From a cup of coffee to a high-tech laboratory for hematology testing

Prof. Jonathan Douxfils
University of Namur
QUALIblood s.a.

12 MARS MAART 2019

MARCHE-EN-FAMENNE

Colloque Dr Paul Janssen

Genesis of QUALIblood

2010

Creation of the NTHC

2011-2015

PhD thesis in the field of hematological biomarkers innovations and validations

2013-2017

Validations of diagnostic kits in collaboration with IVD manufacturers

2016

Collaboration with Biotech companies

Entrepreneurs hip courses

Market study

ADRE - WBC - BEP

2017

DGO 6 – Bourse préactivité

Deposit mark

Contact with investors

QUALIblood

Your expert in blood testing

Genesis of QUALIblood

Start-up from the **University of Namur**

More than 10 years of research in **hematology** with a focus on **hemostasis** and **hemocompatibility** - more than 100 publications in the field with innovative biomarkers development and discovery

Gathering of expertise from **laboratory**, **clinical** and **regulatory** scientists

Potential market needs

Antithrombotics
19 billions $
CAGR 7.6%

193 products in development

Female hormonal therapies
10 billions $

Antineoplasic agents (TKI)
40 millions $

Commercial strategy

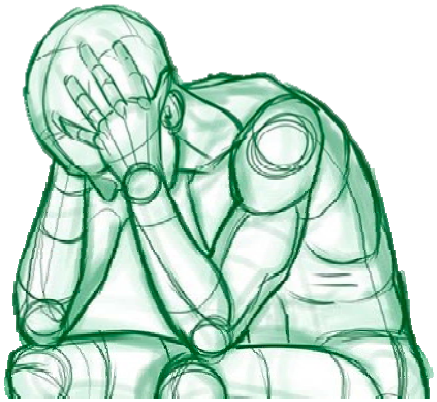
Scientific contacts:

Publications, studies, collaborations

Representation:

Presence at international congress, presentation of clinical studies

Define the offer



We often hear…

“The haematological environment is so complex and a plenty of tests are so constantly renewed that a continuous expertise in this field is hard to reach”

“I risk my time and money in inefficient or outdated blood testing. Could a specific laboratory help me in the choice of the most appropriate biomarkers to ensure transferability to real-world applications?”

Define the offer

Because every result matters, QUALIblood is offering to **pharmaceutical** and **IVD companies** a tailor-made accompaniment in blood analyses.

Define the offer

FACILITIES FOR PHARMACEUTICAL COMPANIES

DEFINITION OF ANALYTICAL PROTOCOLS

- ACCOMPANIMENT IN THE REDACTION OF THE PROTOCOL
- ADVICE AND LITERATURE REVIEW FOR DETERMINATION OF MOST APPROPRIATE BIOMARKERS

PRE-CLINICAL INVESTIGATIONS – GRP AND/OR GLP AND ISO 13485* & 17025*

- IN VITRO INVESTIGATION ON PLASMA, SERUM, WHOLE BLOOD OR CELL LINES
- TAILOR-MADE SOLUTIONS AND TESTING VALIDATED ACCORDING TO REGULATORY REQUIREMENTS
- BLOOD TESTING OF SAMPLES FROM ANIMAL STUDIES

CLINICAL INVESTIGATIONS - GLP AND ISO 13485* & 17025*

- BLOOD TESTING OF SAMPLES FROM HUMAN STUDIES – PHASE I TO III

BATCH RELEASE - GLP AND ISO 13485* & 17025*

- EVALUATION OF THE QUALITY OF PLASMA-DERIVED MEDICINAL PRODUCT ACCORDING TO REGULATORY REQUIREMENTS

* ISO certifications are pending

FACILITIES FOR IVD COMPANIES

DEFINITION OF ANALYTICAL PROTOCOLS

- ACCOMPANIMENT IN THE REDACTION OF THE PROTOCOL

PROOF-OF-CONCEPT – GRP AND/OR GLP AND ISO 13485*

- IN VITRO INVESTIGATION ON PLASMA, SERUM FROM OUR PROSPECTIVE BIOBANK
- IN-VITRO INVESTIGATION ON PLASMA, SERUM OR WHOLE BLOOD FROM HEALTHY SUBJECTS
- METHOD COMPARISON ON SEVERAL ANALYTICAL PLATFORMS – WHEN AVAILABLE
- EARLY ADVICES FOR METHOD IMPROVEMENT

