



Right Treatment, Right Patient.

**ADVANCED MARKER DISCOVERY, S.L.
AMADIX**

Executive Summary - 2016



What if a simple blood test
could tell **Doctors** who will
have cancer in the future?

NON-CONFIDENTIAL

This document is an introduction to Advanced Marker Discovery, S.L., ("Amadix" or the "Company") and is not an offer to sell, or a solicitation to buy an equity position in Amadix. The information, data, drawings and the like contained in this document are proprietary to Amadix and strictly secret and confidential, and are supplied with the understanding that they will be held secret and confidential. The disclosure by Amadix of information contained herein does not constitute any license or authorization to use or disclose information, ideas or concepts presented. No part of this document may be disclosed to any third party, copied, reproduced or stored on any type of media or used in any way by any party without the express prior written consent of Amadix or its direct representatives. This document and all related materials must be returned to Amadix upon the Company's request.

EXECUTIVE SUMMARY



- **Industry:** Biotechnology, Diagnostics
- **Headquarter:** Spain (Valladolid and Madrid)
- **Management Team**
 - Rocío Arroyo, PharmD, MBA, CEO
 - Lucía Reinoso, LLB, BA, MBA, CFO
 - Miquel Tarón, PhD, Development & Regulatory Director
 - Ana Martin, PhD, Scientific Director
 - Miguel Martínez, M.Sc, EPA, Intellectual Property Manager

- **Number of FTEs:** 8

- **Current Investors:**

- Cross Road Biotech SGEGR, S.A.
- Inveready Seed Capital, SCR, S.A.
- Clave Mayor SGEGR, S.A.
- ADE Capital Sodical, SCR, S.A.

- **Investment Required:** €5M

- **Use of Funds:**

The Company is raising up to five million euros (€5M), which together with available soft funds will support its activities until commercialization.



The Company: [Advanced Marker Discovery, S.L.](#) ("Amadix" or the "Company") develops and commercializes innovative diagnostic tests for cancer, which impact patient survival and quality of life. The purpose of these assays is either to improve the diagnosis of different types of cancer through non-invasive testing or to help physicians choose the right treatment in a cost-effective way. At the end of 2012 Amadix acquired [Transbiomed](#), the first spin-off from [Vall d'Hebron University Hospital](#) (VHIR), a leading Spanish oncology centre. Amadix thereby obtained priority access to the intellectual property, facilities, technology, oncologists and researchers of VHIR through a Technology Transfer Agreement.

Business Model: Amadix develops and commercializes breakthrough discoveries in cancer diagnosis with a clear commercial rationale, addressing unmet medical needs in oncology. After the analytical and clinical validation in patients from different hospitals and countries, the products will be commercialized as a service in the US (laboratory developed test, LDT) by an American certified CLIA/CAP laboratory and as a diagnostic service and kit in Europe in parallel. In order to achieve this, Amadix has a network of more than forty pharmaceutical / diagnostic companies, who are the main players in cancer diagnostics. They follow the results of our projects under confidentiality. The company is actively looking for further innovative projects in cancer diagnosis from Universities, Hospitals and Research Institutions to broaden its current pipeline through in-licensing of cutting-edge technology.

Mission: To create value for shareholders by developing and commercializing innovative diagnostic tools, reaching patients and physicians around the world, to improve survival and quality of life. This will benefit the company, society and researchers as well as reducing costs for health authorities.

Strategy: The strategy of Amadix is based on the close collaboration with research groups worldwide to identify breakthrough biomarkers for cancer diagnostics. This strategy positions Amadix in the fore-front of Oncology whilst significantly lowering the risk and costs associated with basic research and early discovery. In implementing its business strategy, Amadix relies on the extensive experience of its management team in identifying and defining clear developmental, clinical, regulatory and commercial

pathways. Our Scientific Team has designed a process with clearly established criteria that allows us to effectively evaluate each opportunity across a range of parameters and compare them. Amadix has built up a comprehensive network of more than a hundred research groups evaluating more than ninety new projects every year coming from more than twenty countries. Amadix has signed **seven option agreements** with Technology Transfer Offices of different hospitals and universities, to follow-up and in-license new biomarkers in different types of cancer in the forthcoming years.

