# VolitionRx

Developing blood-based tests for cancer



Marcum Microcap Conference New York City, May 29 2014



Updated May 2014

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## 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.

This presentation does not constitute an offer to sell or a solicitation of an offer to buy any security. Any such offer, which will be made to "accredited investors," as defined by Rule 501 of Regulation D, promulgated under the Securities Act of 1933, must be accompanied by a Private Placement Memorandum and other documents (the "Memorandum"). The securities offered pursuant to the memorandum are speculative and involve a high degree of risk. See "Risk Factors" herein and in the Memorandum. This presentation is qualified in its entirety by the Memorandum, which contains more complete information about the Company and the risks of investing, and the Company's filings with the Securities and Exchange Commission.



## About VolitionRx

#### WHO WE ARE

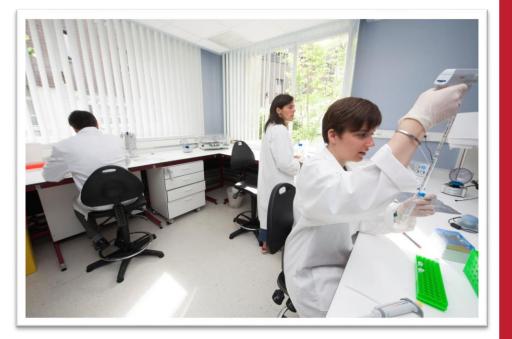
- US OTC-quoted company
- Lab and head office in Namur, Belgium, Europe

#### 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)
- 11,000-individual prospective screening trial in Denmark (collection underway)
- Apply for CE Mark regulatory approval to sell products in Europe
- Apply for FDA approval to sell products in USA
- IP protected 8 patent families in USA/Europe & worldwide





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# Investment Highlights

## **Investment** Highlights

- Blood-based tests are the future of cancer diagnostics higher compliance rates than current tests (colonoscopy and fecal tests)
- Europe initial CRC target market: 175m individuals 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's NuQ platform is cost effective, scalable and patient- and doctor-friendly
- Promising early results: 85% of CRC detected
- Analysis underway for 4,800-individual CRC trial
- VNRX current cash to early 2015
- Comparable companies' market caps: Epigenomics \$114m; Exact Sciences \$845m (04/30/2014)
- FDA Panel hearings in March 2014 recommended Epigenomics/Exact Sciences CRC tests – gave VNRX bar to aim for own tests





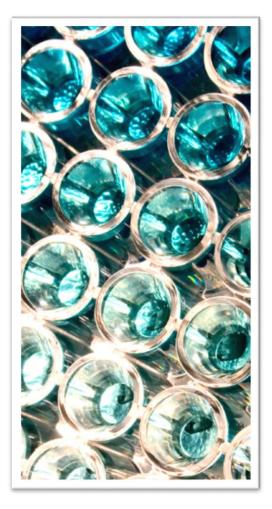
## Milestones 2014-future (Colorectal Cancer)

	Q1-Q2 2014	Q3-Q4 2014	Q1-Q2 2015	Q3-Q4 2015	2016 on
Denmark: Retrospective CRC Clinical Trial		Release of preliminal from first Danish C	ry data data fro 1000 4800 D	om first anish	
Denmark: Prospective CRC Clinical Trial (screening)	Sample collection for 11,000-individual Danish CRC screening trial Analysis of 11,000 individuals' samples				
Regulatory: Europe	CE Mark application using 1000 Danish results (acceptance approx. 6mo.)				
Regulatory: US/worldwide	March: Epigenomics' Septin 9 blood test for CRC was recommended by FDA Panel - set bar at 68% sensitivity	Regulatory trial and initial application for NuQ FDA/worldwide approvals			



## **Need for Better** Colorectal Cancer Diagnostics

- Current CRC diagnostics:
  - Colonoscopy invasive and expensive
  - FIT/FOBT fecal-based tests unpleasant; don't pick up precancerous polyps
- Blood is better for early diagnosis:
  - FIT compliance only 30-60%
  - PSA (prostate cancer blood test) compliance at least 80% - even though the test isn't very accurate
  - 95% of people would rather take a blood test than a colonoscopy<sup>1</sup>
- VolitionRx NuQ test for colorectal cancer shows higher sensitivity/specificity than current fecal tests – but small trials to date



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



Need

for Better CRC

Diagnosis

## The Market for Colorectal Cancer Tests

# 432,000

New CRC cases in Europe p/a<sup>1</sup>

## \$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%2ff789264183896-48-

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 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]

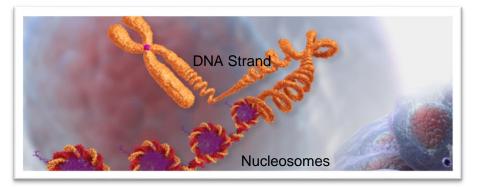
<sup>5.</sup> Ibid.



