



Innovating in **Biotechnology** in charge of the baton:
how I should organize my orchestra?

CNIC – PhD day 2019
Workshop for future entrepreneurs

Dr. Juan José INFANTE VIÑOLO
22 NOV 2019

You need a CEO (CEO + CFO + COO)

THE CEO

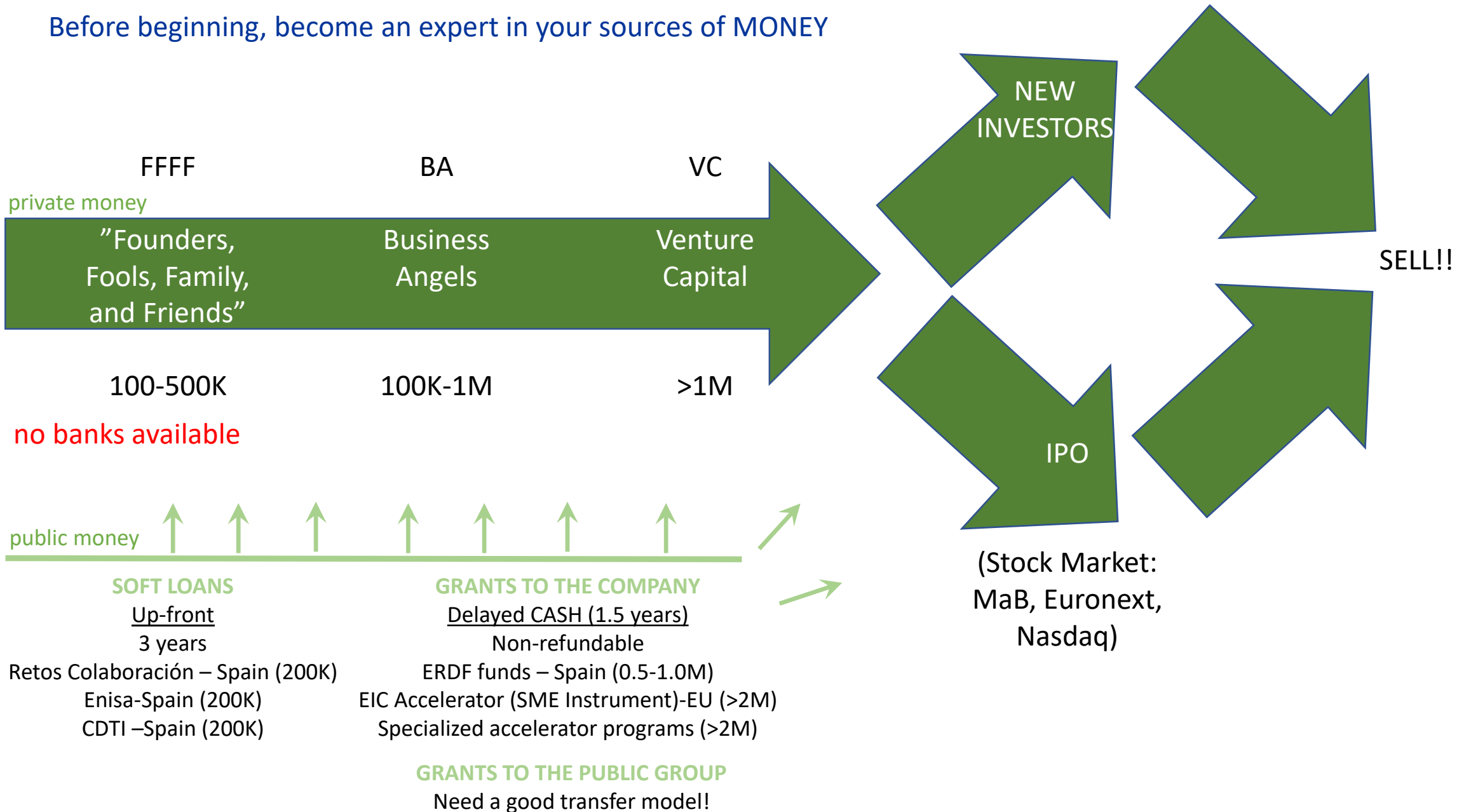


THE CSO



1. THE MONEY
2. THE BUSINESS PLAN - BUSINESS MILESTONES
3. THE SCIENCE – TECHNICAL MILESTONES
4. ALIGNMENT – CLEAR MODEL OF TECHNOLOGY TRANSFER

