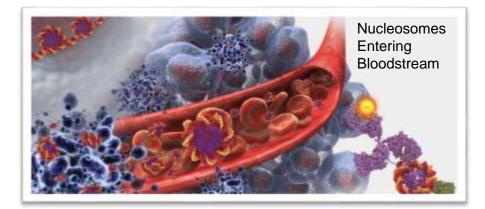
  2. Marketresearchreports.Com: The Market for in-Vitro Colorectal Cancer (CRC) Screening Tests Is Expected to Reach over \$1.6 Billion by 2019 [press release], Available at: http://www.sbwire.com/press-releases/marketresearchreportscom-the-market-for-in-vitro-colorectal-cancer-crc-screening-tests-is-expected-to-reach-over-16-billion-by-2019-411818.htm, [accessed 03.06.2014]
- 3. Ibid.
- 4. Health at a Glance: Europe 2012, op. cit.
- Ibio



# Nucleosomics® - Overview



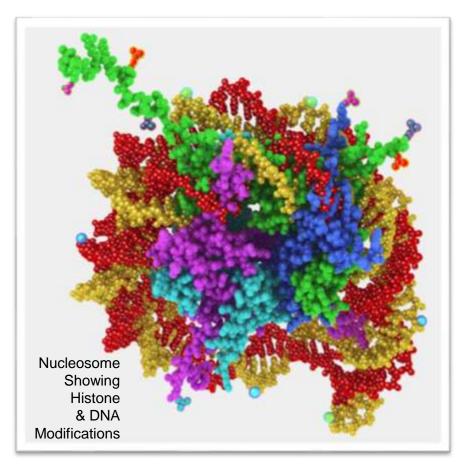
- The DNA in every cell is wound around protein complexes in a "beads on a string" structure
- Each individual "bead" is called a nucleosome



- When a cell dies, the body breaks the DNA string up into individual nucleosomes which are released into the blood to be naturally "recycled"
- Cancer is characterized by uncontrolled and rapid cell turnover. As the body can't recycle such large amounts of cell "debris," the nucleosome level rises in a cancer patient's blood



## Nucleosomics® - Technical Overview



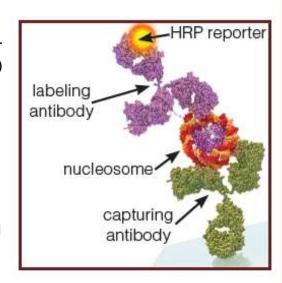
- Nucleosome "beads" consist of DNA wrapped around a core of histone proteins
- Each core consists of four pairs of variants of H2A, H2B, H3 and H4 histones
- Histones and the DNA are subject to a variety of post translational modifications
- Various proteins interact with nucleosomes to modulate gene expression
- Cell death results in fragmentation and release of nucleosomes into the blood
- In cancer, high cell turnover results in large amounts of cell debris, overwhelming the recycling mechanisms and leading to elevated blood nucleosome levels
- Each NuQ<sup>®</sup> ELISA assay captures intact nucleosomes and labels a specific feature



# NuQ® Test - Blood-based CRC Diagnostic

### LEVERAGES PROPRIETARY NUCLEOSOMICS® TECHNOLOGY

- NuQ® tests identify and measure circulating nucleosome structures for the presence of epigenetic cancer signals within blood
- In several trials, have been shown to:
  - Distinguish cancer patients from healthy patients and those with other competing conditions (e.g. irritable bowel syndrome, Crohn's disease)
  - Distinguish one type of cancer from another (prostate from CRC)
- VolitionRx has developed five families of NuQ<sup>®</sup> double antibody ELISA assays
  - Each captures intact nucleosomes and labels (identifies) a specific structural feature
- NuQ® tests can be adapted onto one or more of the four existing ELISA diagnostic platforms
  - Manual ELISA plate (current platform)
  - Automated ELISA machine in a hospital or centralized pathology lab
  - Point of care test administered at oncologist office, in-patient or out-patient clinic
  - Disposable point of care test administered at MD office or, in the case of remission patients, potentially at home





