



Biomarker R&D
Bridging Science to Clinics

BioValley ConnectDay

Mission



Mission

Discover and develop innovative biomarkers for diagnostics in preclinical & clinical applications.

Focus

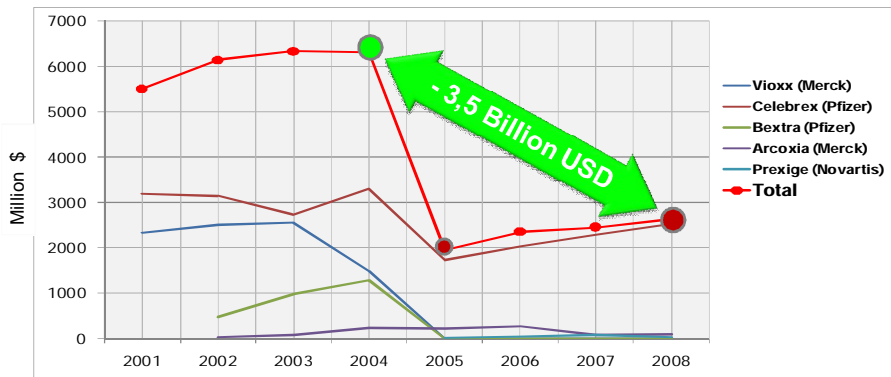
Biomarkers of inflammatory cardiovascular diseases and translational cardiovascular safety, for:

- Early diagnostic of diseases and drug-induced organ toxicities
- Prediction of the cardiovascular risks
- New diagnostic BMs for diseases that currently have no diagnostic

Beyond the Added Value



Coxib Drugs → Safety Problems



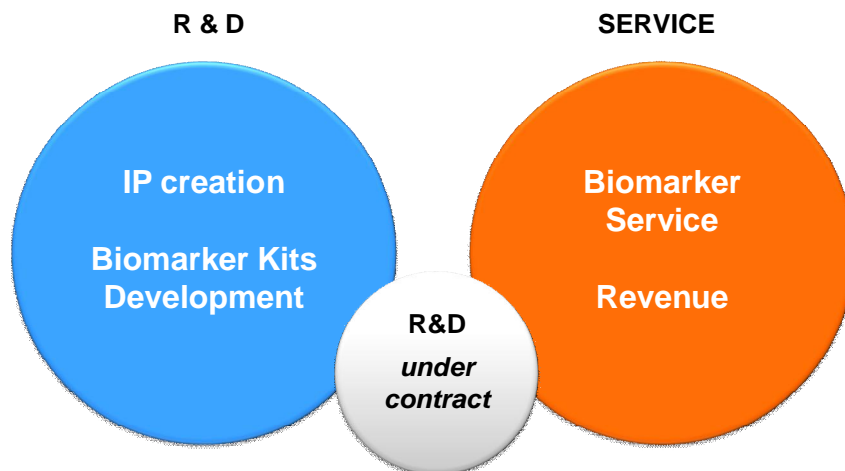
A predictive diagnostic test for cardiovascular safety of coxibs

- Recovering coxib sales volume (~3.5 Billion \$)
- Saving millions of R&D investment

proof of commercial value

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Business Model



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Business Model – R&D



- Coxib Companion Diagnostic Test
(French Research Ministry's National Competition – Winner 2009)
- Translational Safety Biomarkers (IMI-JU¹ Program)
- Renovascular & Cardiovascular Safety BMs
- BM Kits, predicting preclinical and early clinical vascular toxicities
- BM Kits, detecting early renovascular toxicity induced by drugs
- BM Diagnostic Tools for medical use

¹ Innovative Medicines Initiative – Joint Undertaking (EU body)

Business Model – Services



SERVICE PACKAGES	Basic Packages	Integrative Packages	Full Packages
Services	<ul style="list-style-type: none"> - Data Analysis - Interpretation - Publication & Report 	<ul style="list-style-type: none"> - Integrative Data Analysis - Assay Development & Validation - BM* Testing 	<ul style="list-style-type: none"> - Integrative Data Analysis - Assay Development - BM Validation - BM Qualification - BM Testing - Interactions with Health Authorities
Clients	<ul style="list-style-type: none"> - Public & Industrial Laboratories 	<ul style="list-style-type: none"> - Biotechs & Pharmas 	<ul style="list-style-type: none"> - Biotechs & Pharmas

(BM: Biomarker)

Business Model – R&D under contract



First Contract: IMI-JU (Call # 2008.1.5)

SAFE-T Project (Safer And Faster Evidence-based Translation)

- Development of Translational Safety BMs (liver, kidneys and vascular system)
- Overall project budget > 35 Mio € (Firalis budget: ~3.4 Mio €)
- 11 major pharmaceuticals, 4 biotechs and 6 academics as partners
- EMEA¹ and FDA² (as advisor)

Firalis is the initiator and coordinator of SAFE-T applicant consortium, and leader/co-leader (with industry partners) in 4 out of 9 workpackages.

Other European R&D projects are being established under the frame of FP7.