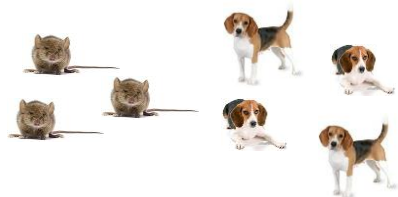
Before beginning, become an expert in your sources of MONEY



What is my pathway?



STAGE 1: PROOF OF CONCEPT



STAGE 2: PRECLINICAL



STAGE 3: PHASE I

I need 1M

My value is 1M

I need 4M

My value is 10M

risk 23%

risk 45%

I need 4M

My value is 80M



STAGE 4: PHASE 2



MARKET AUTHORIZATION

71%



STAGE 5: PHASE 3

I need 300M

My value is 2000M

risk 47%

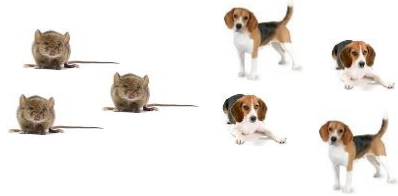
I need 30M

My value is 800M

Licensing contracts



STAGE 1: PROOF OF CONCEPT



STAGE 2: PRECLINICAL



STAGE 3: PHASE I

Licensing IN

I need 1M My value is 1M

I need 4M My value is 10M

risk 23%

risk 45%

I need 4M My value is 80M



STAGE 4: PHASE 2



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STAGE 5: PHASE 3

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risk 47%

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A case of success

30 10 2019

Sanifit announces that the Phase 2b CaLIPSO trial of SNF472 met its primary endpoint in slowing the progression of cardiovascular calcification in patients on hemodialysis

Top line data to be presented at 2019 Scientific Sessions of American Heart Association Webcast to be held on Monday 18 November at 11.00 ET Palma, Spain and San Diego, USA, 30 October 2019 – Sanifit, a clinical-stage biopharmaceutical company focused on treatments for progressive vascular calcification disorders, today announced that the international Phase 2b [...]

Sanifit Announces Enrollment of First Patient in CaLIPSO – a Phase IIb Study for the Treatment of Cardiovascular Calcification in End-Stage-Renal-Disease Patients on Haemodialysis

San Diego, USA and Palma, Spain, January 23, 2017 – Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company focused on treatments for calcification disorders, today announced that the first patient has been enrolled in the Phase IIb “CaLIPSO Study” clinical trial of lead candidate, SNF472, for the treatment of cardiovascular calcification (CVC) in end-stage-renal-disease (ESRD) patients on haemodialysis (HD).



Sanifit starts Phase Ib/II with SNF472 in dialysis patients

Sanifit Laboratories has obtained the authorization from the AEMPS and the ethics committee to initiate Phase Ib/II studies in Hospital Clinic, Barcelona, Spain. This double-blind, placebo-controlled trial will evaluate the safety, pharmacokinetics and pharmacodynamics of SNF472 in dialysis patients up to one month of treatment. SNF472 is an experimental drug for the treatment of vascular calcification and calciphylaxis (CUA), which has demonstrated an excellent safety and PK-PD profile in clinical trials with healthy volunteers.



