

SafeOrthopaedics

Investor Presentation
Biomed Conference
Francfort Midcap Conference

January 2017

www.SafeOrtho.com

# An experienced team



Pierre Dumouchel - CEO and co-founder

### Strong international development experience

- ▶ 11 years within the Spine instruments/implants industry
- ▶ Experienced at managing industrial operations within the automobile industry
- ▶ 2 Master's degree in Management and Advanced Materials Engineering from the *Conservatoire des*Arts et Métiers and Institut Supérieur de Technologie et Management



Thierry Lambert - CFO

### Experience of financial and regulatory issues of listed companies

- ▶ 15 years of experience in finance, CFO of NATUREX
- Certified accountant, MBA from INSEAD



Thomas Droulout - CTO and co-founder

### Recognized technical expertise

- ▶ 15 years of experience in the spinal device industry
- ▶ 10 years of experience in Spine Vision in R&D

### Our mission

## Offer surgeons innovation to:

Secure back surgery with

Single Use

Facilitate the use of minimally invasive surgeries (MIS)

### **Eliminate**

The risk of contamination Loss of time linked to logistics



### Lower

The risk of infection
The risk of complications

Spine surgeries that are safer and less burdensome for patients

## Single Use technology changes the game!

1950 2010



Natural trend towards disposable

(surgical gloves, clothes, cap, gauze swab, surgical drape...)

Now...



**SINGLE USE TECHNOLOGY** 

40,000 patients infected per year<sup>1</sup>



Up to 14% infections<sup>2</sup>



Infections double the Mortality risk<sup>3</sup>



Prolonged Hospital stay<sup>4</sup>



300% costs increase<sup>4</sup>

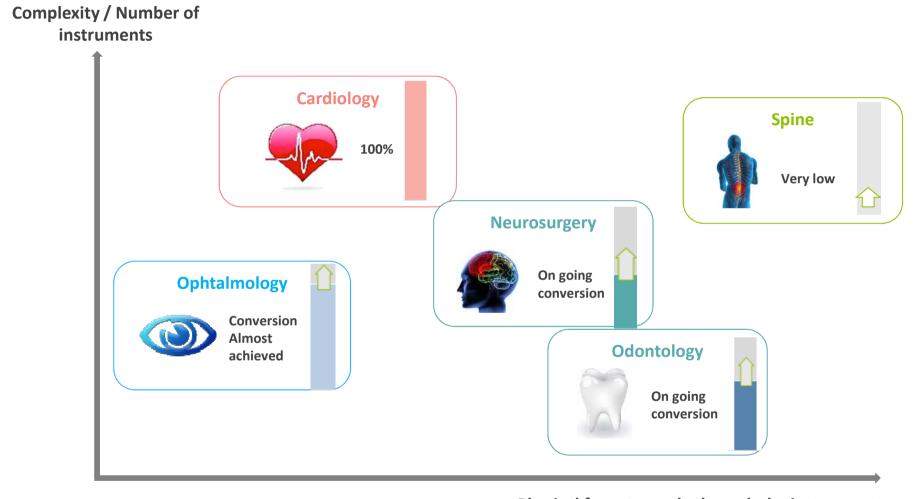
**EASIER SURGICAL PROCEDURE** 

**NO RISK OF CONTAMINATION LESS RISK OF INFECTION** 

**COST SAVINGS** 

Sources: 1 WHO (World Health Organisation) / 2 Spine (Phila Pa 1976). 2009 Jun 1;34(13):1422-8 / Eur Spine J. 2011 Aug;20 Suppl 3:397-402 / 3 Risk of mortality in 30 days; Guide to the Elimination of Orthopedic Surgical Site Infections: An APIC Guide, 2010 / 4 Two week average; Infect Control Hosp Epidemiol. 2002;23(4):183-189

# Single Use for back surgery: part of an inevitable trend



Physical force to apply through the instruments

Safe Orthopaedics PROVED THAT IT IS POSSIBLE...