ANALYTICAL PERFORMANCE – GLP AND ISO 13485*

- DEFINITION OF ANALYTICAL PERFORMANCES ACCORDING TO REGULATORY TEMPLATES – VALIDATION PROCESS
- DEFINITION OF NORMAL RANGE FROM OUR AVAILABLE BIOBANK FROM HEALTHY SUBJECTS

REAL-LIFE EVALUATIONS – GLP AND ISO 13485*

- STUDY PERFORMED IN COLLABORATION WITH OUR UNIVERSITY PARTNERS
- SUPERVISION OF MULTI-SITE STUDIES

* ISO certifications are pending

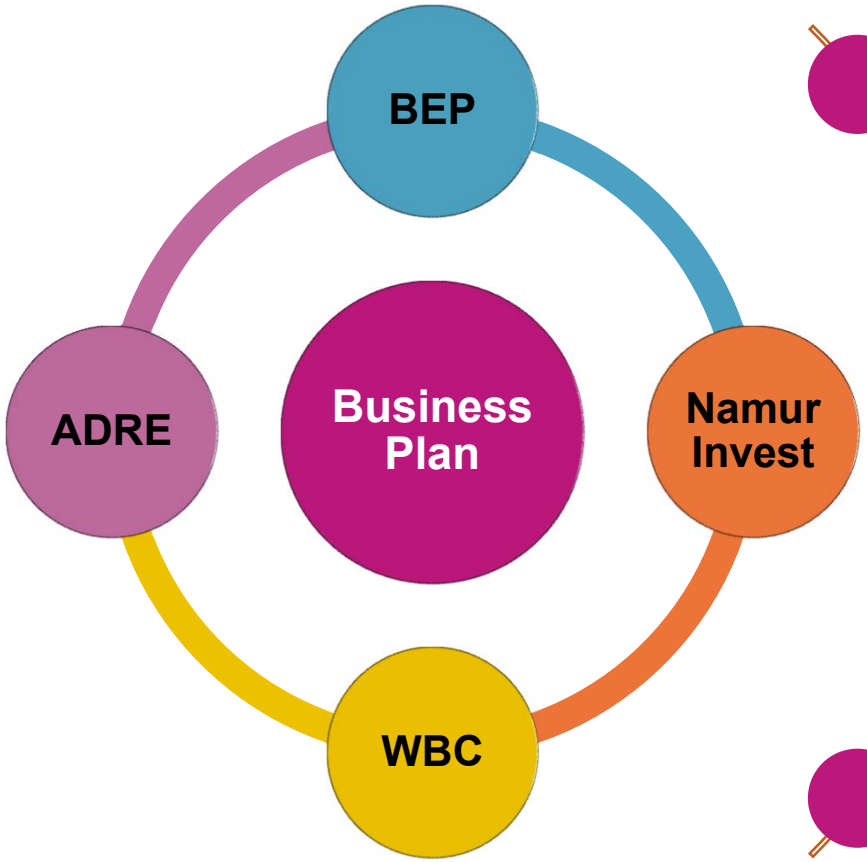
Partners and first customers