New approach to calcification disorders



JOAN PERELLÓ
CEO and co-founder

26 06 2019

Sanifit announces €72.2M (\$80.9M) financing in Spain's largest private biotech fundraising

– Proceeds to enable progression of orphan designated lead candidate SNF472 into pivotal phase 3 trial for treatment of calciphylaxis – Round led by Spanish investor Caixa Capital Risc – Deal supported by new investors Columbus Venture Partners and Alta Life Sciences in addition to international consortium of existing shareholders – Palma, Spain and San [...]

Sanifit raises €36.6M (\$41.3M) in Series C financing round

Financing will advance Sanifit's lead drug candidate through phase IIb as a treatment for cardiovascular diseases linked to calcification and through phase II/III for calciphylaxis

Palma de Mallorca, Spain, September 8, 2015 – Laboratoris Sanifit S.L., a clinical-stage biopharmaceutical company, today announces that it has raised €36.6M (\$41.3M) in a Series C financing round. The company is focused on the development of SNF472, an experimental drug for the treatment of cardiovascular diseases linked to calcification in patients with End Stage Renal Disease (ESRD) undergoing haemodialysis.



Sanifit closed a 3.6 million euros financing round

Sanifit has accomplished a series B capital increase of 3.6 million Euros in an operation led by “la Caixa”. The venture capital firm HealthEquity, the company Somtobir, and the Nefrona Foundation were also involved in this round. The entrance of a group of private investors with extensive experience in the field of life sciences, among which are several ex – Phadia managers, is also worth mentioning. It is the largest financing round of 2014 in the biotechnology sector in Spain.

It's all about MONEY

In order to reach my 1st important business milestone, I need to borrow money:
when? who? how much? how will I success?



- ✓ The more I increase **valuation of the Company** with founders' money, the better
- ✓ If I want to ask for 8M and give 40%, then I have to convince investors that the company's value is $8M/0,4= 20M$
- ✓ If I have access to a grant covering 4M, then the value is $4M/0,4= 10M$

when? High valuation; when you need it!!

who? Specialized investor (understand the business, connection with licensors, good track record)

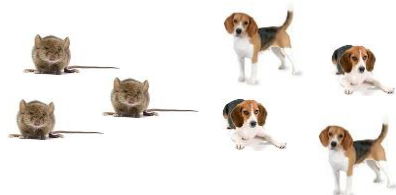
how much? The money that you really need to reach a key business milestone

how will I success? TEAM; BUSINESS PLAN; PAST (results translated into business; KoL's support); CONFIDENCE; TIME (alignment, the deal breaker)

