

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
The Product
Partnering Opportunities

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**



miColon – CRC Cancer / Diagnostic Use

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 (mainly FIT®, Cologuard® and Epi proColon®)
- **Non- invasive** blood RNA test - better acceptance and **higher compliance** from patients in screening programs than fecal tests

miColon – CRC Cancer / Diagnostic Use

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)

* European Cancer Recommendation of Cancer Screening

- 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

miColon – CRC Cancer / Diagnostic Use

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

miColon – CRC Cancer / Diagnostic Use

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)

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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.



miColon – CRC Cancer / Diagnostic Use

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**



Amadix – Translating innovative
science into **successful**
innovative diagnostics



Thank You for Your Attention