The Team: Amadix has built a top level management team with international experience in cancer diagnostics, the pharmaceutical industry, the biotechnology sector and intellectual property, gained in Institutions and companies such as the Mayo Clinic, Lilly, Dako and Genentech. We have a network of more than twenty international clinical advisors (physicians) in different countries, many of them in the US. They are gastroenterologists, urologists, GPs, pulmonologists and oncologists, and they support us in evaluating new projects from the academic sector. Amadix also has independent board members with international profiles and many years of experience in oncology and diagnostics, who advise the management team on strategy, commercialization and business development in Europe and the US.

The professional profiles of the Amadix team are described below:

▪ **Rocio Arroyo Arranz (PharmD, MBA) - Chief Executive Officer**

Ms. Arroyo has more than 15 years experience in the Pharmaceutical and Biotechnology industry. She held the position of General Manager in Bionostra Biotechnology Applications in the Oncology area, which commercialized diagnostic assays for different types of cancer. She held a range of positions in Eli Lilly (2002-2009), in a variety of therapeutic areas from oncology and gynecology to urology and endocrinology. With extensive pharmaceutical, biotechnology and health-sector knowledge, her expertise covers the full scope of the business starting as a researcher in Pharmacology, moving to sales and marketing operations, to business development, to fundraising and P&L optimization. With a strategic vision oriented to maximize profitability in biotechnology and pharmaceutical companies, Rocio holds a BSc in Pharmacy from the Complutense University (Madrid, Spain) where she also completed graduate courses in Pharmacology, and a MBA from the IE Business School (Madrid, Spain). She is a Board Member of different Business Schools and Universities.

▪ **Miquel Taron (PhD) – Development & Regulatory Director**

Dr. Miquel Taron is a leading expert in cancer molecular biology (R&D & Diagnostics). For ten years, Dr. Taron was Head of the Molecular Biology Cancer Laboratory at the Germans Trias I Pujol Hospital (Barcelona, Spain), which forms part of the Catalan Institute of Oncology (Barcelona, Spain). In 2007, he was a founding member of Pangaea Biotech S.L. (Barcelona, Spain). Since then he has been a Board Member, as well as Director of Experimental Research and then EVP Diagnostics, where he was instrumental in building a state-of-the-art molecular biology laboratory dedicated to breakthrough technology in personalized anticancer therapy.

Dr. Taron has extensive experience in management and leadership of multidisciplinary teams, coordination of multicentre clinical trials and quality control. Furthermore, he is co-author of more than 100 scientific publications in high-ranking international journals and more than 400 presentations at National and International Congresses. Dr. Taron is frequently an invited speaker at international conferences on clinical oncology, lung cancer and molecular diagnostics. He is an active member of the Spanish Lung Cancer Group, President of the Spanish Society of Pharmacogenomics & Pharmacogenetics and Member of the European Society of Pathology (ESP), Molecular Pathology Working Group.

▪ **Ana Carmen Martín (PhD) – Scientific Director**

Dr. Martín has more than 20 years research experience in academia and biotechnology companies. Prior to joining Amadix, Dr. Martín filled the position of Scientific Director at Bionostra for 10 years, successfully building and leading a team of 12 scientists in a wide range of activities related to genetic diagnostics in different areas. She has experience in implementing ISO quality standards as well as securing laboratory accreditation for human testing. Before entering into biotechnology, Dr. Martín spent 8 years working in basic research at different laboratories. She completed her PhD degree with “Cum Laude” in 1996 in the Molecular Microbiology Department of the Biological Research Center (CIB) from CSIC (National Research Council, Madrid, Spain) and was a postdoctoral fellow at the Department of Molecular Biology in Plants of Biotechnological National Center (CNB, Madrid, Spain) CSIC for 3 years.

▪ **Miguel Ángel Martínez (M.Sc) – Intellectual Property Manager**

Mr. Martínez is a qualified European Patent Attorney with more than 10 years experience in the Intellectual Property field. Before joining Amadix, he held different positions as patent counsel in private law firms where he successfully advised his clients in the management of their patent portfolios, being responsible for more than 300 patents and patent applications. He holds a BSc in Biology from the University of Leon (Spain), a Master in Biotechnology Companies Management from the Aliter Business School (Madrid, Spain), an Advanced Course in Industrial and Intellectual Property from the IE Business School (Madrid, Spain).