Founder's share



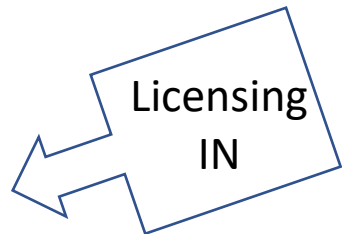
STAGE 1: PROOF OF CONCEPT



STAGE 2: PRECLINICAL



STAGE 3: PHASE I



I need
1M

My value is
1M

Founder's share
100%

I need
4M

My value is
10M

Founder's share
75%

risk 23%

Founder's share
51%

risk 45%

I need
4M

My value is
80M



STAGE 4: PHASE 2



MARKET AUTHORIZATION

71%



STAGE 5: PHASE 3

I need
300M

My value is
2000M

Founder's share
37,09%



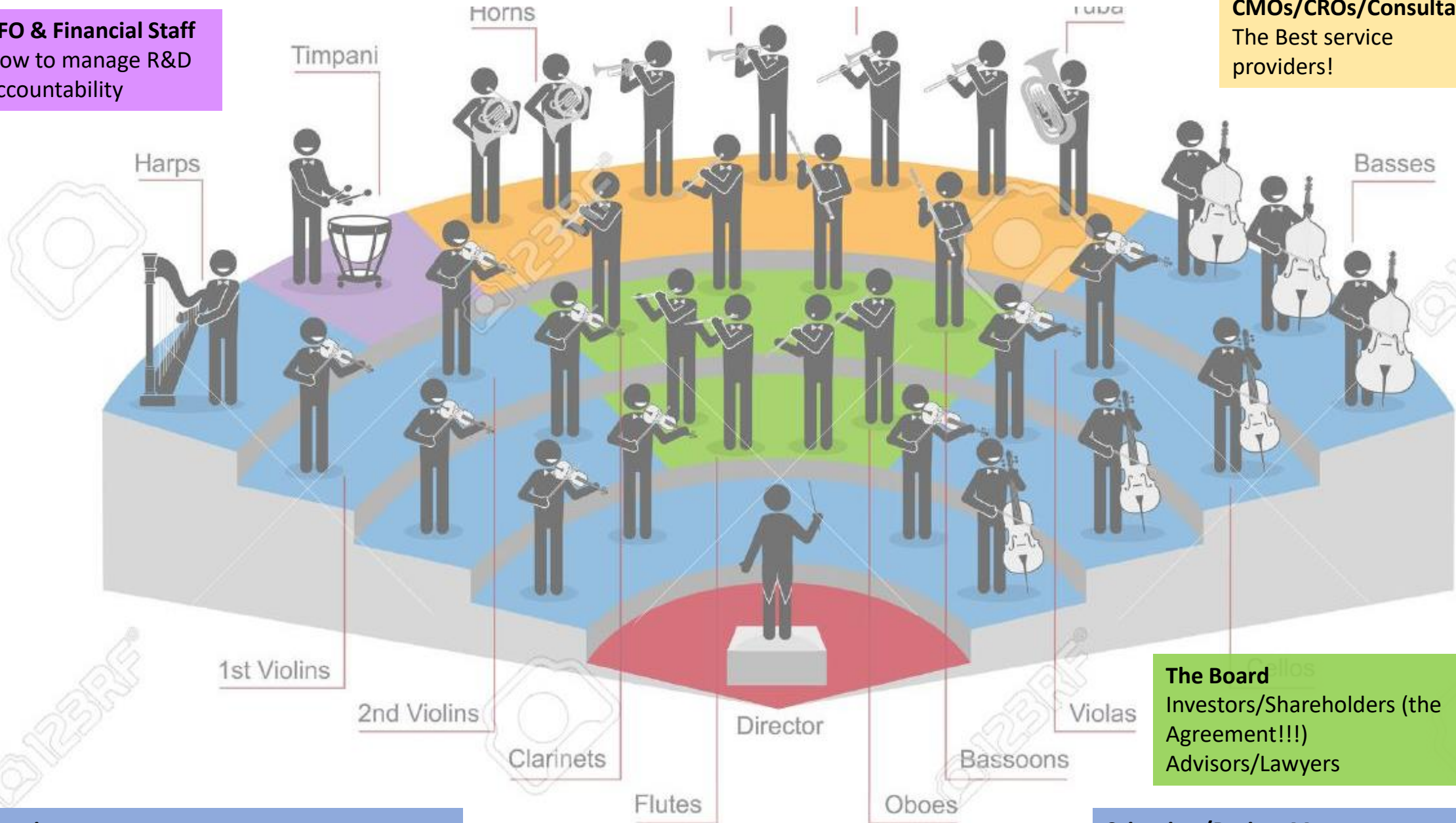
risk 47%

I need
30M

My value is
800M

CFO & Financial Staff
How to manage R&D
accountability

CMOs/CROs/Consultants
The Best service
providers!



The Board
Investors/Shareholders (the
Agreement!!!)
Advisors/Lawyers

Scientists
Services/Co-development Agreement with
Public Institution (ALIGNMENT!!)