Partners and invests

Customers

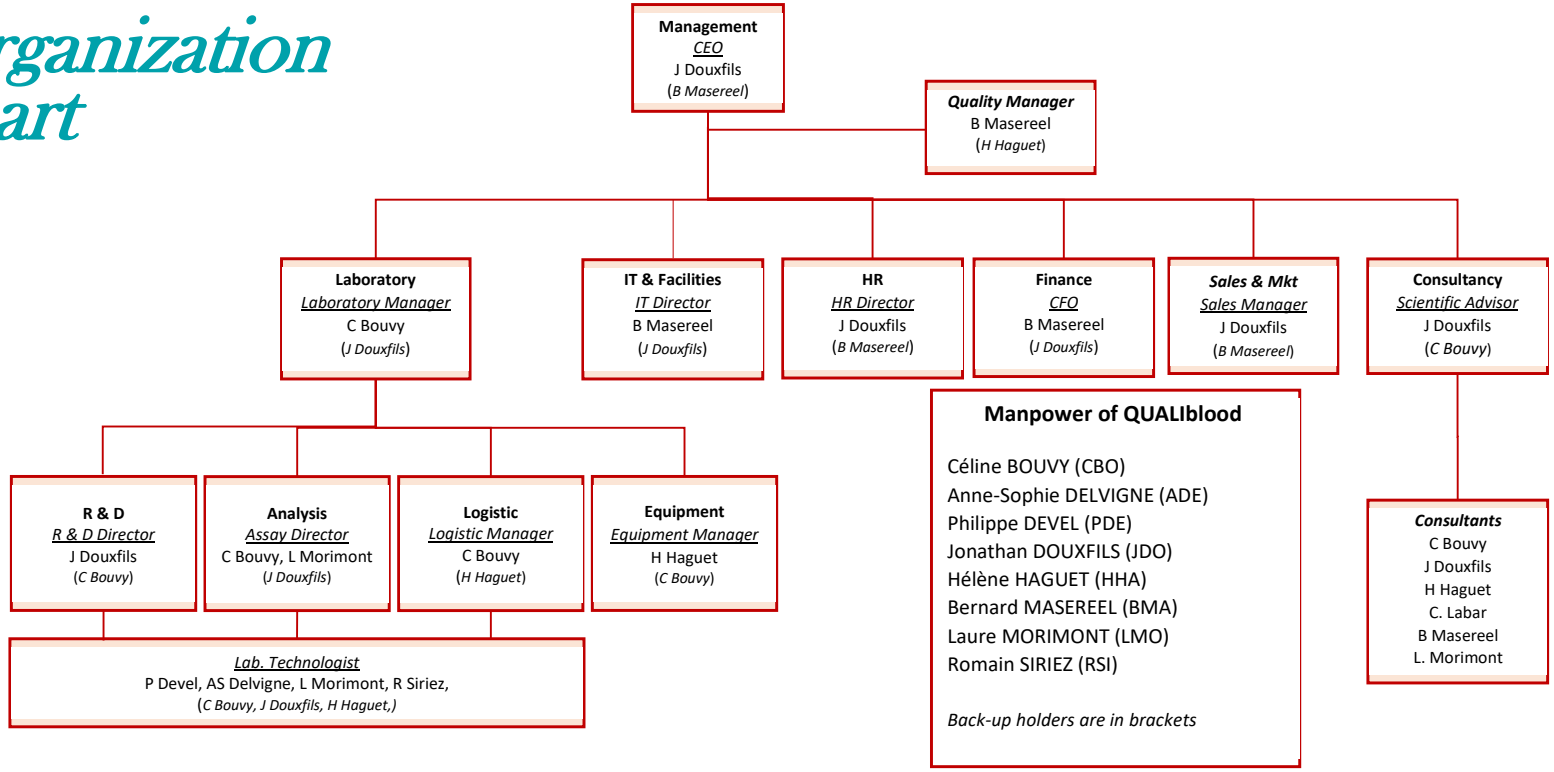
2016-2017

Pivotal years



- Elaboration of the business plan and related tools like BMC or financial plan
- Validation of the company's project and searching for investors/partners
- Thinking about facilities and localisation
- Accompaniments during fundraising
- Critical analysis of financial resource finding and business plan
- Marketing culture
- Reinforcement of existing network

