#### XI Encuentro de Cooperación Farma-Biotech

## miColon - Non-invasive screening test for Advanced Adenomas and Colorectal Cancer in blood



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#### The Company

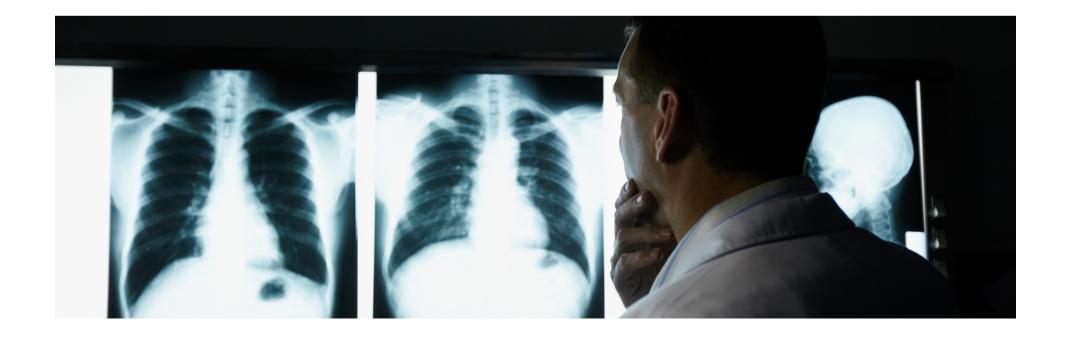


## **Amadix** - Developing innovative biomarkers into IVD products for cancer

- Founded in June 2010, spin-out of TCD Pharma
- Acquisition of Transbiomed in 2012
- Technology Transfer Agreement with Valld'Hebrón Hospital: IP, facilities and researchers in a leading Spanish hospital
- A Stronger Pipeline: 4 products in development
- A Specialized Team in cancer diagnostics

#### **Pipeline of Products**

Pipeline of 4 innovative tests in development for diagnostic, prognostic and predictive uses, addressing unmet medical needs in colon, prostate and lung cancer



**Target Indication** — Non-invasive screening test for identifying patients with CRC and advanced adenomas, reducing the mortality rate, offering higher sensitivity, specificity and compliance versus fecal tests in a cost-effective way

#### Differential features facing the market

- Innovative test based on a 6 miRNAs profile, qRT-PCR in plasma
- Higher sensitivity for Advanced Adenomas than any of the test already in the market or being developed (mainlyFIT®, Cologuard® and Epi proColon®)
- **Non- invasive** blood RNA test better acceptance and **higher compliance** from patients in screening programs than fecal tests

**Need - Reliable screening tools** for early detection of CRC with higher **sensitivity / specificity**, better **compliance** than fecal tests and **cost effective** for healthcare

systems

**Target** – average risk population for screening programs are men and women between 50 - 70 years old \* (300 M people in EU, US and Japan)

- CRC cancer is a clear candidate for screening programs long development cycle (>10 years), lack of symptoms and increased risk with age
- While 5-years survival rate is 90% when CRC is diagnosed at early stages, it drops to 12% when it's diagnosed at late stages

<sup>\*</sup> European Cancer Recommendation of Cancer Screening

#### **Cost – Effectiveness of the Test**

Treating patients diagnosed **at stage III** of CRC costs typically **double / triple** than treating them **at stage I** 

- Significant potential savings would be achieved if CRC patients were diagnosed earlier
- Screening for colorectal cancer has been found to be cost-effective
- Experts conclude that probably the new techniques based on DNA/RNA detection will be the most cost-saving strategy in the next 2-3 years.
- Global market size of 466M€ in 2017

#### **Current status of development**

**Discovery phase** to assess a 6 miRNA signature to discriminate patients with Advanced Adenomas, CRC and healthy individuals - microarray results confirmed by qRT-PCR

- Clinical validation through a prospective study in 2 different cohorts
- **Current Status** First training group of 273 patients
- On going Validation group of 2,400 patients (1,500 Germany; 900 Spain)

#### **IPR** Protection

- First patent application October 2011
- PCT published June 2013
- National phases April 2014 in 11 markets: US, EU, Japan, Brazil, Canada, China,
   India, Korea, Mexico, Australia and Russia

Developing innovative diagnostic tools in oncology.



#### Pitfalls & Risks to be considered

- Reimbursement will be a market barrier for new CRC screening tests. Currently,
   DNA-type screening tests are only reimbursed by a single insurer (Swiss Life in France)
- IPR degree of uncertainty, as to how a decision that went against Myriad Genetics will impact on the development of new DNA-based screening tests, after the US Supreme Court's decision in June 2013
- Local Screening Programs there are many different CRC screening strategies around the globe

# We are looking for international partners to commercialize our products

- ✓ Pipeline of four innovative tests for diagnostics in colon, prostate and lung cancer
- ✓ New Products Address clear unmet medical needs in Oncology
- ✓ Benefits for patients and physicians all around the world





**Thank You for Your Attention**