Scientists/Project Managers
Patent Lawyers (the patents!!)
Regulatory People

Opportunity

Vaccines to prevent antibiotic-resistant infections

70% of R&D expenses covered until key business milestone

Dr. Juan José Infante

CEO

Juanjo.infante@Vaxdyn.com

November 2019

LISBON INVESTORS CONFERENCE

Antibiotic-resistant infections: emergency

Population at risk 2019: 74 million

Deaths in 2018: 700.000

Cost associated in 2018: 40 billion \$

Deaths forecasted for 2050: 10 millones

Vaccines should come first - The review on antimicrobial resistance chaired by Jim O'Neill, May 2016

2 Barriers: technology & market introduction



Priority 1: CRITICAL[#]

Acinetobacter baumannii, carbapenem-resistant

Pseudomonas aeruginosa, carbapenem-resistant

Enterobacteriaceae^{*}, carbapenem-resistant, 3rd generation cephalosporin-resistant

^{*} Enterobacteriaceae include: *Klebsiella pneumoniae*, *Escherichia coli*, *Enterobacter* spp., *Serratia* spp., *Proteus* spp., and *Providencia* spp., *Morganella* spp.

Priority 2: HIGH

Enterococcus faecium, vancomycin-resistant

Staphylococcus aureus, methicillin-resistant, vancomycin intermediate and resistant

Helicobacter pylori, clarithromycin-resistant

Campylobacter, fluoroquinolone-resistant

Salmonella spp., fluoroquinolone-resistant

Neisseria gonorrhoeae, 3rd generation cephalosporin-resistant, fluoroquinolone-resistant

Priority 3: MEDIUM

Streptococcus pneumoniae, penicillin-non-susceptible

Haemophilus influenzae, ampicillin-resistant

Shigella spp., fluoroquinolone-resistant

Old solution – Modern challenge: Vaccines



Table 1. Vaccines against resistant bacteria. Industry pipeline as of Feb 2018

TARGET	CLINICAL STAGE PIPELINE				Registered	Expected New
	Phase 1	Phase 2	Phase 3	Total		
<i>Candida</i>	0	1	0	1	0	0.3
<i>Clostridium difficile</i>	0	1	1	2	0	0.9
Priority 1 █ <i>Escherichia coli</i>	1	1	0	2	0	0.5
Priority 3 █ <i>Group B Streptococcus</i>	1	1	0	2	0	0.5
<i>Shigella</i>	0	1	0	1	0	0.6
Priority 2 █ <i>Staphylococcus aureus</i>	1	1	1	3	0	1.1
Priority 3 █ <i>Streptococcus pneumoniae</i>	1	3	0	4	3	1.1
<i>Mycobacterium tuberculosis</i>	0	2	0	2	1	0.6
<i>Acinetobacter baumannii</i>	0	0	0	0	0	0
Priority 1 █ <i>Pseudomonas aeruginosa</i>	0	0	0	0	0	0
<i>Klebsiella pneumoniae</i>	0	0	0	0	0	0
Total	4	11	2	17	4	5.6



Dr. Michael J. McConnell
Bacteriologist, CSO
KOL

Dr. Jerónimo Pachón
25 years director Infection
Diseases Unit at Hospital
Univ. Virgen del Rocío of
Seville



Dr. Francisco León
Immunologist, pharmaceutical developer, entrepreneur
Ex-VP Janssen-Johnson & Johnson
Co-founder Celimmune & Provention Bio (NASDAQ)



Dr. Juan José Infante

CEO

12 years private biotechnology

vaccines valuation

Univ. Washington Hospital

(Seattle)



Dra. Pilar Pérez

Virologits

Immunologist



National Microbiology Center of Spain Health Institutes (ISCIII, Madrid)

Institute of Biomedicine of Seville (IBiS)



Biodextris (CMO active ingredients; Montreal)

Laboratorios Reig-Jofré (CMO final product; Barcelona)