# Clinical Milestones 2014-Future (Colorectal Cancer)

	Q1-Q2 2014	Q3-Q4 2014		Q1-Q2 2015		5	Q3-Q4 2015		2016 on
Denmark: Retrospective CRC Clinical Trial			set fror 4,800-s	nary data n first		data 4,80	ease of full from first 0-subject ish CRC		
Denmark: Prospective CRC Clinical Trial (screening)	Sample collection for 14,000-subject Danish CRC screening trial  Analysis of 14,000-subject trial samples								
Regulatory: Europe			CE Mark (European) application using 1000 (approx.) Danish subjects' results (acceptance approx. 6mo.)						
Regulatory: US/worldwide	March: FDA Panel recommended Epigenomics' Septin 9 blood test for CRC - set bar at 68% sensitivity		Regulato approval:		nitia	al app	lication for Nu	uQ® FD≀	A/worldwide



# **Multiple** Clinical Trials

#### FIVE CURRENT VOLITIONRX-SPONSORED TRIALS

## Hvidovre Hospital University of Copenhagen, Denmark (Professor Hans Jorgen Nielsen):

- Two clinical trials, for a total approx. 19,000 individuals:
  - 4,800-subject Danish CRC trial: Retrospective study analyzing samples collected in 2010-2012 of approx. 4,800 patients with CRC, polyps or adenomas, benign bowel diseases and other malignancies, all of whom have undergone a colonoscopy; with full access to all national registries and databases (electronic audit)
    - Analysis commenced late 2013 with a pilot study of approx. 1,000 of these samples
    - Top-line results of initial 938 subjects showed NuQ® test detects 84% of subjects with CRC
  - 14,000-subject Danish CRC screening trial: Prospective study; collection commenced in Denmark in April 2014 for a 14,000-subject CRC screening population trial. All patients will also have a fecal occult blood test and colonoscopy; with full access to their medical history (electronic audit)

## Bonn University Hospital, Germany (Priv-Doz Dr Stefan Holdenrieder):

- Two clinical trials:
  - 4,000-subject German trial of 20 most prevalent cancers: Large multi-year prospective study, during
    which blood samples will be initially collected from 4,000 patients at University Hospital Bonn, including
    healthy individuals; patients with cancers; and patients with other conditions; analysis to begin 2015
  - A validation of the tests as a predictor of the performance and therapy monitoring of chemotherapy

## Mont-Godinne Hospital, Belgium

- One clinical trial:
  - 250-subject Belgian CRC trial: A prospective longitudinal study of approximately 250 patients with suspected colorectal cancer, to take place 2012-2014; aims to develop and clinically evaluate non-invasive cancer detection blood tests for early detection and prognosis of colorectal cancer



# Key Validation from ~1,000-Subject Sample

### SIGNIFICANT ACCURACY DEMONSTRATED

- 4,800-subject Danish CRC Study Design
  - Samples of patients with CRC, polyps or adenomas, benign bowel diseases and other malignancies, all of whom have undergone a colonoscopy
    - Symptomatic subjects (CRC versus no findings on colonoscopy and no comorbidities)
  - Analysis commenced late 2013
- Initial representative 938-subject Sample Analysis
  - NuQ® CRC diagnostic test demonstrated:
    - 84% sensitivity (accurate detection) at 78% specificity
    - 60% detection of adenomas (polyps)
    - Detection of early (I or II) and late-stage (III or IV) disease with similar accuracy
  - 3-assay test panel using about 1 drop of blood serum in total
  - Study group were all aged over 50; results were age- and gender-adjusted

Bar set by FDA's panel recommendation for a competitor's CRC blood test 68% sensitivity



# Strong Results to Date

- Presented at the International Society of Oncology and Biomarkers Congress, March 2014
  - Findings in both prostate (PRC) and colorectal (CRC) cancers released
  - Colorectal cancer
    - 86% detection at 86% specificity
    - 50% detection of precancerous polyps
  - Prostate cancer
    - 80% detection at 70% specificity
    - Profiles of nucleosomes in two cancers shown to be different
- Published in Anticancer Research, May 2014
  - Colorectal cancer single-assay test (90 subjects, confirmed on 113 subjects):
    - 75% detection at 70% specificity





## Finance at a Glance

- Listed on the OTC Markets in the U.S. under symbol VNRX
  - Total shares issued & outstanding (as of 9/1/14): 13,468,164
  - Fully diluted: 18,553,388
  - Market cap (as of 9/8/14): \$27.2m
  - More than 37% held by insiders
- Investment since Dec 2010:
  - US~\$12m (priced between \$0.50 and \$2.20 per share)
- Non-dilutive funding through government research grants:
  - €1,048,020 (approx. US\$1.4 million) Wallonian Government (Belgium) assistance grant
  - €420,000 (approx. US\$563k)
     Eurostars grant





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