Organization chart

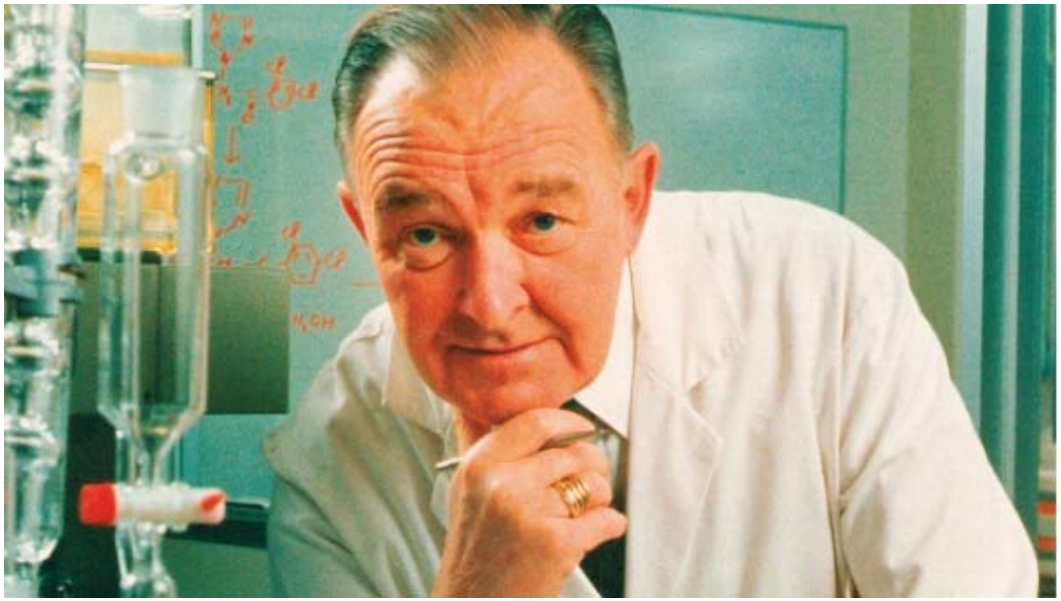


Growth plan

2017	2018	2019	2020	2021
University exit Laboratory installation for GLP certification	GLP and ISO implementation Batch release prospection	Management of serious contracts of phase-III studies GLP and ISO certification	New laboratory (↗ Infrastructure) **Refinancing**	

Take home message and advice

- As a medical scientist, there is a real need to follow specific entrepreneurship courses
- Fundamental or medical sciences are not business science, so don’t see businessman as profiteers of your ideas but rather as a catalyst
- Continue to elaborate your scientific network by publishing, attending congress and so on, this is the core business of your society
- Hire different profiles and people for which you would like to work for! As a small company each collaborators is of utmost importance!
- Keep your motivation for innovation and enjoy the adventure!



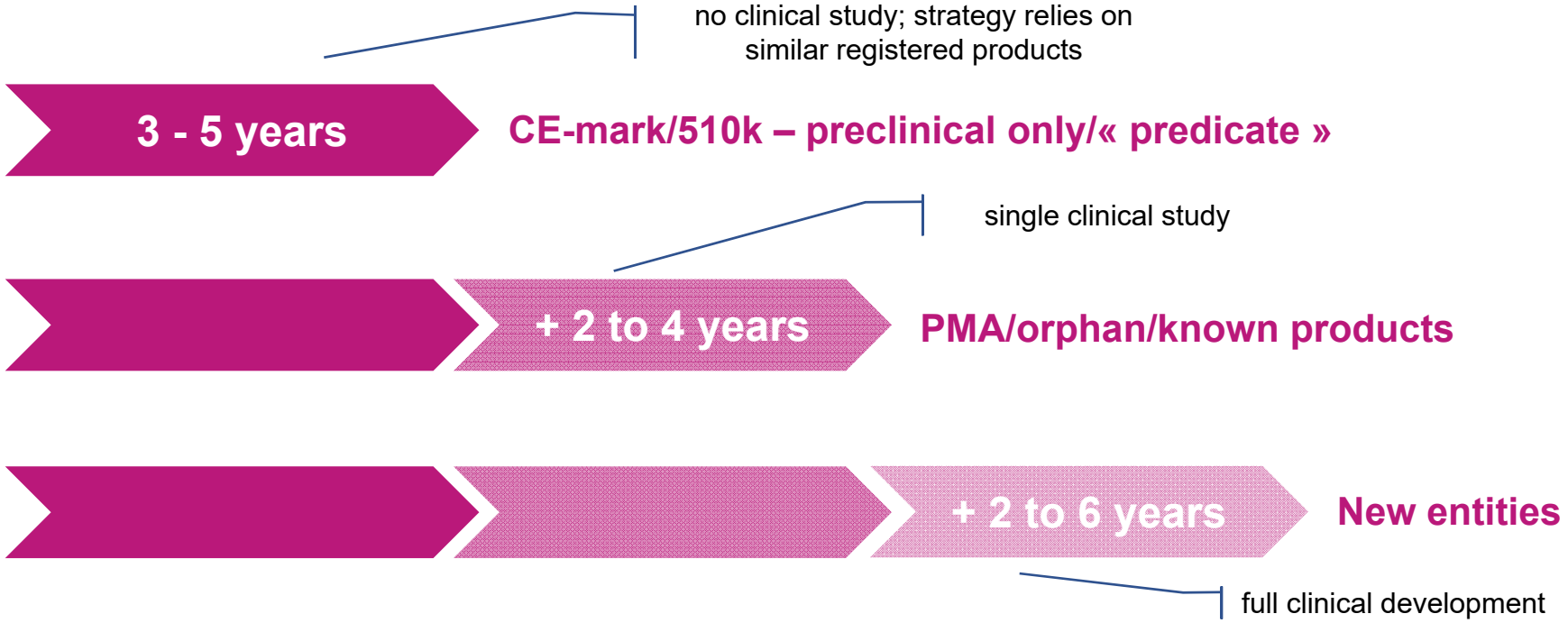
“The human mind is like a parachute. It works best when it is open”