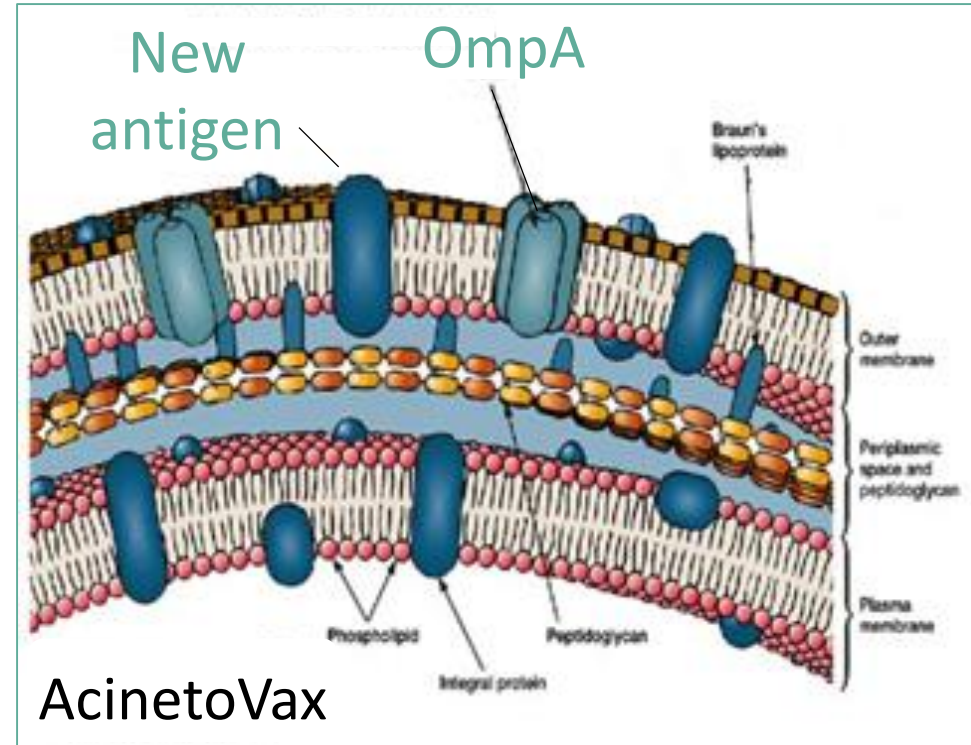
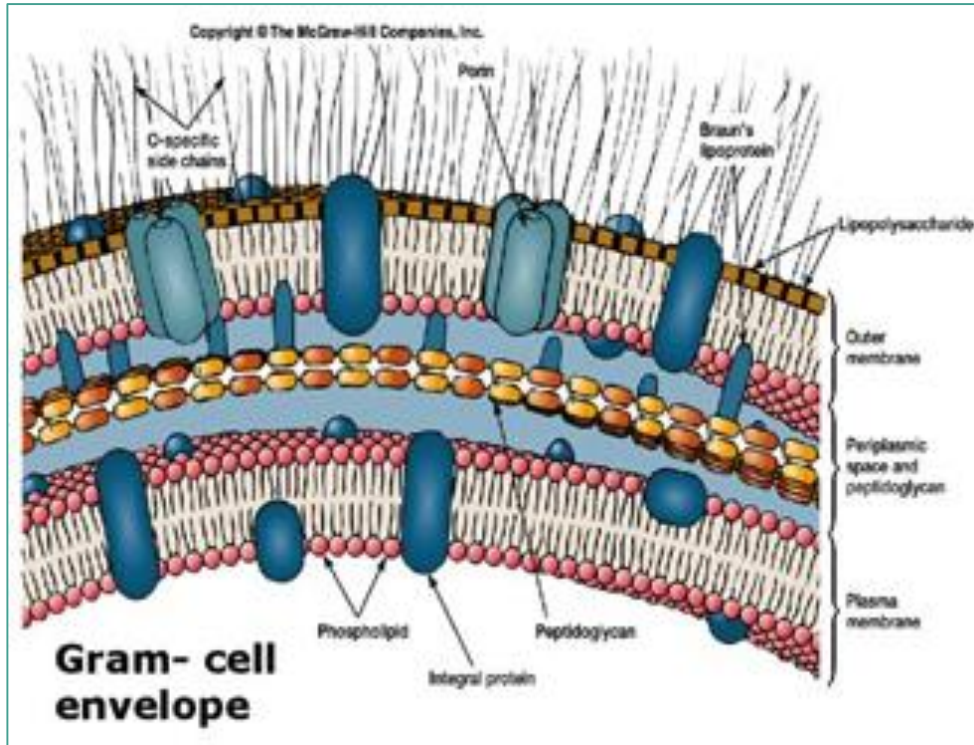
- ✓ EUR 5.2 MILLION GRANT (70% R&D)
- Non refundable
- Non dilutive