1 European Medicines Agency
2 Food and Drug Administration, USA

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Intellectual Property



Firalis owns the international patent application

WO 2006/095259 in force in EU and USA

- Protection : 250 genomic and 50 peripheral BMs
- Terms of transfer by Novartis : Right of First Refusal for Novartis

Foreseen applications

- Two additional patent applications on the horizon of 12 months
Protection: BMs of renovascular toxicities upon treatments
- Firalis shall co-file several patent applications within the IMI-JU project
(requesting exclusive exploitation rights)
Protection: Translational vascular safety biomarkers

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Management Team



A team of competent & complementary expertise

Hueseyin Firat	: CSO, former Novartis, where he established and headed the global section of biomarker data analysis at Biomarker Department
Béatrice Molac	: Director of Regulatory Affairs & IP, former Novartis, 30 years experience as European patent attorney
Christoph Borg	: Global R&D Head, responsible for anti-body production , scientific director of "French Establishment of Blood", member of INSERM
Fuat Firat	: Business Developer, 3 years experience in corporate banking
Peter Thomann	: Head of Integrative Data Analysis, formerly statistician at Novartis
Fidan Aras	: Director of Assay Development, senior clinical specialist in systemic vasculitis
Kaidre Bendjama	: Head of Laboratory, experience in cardiovascular pharmacology
Barbara Fischer	: Biomarker Expert, PhD in cellular and molecular biology
Stella Suzanne	: Project Manager & Quality Controller

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Advisory Boards



Scientific Advisory Board

- **Prof. Olivier DANOS**, PhD, former scientific director of Généthon, professor at UCL¹
- **Prof. François Albert LEMONNIER**, MD, PhD, DRE, Director of the antiviral cellular immunity of the Pasteur Institute, Paris
- **Prof. Pierre ROHRLICH**, PU-PH² at the University of Franche-Comté
- **Prof. Patrice CACOUB**, PU-PH at the Pitié Salpêtrière, specialist of vasculitis and autoimmune diseases, founder and president of GERMIVIC³
- **Prof. Nadir ARBER** (TASMIC)⁴, principal clinical investigator of Celebex®

Business Advisors / Consultants

- **Jean C. Wehrle**, former CEO at NanoVivodiagnostics
- **Brice Suire**, former collaboration manager (with biotechs) at Novartis,
- **Joerg Staeheli**, DMan, retired Novartis manager

1 University College of London
2 PU-PH: University professor and clinician
3 GERMIVIC : Group for Study and Research of Internal Medicine and Infectious Diseases
4 Tel Aviv Souraski Medical Centre

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Major Achievements



- Assignment of Novartis exploratory development program (~4 Mio € investment) to Firalis, including the intellectual property and associated know-how.
- Funding secured (> 3 Million €)
 - IMI-JU¹ 2.566 k€
 - French Ministry of Research 245 k€
 - OSEO²-PPA³ 137 k€
 - Capital Increase 100 k€
 - Others 25 k€
- Regional, national and international recognition established through:
 - Several innovation prizes in Alsace BioValley region
 - National innovation prize by French Ministry of Research (OSEO)
 - Initiation and coordination of European IMI-JU project (SAFE-T)
- Establishment of first R&D facility in its own premises in BioValley

1 Innovative Medicine Initiative-Joint Undertaking
 2 Largest public holding in France providing assistance and financial support to French SMEs and VSEs
 3 Pret participative d'amorçage is an OSEO loan without guarantee

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Milestones



- **M1: 12/2009**
 - R&D Laboratory is operational
 - Servicing Activity: IMI Contract started, first contracts signed with pharmaceutical industry and academic laboratories
- **M2: 12/2010**
 - Servicing activity: 1 Medium size contract signed with industry
 - Coxib program: Translational BM study and clinical validation completed
 - A second R&D program started under IMI-JU
- **M3: 12/2011**
 - Servicing activity: First results of IMI program
 - Coxib program: Negotiations finalized for out-licensing or co-development

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Market Opportunity

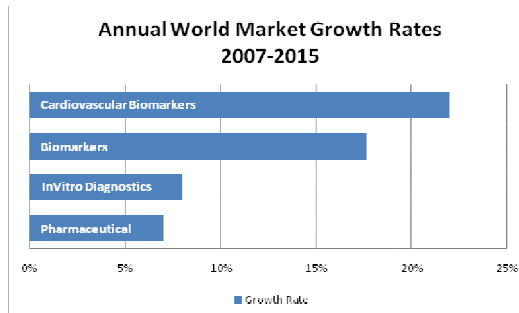


World BM market

- 5.5 Billion \$ in 2005
- 11.8 Billion \$ in 2008
- > 20 Billion \$ in 2012
- Annual Growth ~ 18%

Cardiovascular BM market

- 1.3 Billion \$ in 2007
- 6.6 Billion \$ in 2015
- Annual Growth ~ 22%



¹Business Insights (2007), BCC Research (2007) and Research & Markets (2008).
²Episcum, Cancer, CNS & CV biomarkers (2008)

BM Market Opportunities

- Strong growth in the World Cardiovascular BM Market
- Increasing trend of out-sourcing BM R&D within the pharmaceutical industry
- Specialized SMEs are more efficient in BMs R&D
- Public-private joint efforts for precompetitive BMs (IMI-JU in Europe, PSTC¹ in USA)

¹ PSTC, Preclinical Safety Testing Consortium

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Strengths



- Firalis is the unique company¹ in the world, having proprietary biomarker candidates for vascular safety of **coxibs**
 - WO 2006/095259 in force in EU and USA
 - Protection: 250 genomic & 50 peripheral BMs
 - Terms of transfer by Novartis: Right of first refusal for Novartis under certain conditions
- Positioning on Cardiovascular biomarkers, biggest segment of World BM market
- Recognized leadership in clinical qualification of « Safety BMs »
- Competent team members with complementary expertise
- Established international network of academia and pharma industry
- Access to specific biobanks of Firalis' interest
- Servicing activities started with a major R&D program under contract

¹ Regarding Firalis research and the BiomarkerCenter (BM Database) of Thomson Reuters

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Contact



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