Product Development – a few keys & pitfalls

Enrico Bastianelli,
Scientific & Business Biotech Advisor

A Brief Introduction to "Main" Development Paths

Products - Main Development Paths



Products - Main Development Paths

Preclinical Med Dev.

CE-mark/510k

Cyto/genotoxicity, biocompatibility, histocompatibility, performance, acute/chronic toxicity…; industrialization

Preclinical pharm/biotech

New entities

GLP toxicity, reprotox, embryo-fetal development tox., carcinogenicity….

Safety & PoC → **Confirmation**

Phase IA, IIB, IIA, IIB, III – randomized controlled studies

Products Development – A Common Trap

Duration & (people) resources too often underestimated

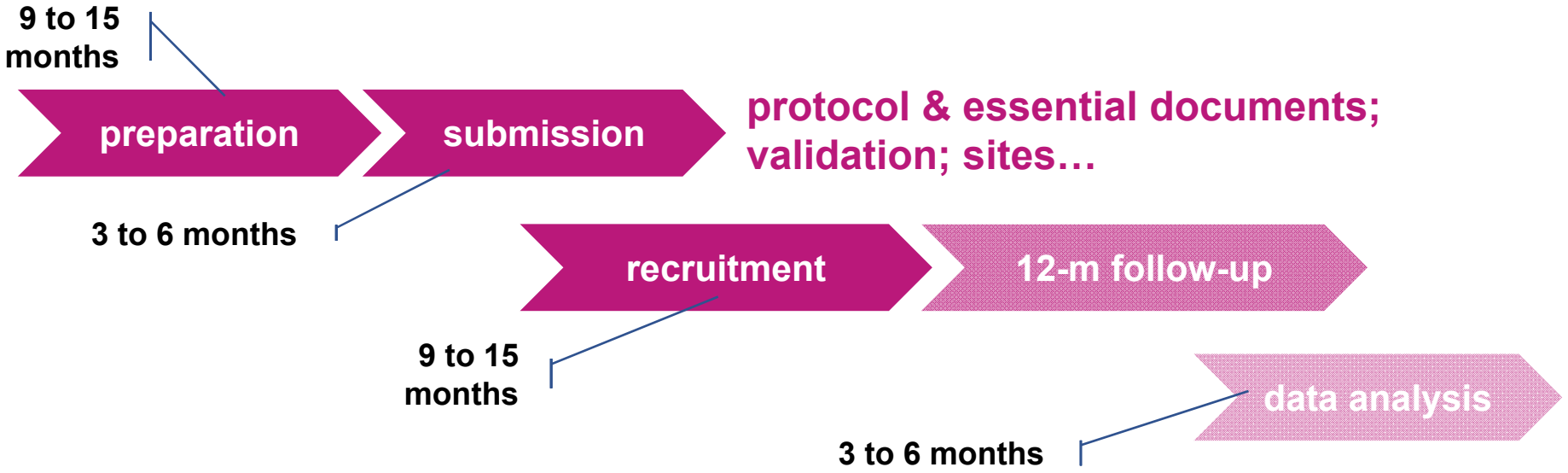
A phase IIb study example: 2 groups, 50 patients & 12-month follow-up, CRO-managed…

12-m follow-up

Products Development – A Common Trap

Duration & (people) resources too often underestimated

A phase IIb study example: 2 groups, 50 patients & 12-month follow-up, CRO-managed



Some Success Factors to Consider

Planning

The regulatory perspective first:

- Plan preclinical, production & clinical on market access strategy
- Plan from max to required
- Be prepared to be challenged / to challenge
- Validate through Scientific Advice/Protocol Assistance

Planning

Market and HTA impact into development and product success:

- Becoming a significant hurdle
- To be assessed very early on in the process: medical need, competition, price/reimbursement, costs…
- To be integrated into development plan

Execution

The key of a successful execution is keep control (of development) internally by adding to a well-thought/reasonable (retro-)planning:

- Enough (management) resources
- Right expertise
- Quality/excellence mindset

Execution

The (internal) Human Factor: challenge of talents:

- How to recruit? (Where is our attractiveness level)
- How to train: experience vs. « trial & error » / on the spot training
- How to retain?

Advices & Consulting:

- The same challenge

Resources

"World-class" Walloon Ecosystem:

- Infrastructure (offices, labs, production…)
- Incubation(s) – support & services (acceleration, business development, international…)
- Networks (industrials, consultants, hospitals, patients…)

Resources

Financials:

- Clinical studies cost from a few hundreds to millions of euros
- Growing basis of Business Angels & VCs to support company funding (from seed through series A/B/…)
- Has not caught up yet / still lagging

Resources

Subsidies:

- Unique/top-class Walloon subsidies system
- A must-have in current “funding” landscape

Conclusion

=> Plan/prepare development with exit/next round in mind

Collaborer avec le monde pour le bien-être de tous

Janssen Pharmaceutical Companies of Johnson & Johnson

Sonja Willems Managing Director| Janssen Benelux | 12 March 2019

janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Janssen et J&J en Belgique

Merksem

Janssen Pharmacology Unit

32 collaborateurs

Mechelen

Actelion

16 employees

La Louvière

Janssen European Distribution Center

10 collaborateurs

Diegem

J&J Medical NV
- J&J Medical NV
- GMED bvba
- J&J Fonctions Corporatives
- European Logistics Center
- One MD Regional Office

502 collaborateurs

Olen

Janssen

20 employees

Courcelles

J&J European Distribution Center

40 collaborateurs

Beerse 1

Janssen
-R&D
-Chaîne d'approvisionnement
-Liquides & crèmes
-Parentéreaux
-Centre de distribution
-Services généraux

3,420 collaborateurs

370 collaborateurs

Beerse 2

Janssen-Cilag NV
la commercialisation de tous les médicaments Janssen en Belgique