Private international organization with headquarters in the USA

- ✓ Phase I completed in 4 years
 - ✓ Technology validation
 - ✓ Access to NIH preclinical services; Expert Advisory Board
-

Technology validated; Manufacturing validated

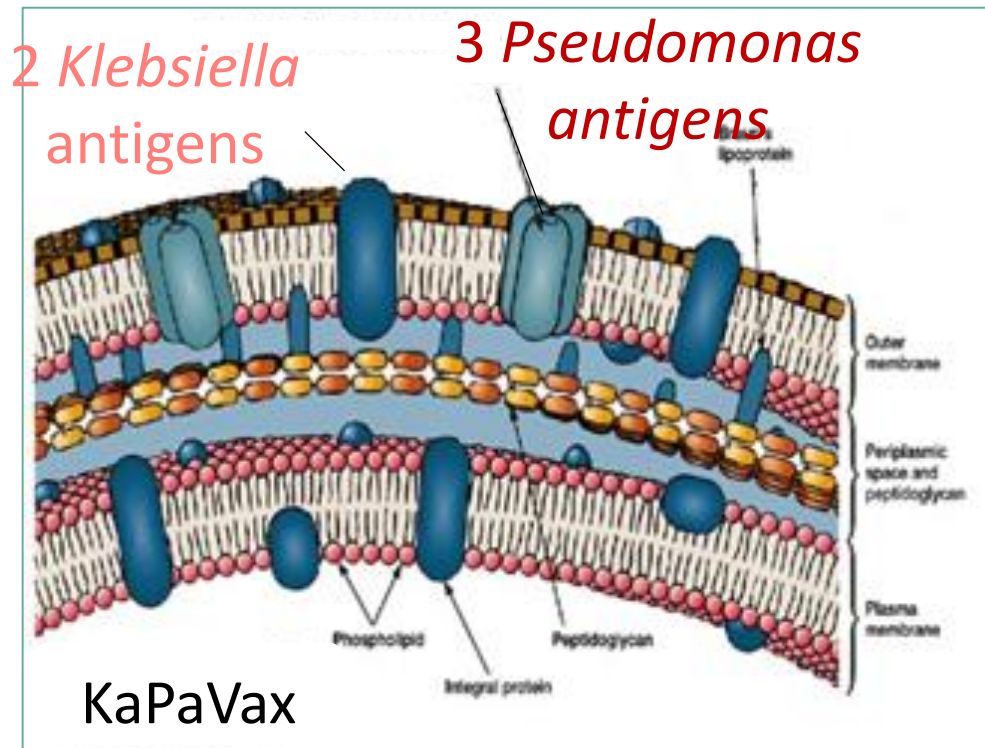
Inactivated multi-antigen whole-cell vaccines based on a LPS (endotoxin)-negative strain of *Acinetobacter baumannii*



IP-protected in Europe, USA, Japan, China, India, and México

KaPaVax: multivalent vaccine

KaPaVax: Multi-Presentation of antigens from *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* in the LPS-negative cell of *A. baumannii*