▪ **External Committee for business, science and clinical issues**

We have established a Committee of Advisors (Board Members) with **international profiles**, who advise the management team on strategy, business development and commercialization including: Ferran Prat - with extensive global expertise in the In Vitro Diagnostics sector, where he had several leading positions for more than 25 years in cancer diagnostics and personalized medicine. He devoted most of his career to Dako where he was General Manager/Vice-President for Europe, America and Asia Pacific, and also was responsible for Global Strategic Marketing and Corporate Business Development; Howard Robin (MD) - Medical Director of laboratory services at Sharp Memorial Hospital and Sharp Pathology Laboratory for more than 25 years, who is advising Amadix to commercialize diagnostic assays as laboratory developed tests (LDTs) through the CLIA approval process. As a member of the College of American Pathologists and an Inspector for the CAP he is well versed in the preparation steps required for CAP accreditation. Some of the top level scientists are participants of the clinical studies run by Amadix, as Josep Taberner MD, PhD (Head of the Medical Oncology Department of Vall d'Hebron University Hospital, Barcelona, Spain).



Pipeline: The objective of Amadix is to have a pipeline of innovative tests under development for diagnostic, prognostic and predictive uses in colon, lung and pancreatic cancer. The company has conducted clinical studies in more than twenty hospitals for different types of cancer. All Amadix products are duly protected by patents worldwide, with patent protection in around eleven territories including the US, Europe and Japan.

First Product: The most advanced product developed by Amadix is *ColoFast*, an innovative non-invasive screening signature for colorectal cancer (CRC) and advanced adenoma diagnosis in blood. It performs better in the detection of advanced adenomas and early CRC than any commercialized test, identifying more patients in early stages of the disease. It achieves better patient acceptance and compliance than fecal tests. ColoFast is based on the determination of a 6 miRNA signature using qPCR in plasma samples. Screening programs have been implemented worldwide, addressing a large and expanding target population of men and women aged from 50 - 70 years old (300M in Europe, the US and Japan). Given the current rollout of screening programs in the main international markets, we expect that 60M people in the US, EU and Japan will take part in these programs after receiving an invitation from their National Health Services in 2021. The global market is growing at a CAGR of 26% (51% in the US market). After a first training group of 196 patients (prospective study), a clinical validation for the test was performed in a cohort of 360 patients from 9 different hospitals, which reproduced the results obtained in the previous cohort. Another set of 4,000 patients (1,000 from Spain and 3,000 from Germany and Poland) are currently being recruited. *ColoFast* has been recently awarded with the Horizon 2020 'Seal of Excellence' certificate by the European Commission (February 1st, 2016).

Creating value

for patients, physicians and researchers,
supporting technology transfer all around the world

Current Venture Capital Investors: Amadix has been supported from the beginning by a number of the most solid venture capital funds in Spain, some of them specialized in biotechnology and medical devices, such as [Cross Road Biotech](#), [Inveready](#), [Clave Mayor](#) and [ADE Capital Sodical](#). All of these VCs have in-depth knowledge of the in vitro diagnostics (IVD) market, giving us financial and business development support. The current shareholders of Amadix have committed their financial support to future investment rounds the company may need.

The Opportunity: Amadix will offer significant value to investors in 2018, with three key advantages: 1) a high level **specialized team** in cancer diagnostics; 2) a pipeline of **products backed by solid science**, addressing unmet medical needs in oncology with a strong patent protection; 3) and a solid **network of Research Institutions** and international diagnostic and pharmaceutical companies around the world.

A View to the Future: By the end of 2019 Amadix will be in a position to commercialize two diagnostic tests in Europe and the US. According to our current strategy, an additional New Opportunity is anticipated to be in-licensed and undergo biomarker validation by the end of 2016. In order to realize our plan we seek to raise 5 million Euros.

Advanced Marker Discovery, S.L. (Amadix)

Main Office
2 Acera de Recoletos St, 1B
47004 Valladolid -Spain

Branch
21, Génova St, 3ºD
28004 Madrid-Spain

Tel.: +34 983 10 20 60 / Fax: +34 983 10 20 61

www.amadix.com