Beerse 2

Consumer GCO

760 collaborateurs

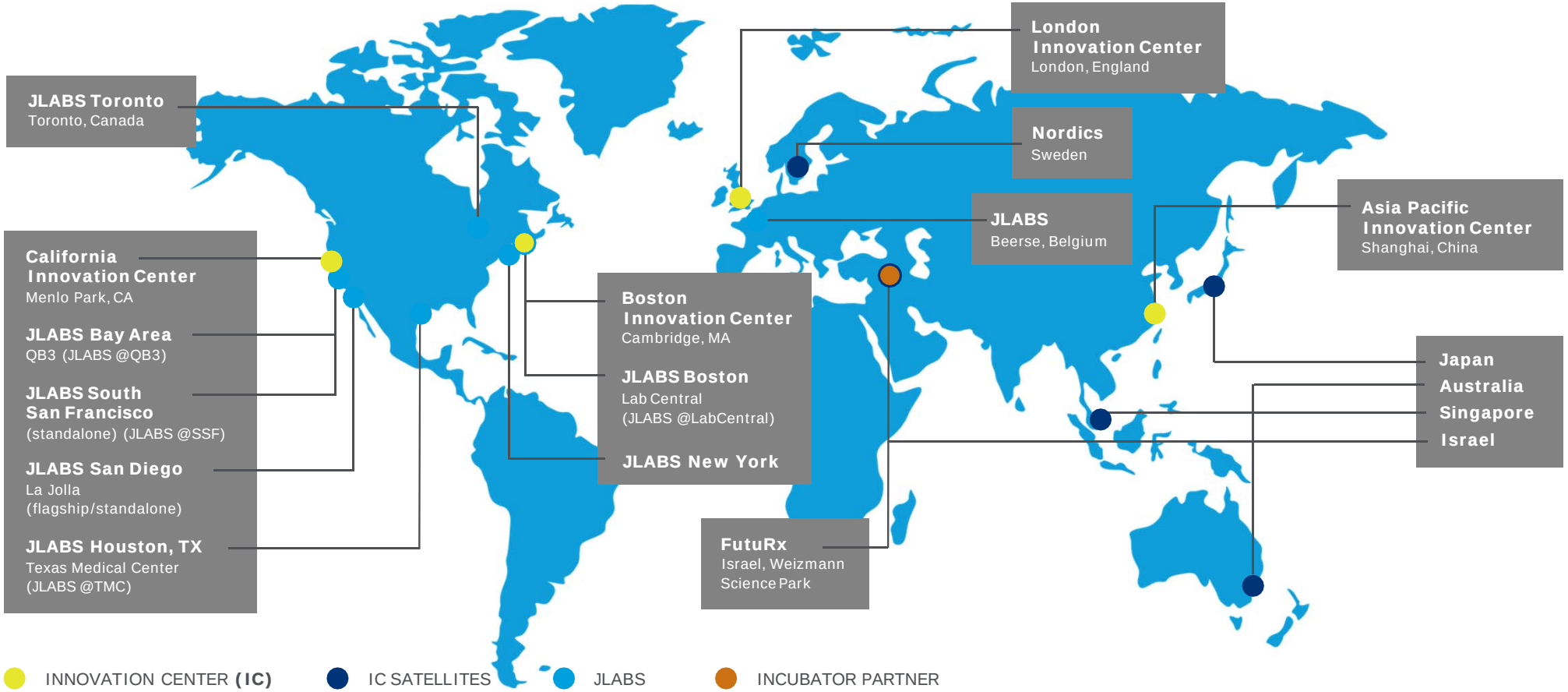
Geel

Janssen Supply Chain
API/petites molécules

- **Janssen**
- **Johnson & Johnson**

janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Famille d'innovation Johnson & Johnson



Encourager la meilleure science

Innovation Centers

4 Innovation Centers
sur 3 continents

>400 investissements depuis 2013

>1 milliard de $ capital déployé depuis 2013

JLABS

13 sites à travers le monde
+ de 480 entreprises en residence, financement de plus de 11 milliards de dollars au cours des 6 dernières années
+ de 120 collaborations avec J&J

JLABS @ BE

Modèle unique, libre de droit,
18 sociétés en résidence

Johnson & Johnson Development Corporation

+ de 45 ans d'investissements en capital-risque

+40 investissements en 2018

>450 MM de $ capital déployé en 2018

À propos de JLABS

Un environnement flexible et économe en capital

pour réduire le temps et les coûts d'innovation pour les patients

Permet aux entrepreneurs de mettre du capital au travail

immédiatement dans un environnement optimisé et efficace

Réduction des coûts d'infrastructure et gestion centralisée

des installations partagées

Programmes éducatifs

pour développer les compétences, les connaissances et les réseaux afin d'autonomiser la communauté locale de l'innovation

Programmes d'affaires, partenaires financiers et un **réseau d'innovation en sciences de la vie**

Sans obligations!

Notre partenariat avec Liege

Merci

www.facebook.com/janssenbelgium

www.twitter.com/JanssenBelgium

www.linkedin.com/showcase/janssen-belgium/

janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Clés de réussite & expertise - Liège

Julien Compère, CEO CHU Liège

Who am I ?

- CEO University Hospital of Liege
- Member of the BoD: CHR de la Citadelle, CH Bois de l'Abbaye, Clinique André Renard
- Former Chairman of the BoD: Belgian Federation of Academic Hospitals
- Member of the BoD: Gesval, Bridge2Health, ATC

1. Strong Research and Clinical Activities

- Academic Hospital (access to patients, PI & KOLs)
- Complete University (10 faculties and 1 business school)
- Dedicated Research Institutes (especially Giga)
- Technological platforms

2. Dynamic biotech and medtech cluster

- Over 70 life sciences companies
- Staff: + 2.850 jobs (250 new jobs/year)
- Funds raised in 2018: 200M€
- Sectors: oncology, cardiology, immunology, medical device

3. Ambitious investment plan in hosting infrastructure

Actual infrastructure from Labhotel to GMP facilities:

- GIGA: 3.000 m^2 in the immediate vicinity of the CHU

  => For R&D in close collaboration

- Accessia: 800 m^2 cleanrooms & 800 m^2 labs & offices

Available in the next years, new buildings for growing companies:

- Totalling 50.000 m^2

  => For biomedical production and research

Conclusion

A fully-integrated ecosystem providing efficient and coordinated access to:

- Scientific and clinical expertise
- Specialized infrastructure
- Different funding schemes
- Partnerships

Clés de réussite & expertise - Charleroi

Florence Bosco, CEO – Biopark Dev

CATCH

Biopark dev

CHARLEROI BRUSSELS SOUTH BIOPARK

A strategic biotech hub in the heart of Europe since 20 years

- 50 companies
- 1.700 jobs
- 200M€ deal flow in 2018
- 350 researchers
- 15 clinical trial sites (incl. 3 academic)
- Bachelors, Masters & continuous training

A dense network of scientific & clinical expertise

CATCH

Biopark dev

	Translational Research	Preclinical Research	Clinical Research
Cancer	 **ULB Cancer Research Center** Director: Prof François Fuks	  **Center for Medical & Molecular Imaging** Director: Prof Serge Goldman & Mrs Laure Twyffels	Hôpital Erasme ULB Universitair Ziekenhuis Brussel Cliniques universitaires SAINT-LUC UCL BRUXELLES 
Neuro-sciences	 **ULB Neurosciences Institute** Diretor: Prof Axel Cleeremans	BUC *Animal Lab*  **Biopark ULB Charleroi Animal Lab** Director: Prof Philippe Horlait CER Groupe	
Immu-nology	ULB Immunology Institute  **ULB Immunology Institute** Director: Prof Oberdan Leo		

A specific and affordable real estate strategy

CATCH

Biopark dev

Shared lab & office facilities: i-Tech Incubators 1 to 5

Brownfields and Greenfields

Next project: i-Tech 6

- Service center
- R&D facilities
- Manufacturing facilities

- 25.000m²
- 100M€
- 10 years

- Real estate holding under creation
- Igretec, SRIW + private partner(s)

A dedicated team to leverage development opportunities

CATCH

Biopark dev

Shareholders:

ULB · Sambrinvest · IGRETEC · CENTRE D'ENTREPRISE HÉRACLÈS

Missions:

- Services to members
- Seed acceleration
- Soft landing services
- Ecosystem development
- International promotion
- Real Estate development with Biopark IMMO

Florence Bosco
CEO Biopark Dev
Seed Acceleration Program Manager

Michel Coulon
CEO Biopark
Science & Education

Augustin Coppée
Business Developer

Perrine Schepers
Member Services Manager

Nathalie Roelandt
Business Analyst

Anne-Marie Bauduin
Scientific Director

Michel Toungouz
Medical Director

Helena Pozios
Investors Liaison Manager

CATCH

Biopark dev

BRUSSELS SOUTH BIOPARK,

a business unit of the vibrant Walloon & Belgian Biotech ecosystem

Wallonie

.be BELGIQUE

ATB Therapeutics – Next immunotherapeutics generation

Bertrand Magy, CEO ATB Therapeutics

ATB Therapeutics – Next immunotherapeutics generation

Versatile platform
Unique manufacturing abilities
Oncology Market

An idea – 3 co-founders

A company – ATB Therapeutics

A proof of concept – Value creation

Technology market compliance

Funding & advises

Facilities & Expertise

Experts & advisors

3 keys of success and differentiation

Key 1 - Funding & advises

Wallonie

DGO6

Spin Venture

INVESTSUD
votre associé capital & croissance

Fournier-Majoie Foundation

Financial structure and Strategic development

3 keys of success and differentiation

Key 2 - Facilities and Expertise

- Offices
- BL2 Laboratories fully equipped
- Characterization assays development
- In vitro & in vivo preclinical development
- Quality control expertise

- Modular production container

3 keys of success and differentiation

Key 3 - Experts & Advisors

KOL : business & technology relevance

Project Challenging
POC choices relevance
Unmet need targeted

Advisors: strategic development and value creation

IP driven development
Market driven development

ATB Therapeutics

Spin Sventure

INVESTSUD
votre associé capital & croissance

Wallonie

CER Groupe

IDELUX

Fournier-Majoie Foundation

ATB Therapeutics is looking for midterm financial partner
bertrand.magy@atbtherapeutics.com 084 84 02 49 – 0478 62 50 59