Belgian Volition SA - a VolitionRx Company-



Technological company presentation BIOWIN DAY 2014

About VolitionRx

Who we are

- Lab and Head office in Namur, Belgium
- Creation: Oct 2010
- 8 employees + International Board of Directors



What we do

- A life sciences company focused on developing blood-based diagnostic tests
- Beginning with diagnostic blood-based tests for cancer
- The tests are based on the Company's proprietary Nucleosomics[®] platform



Nucleosomics® overview





- The DNA in every cell is wound around proteins complexes in a "beads on a string" structure.
- Each individual "bead" is called a nucleosome
- Nucleosome consist of DNA and histone proteins. Histones and DNA are subjected to a variety of **epigenetic modifications**
- Cell death results in fragmentation and release of nucleosomes into the blood
- In cancer, high cell turn over results in large amounts of cell debris, overwhelming the recycling mechanism and leading to elevated blood nucleosome levels



NuQ® Test – Accessing the Epigenome



- NuQ[®] assays identify and measure circulating nucleosome structures for the presence of epigenetic signals within blood
- VolitionRx has developed five patentprotected families of NuQ[®] double antibody ELISA assays:
 - NuQ®-X specific DNA modifications
 - NuQ®-V histone variants
 - NuQ[®]-M histone modifications
 - NuQ[®]-A nucleosome-protein adducts
 - NuQ[®]-T total nucleosomes

20 different assays have been developed and can be used alone or in combination



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 50%
- Only blood test commonly used (PSA prostate cancer blood test) has high compliance (around 85%)
 however test is not very accurate (sensitivity 72%)
- 95% of people would rather take a blood test than a colonoscopy





NuQ[®] Test – Blood based CRC Diagnostic

Published in Anticancer research: Colorectal cancer single-assay test (90 subjects)
 75% detection at 70% specificity

Holdenrieder et. al. ANTICANCER RESEARCH 34: 2357-2362 (2014)

- **4 800-subject Danish** CRC study design (symptomatic population)
 - 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
 - ^o Study group were all aged over 50; results were age- and gender-adjusted





NuQ® Test – Additional Results to Date

Presented at the international Society of Oncology and Biomarkers Congress, March 2014

- Finding in both prostate (PCA) and colorectal cancer Pilot study: 39 subjects referred for colonoscopy, 9 male subject newly diagnosed with PCA and 10 male control subjects
- Colorectal cancer:
 - 86% detection at 86% specificity
 - 50% detection of the precancerous polyps
- Prostate Cancer:
 - 80% detection at 70% specificity

Profiles of nucleosomes in two cancers shown to be different





Multiple clinical trials

Cancer Type		Sample Collection	Start Date (approx.)	No of subjects
Colorectal (symptomatic population)	Hvidovre Hospital (Dermark)	Retrospective: took place 2010-2012	Analysis began late 2013	4,800
Colorectal (screening study)	Hvidovre Hospital	Prospective: commenced April 2104	Analysis expected to begin 2015	14,000
Colorectal	CHU Dinant Godinne UCL NAMUR	Prospective: commenced 2012, ongoing	Analysis underway	250

Cancer Type		Sample Collection	Start Date (approx.)	No of subjects
	Institution			
20 most prevalent cancers	universität bonn	Prospective (2,000 samples collected to date)	Analysis expected to begin 2015	4,000
	Bonn University Hospital (Germany)			
Prostate cancer	MD Anderson Cancer Center (USA)	Retrospective	Analysis expected to begin late 2014	TBC



NuQ[®] Test – Lung Cancer pilot study

- NuQ[®] tests able to detect lung cancer in 85% of patients using airway secretion (sputum) and 76% using blood
- Findings are the first using NuQ platform outside blood.
- Samples were collected at the Pneumology department of the CHU Liège
- 46 individuals with either NSCL cancer, chronic obstructive pulmonary disease (COPD) or with no diseases







Nucleosomics® - Revolutionizing Cancer Diagnosis

- VolitonRx aims to meet the need for cost effective, scalable and patient- and doctorfriendly test with its NuQ[®] tests for cancer diagnosis
- The tests are based on the Nucleosomics[®] platform, which identifies and measures circulating nucleosome structures for the presence of epigenetic cancer signals within the blood and now airway secretion.
- Apply for CE mark for colorectal screening diagnosis in 2015
- Select first CLIA partner for initial US market entry in 2015
- Nucleosomics biomarker platform is expandable to other diseases (endometriosis, inflammatory disease, others) and the technology is adaptable to point of care/point of use.





VolitionRx – Potential partners

We are looking for partners to assist in:

- Extending our diagnostics assays to other cancer types and inflammatory diseases
- Developing new applications of the Nucleosomics[®] platform
- Immunoassays related innovative technologies
- IVD manufacturers/subcontractors
- Logistic solutions





VolitionRx

Revolutionizing Cancer Diagnosis



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