KAPAVAX VACCINE

MULTIVALENT

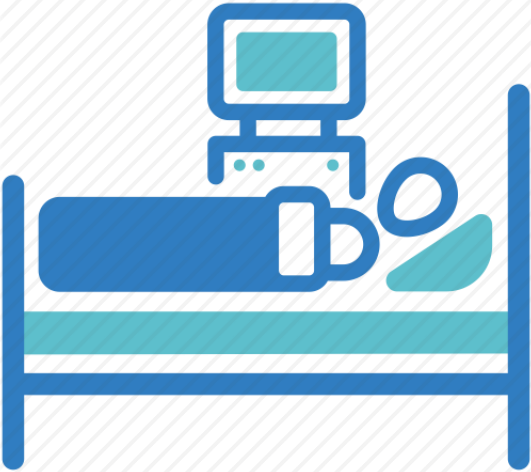
the 3 top priority 1 pathogens, responsible for 50% bacterial infections causing pneumonia

SAFE

SCALABLE

8000 doses/L

Overcoming the barriers: looking for the target population



1/3 (12 million) with advanced airflow obstruction ($FEV_1 < 50\%$ expected value)

Primary Target Population



Recruitment of those with severe acute exacerbations requiring mechanical ventilation for clinical phases II-III

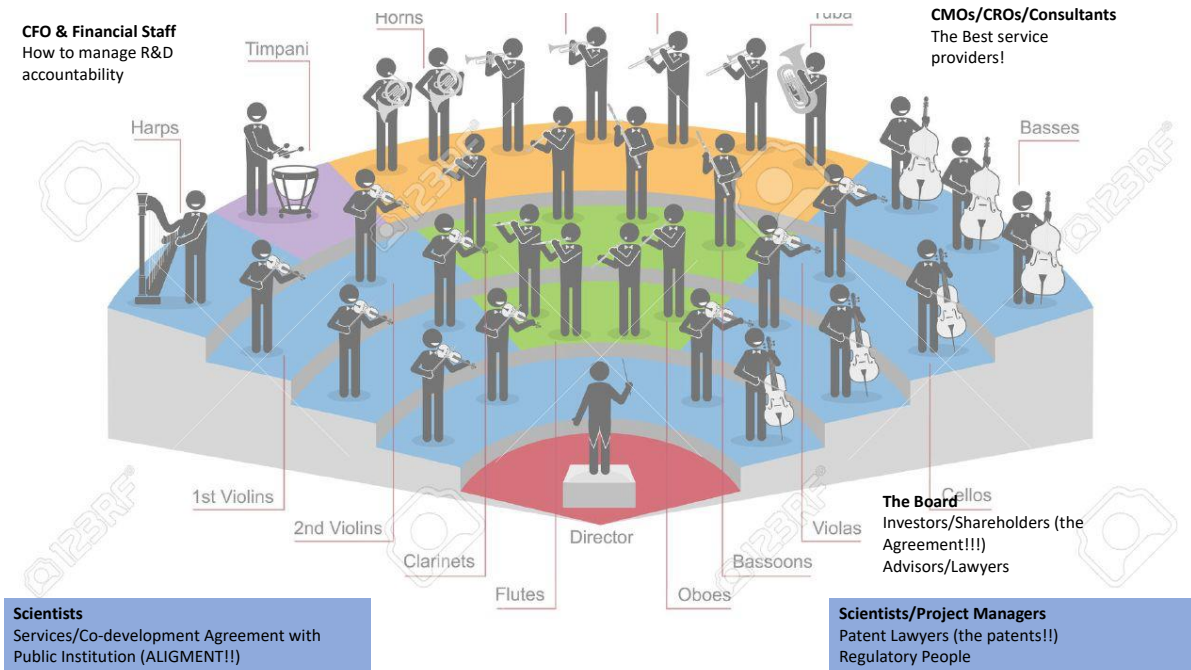
36 million people with COPD in EU and USA

1. Innovative and validated technology for a public health **highly unmet need**
2. Project and Plan **validated** by an international organization with highly qualified experts in the field in the Advisory Board
3. Substantial non-dilutive grant resulting in **highly discounted equity**
4. The **sponsorship** of this organization and current talks with pharmaceutical companies support the potential **exit** and **ROI** of investment

Are you willing to take the journey?

THE CEO

THE CSO



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