<sup>3.</sup> Ibid.

<sup>4.</sup> Health at a Glance: Europe 2012, op. cit.

## **Nucleosomics<sup>®</sup>** – How It Works (in brief)



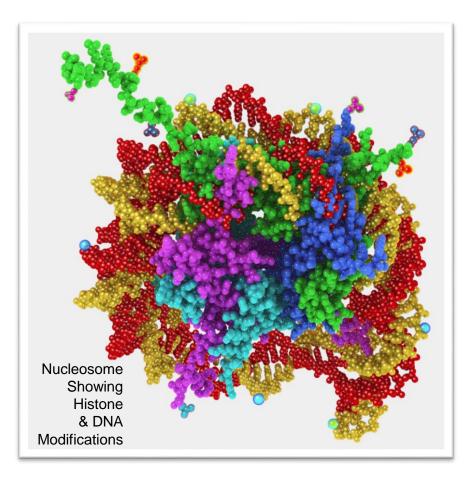
- The DNA in every cell is wound around protein complexes in a "beads on a string" structure.
- Each individual "bead" is called a nucleosome.



- 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<sup>®</sup> –** How It Works (technical)



- 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.



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## **Clinical** Trials

#### **Current External Trials:**

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

- Two clinical trials, for a total 16,000 individuals:
  - A retrospective study analyzing samples collected in 2010-2012 of approximately 4,800 patients with colorectal cancer, other malignancies, polyps or adenomas, and benign bowel diseases 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 1,000 of these samples.
  - A prospective study; collection commenced in Denmark in April 2014 for an 11,000 patient colorectal cancer screening population trial. All patients will also have a fecal occult blood test and a colonoscopy and we have full access to their medical history through electronic audit.

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

- Two clinical trials:
  - A 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.
  - A validation of the tests as a predictor of the performance and therapy monitoring of chemotherapy.

#### Mont-Godinne Hospital, Belgium

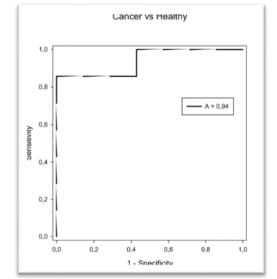
• A prospective longitudinal study of approximately 250 patients with suspected colorectal cancer, to take place through 2012-2014. The project aims to develop and clinically evaluate non-invasive cancer detection blood tests for early detection and prognosis of colorectal cancer.



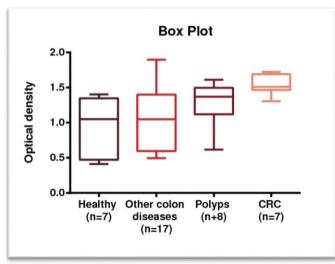
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## Results to Date

- Results presented at the International Society of Oncology and Biomarkers Congress, March 2014
  - Findings in both prostate (PRC) and colorectal (CRC) cancers released
  - Colorectal cancer
    - 85% detection rates at 85% specificity
    - 50% detection of precancerous polyps
  - Prostate cancer
    - 80% detection rate at 70% specificity
    - Profiles of nucleosomes in two cancers shown to be different
- Results presented at Clinical Genomics and Informatics Europe, Dec 2013
  - Preliminary findings from CHU Dinant Godinne | UCL Namur Hospital in Belgium.
  - Colorectal cancer two-assay panel test
    - 85% detection rates at 85% specificity
    - 50% of precancerous polyps detected
- Results presented at CNAPS conference, Nov 2013:
  - Colorectal cancer single-assay test:
    - 75% of cancers detected, 70% specificity (90 patients, one single assay); data reconfirmed on further 113 patients



Preliminary findings from CHU Dinant Godinne trial



Differentiation between healthy subjects and those with CRC, polyps and other conditions



### **Finance**

VolitionRx Limited is currently quoted on OTC Markets in the United States of America under symbol VNRX.

At 05.01.2014:

- Total shares issued: 13,307,936
- Fully diluted: 17,638,160
- More than 37% held by insiders

Investment since Dec 2010:

- US\$10.38m (priced between \$0.50 and \$2.05 per share)
- Plus €1,048,020 (approx. US\$1.4 million) Wallonian Government (Belgium) assistance grant and €420,000 (approx. US\$560k) Eurostars grant





Finance

# VolitionRX

**OTCBB:** VNRX





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