<sup>1</sup> Estimation of single use adoption Source: Safe Orthopaedics

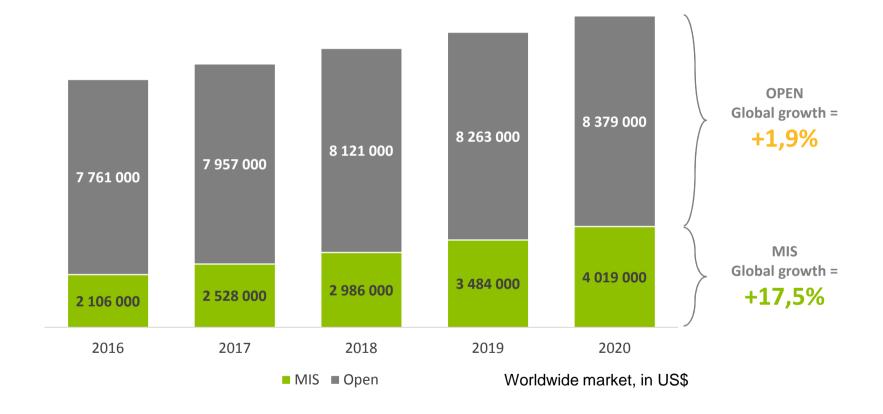
# ...while making easier MIS



# A smart and modular technology to make possible all kind of spine surgeries in one single kit

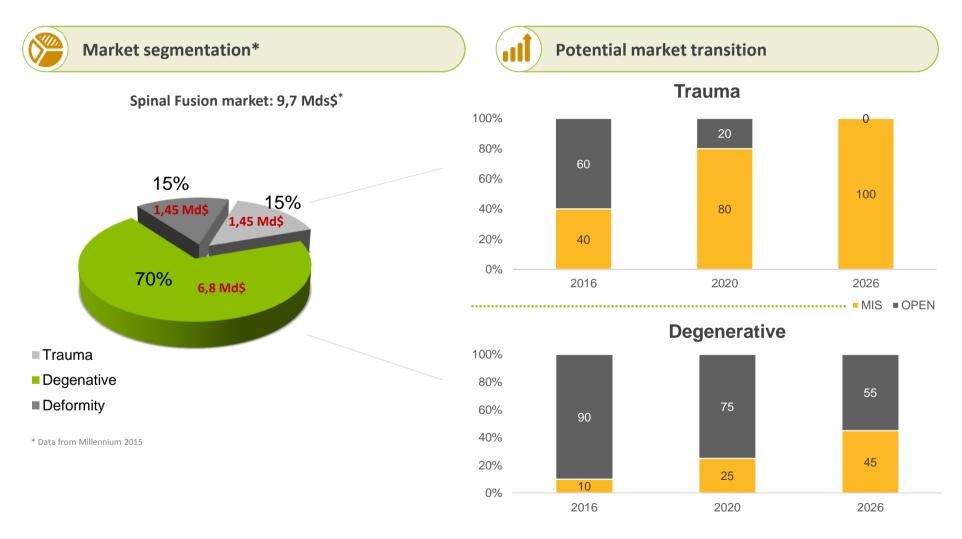
	TRA	UMA	DEGEN	RATIVE
	Open	MIS	Open	MIS
Single Kit for all cases	<b>✓</b>			
Competitor's Product A				
Competitor's Product B		<b>✓</b>		
Competitor's Product C				
Competitor's Product D				

# Trend of Minimally Invasive Surgery (MIS)



Safe Orthopaedics: a key player in the MIS transition

# Potential Market of MIS



Around 50% of the market targeted converted to MIS within 10 years

# Acceptance of MIS: S.O. creates Opportunities (1/2)

1 Availability of MIS technology on hospital shelves

Classic Player

MIS INSTRUMENT = LARGE INVESTMENT

VERY LIMITED for TRAUMA LIMITED for DEGENERATIVE

**Safe Orthopaedics** 



LOW INVESTMENT

AVAILABLE FOR ALL CASES

2 Complex solutions: Numerous sets to perform a single procedure

**Classic Player** 

Between 7 to 20 trays









**Safe Orthopaedics** 



Only 4 boxes



# Acceptance of MIS: S.O. creates Opportunities (2/2)

3 Highly technical procedure

	Classic Player					Safe Orthopaedics	
(Degenerati	ogies = 4 trainings ve OPEN + degenerative MIS + EN + Trauma MIS	LONG	LEARNING CURVE	÷4	SHORT	1 training (1 technology for all)	<b>.</b>
		LONG	LOGISTIC TIME	-80%	VERY SHORT*		
		LONG	OPERATING TIME	-7%	SHORT*		

4 X-ray exposure

### **Classic Player**

### HIGH

Metallic instruments create artefacts and increase number of images



### Safe Orthopaedics

### REDUCED

Radiolucent instruments minimizes exposure to X-Rays



## **Achievements since IPO**

- Successful development of new products (trauma, cervical, fenestrated screw)
- ► Clinical and economic confirmation of Safe Orthopaedics advantages
- Constant growth in France
- ► Launch of new territory outside of Europe (Oceania and South America)
- ► Restructuring of management team:
  - Chairman, Alain Coudray
  - CEO, Pierre Dumouchel
  - CFO, Thierry Lambert

## Lessons learned after 2 years listed

- ▶ Back out of the US market to come back once strongly implemented in Europe:
  - Refocusing on Europe and emerging markets first
- ► Favor direct distribution based on the French model:
  - French model to be replicated in Germany
- Improve our development strategy segment by segment:
  - Prove our superiority in Trauma and in certain sub-segments of degenerative
- Strengthen marketing work towards surgeons:
  - Strengthen scientific recognition of our solutions by surgeons (SAB, Clinical studies, training)

An action plan supported by the new management to accelerate short-term growth

# Full year sales 2016

in thousands of euros	Full-year 2016	Full-year 2015	Change
France	1,182	1,016	+16%
Rest of the world (excluding United States)	1,086	1,055	+3%
Total adjusted* revenue	2,268	2,071	+10%
United States (discontinued operations)	100	454	-78%
Total revenue	2,368	2,525	-6%

<sup>\*</sup>Adjusted for operations in the United States discontinued since March 1, 2016.

- France: continuing growth of +16% despite traditionally modest sales and marketing resources
- ▶ Rest of the world (excluding the United States): revenue growth was fairly sedate during FY 2016 (+3%) impacted by disappointing performance in the third quarter of 2016.

# **Strategy**

SPEED-UP IN EUROPE AND EMERGING MARKETS FOCUS ON TRAUMA AND SUB-SEGMENTS OF DEGENERATIVE STRENGTHEN MARKETING WORK TOWARDS SURGEONS REPLICATE FRANCE SUCCESSES IN GERMANY



# Speed-up in Europe and Emerging markets





# Open new territories beyond Europe



### Worldwide opportunities in Emerging countries...

- Less-intensive competition with players who typically offer older-generation instrument sets
- Favorable demographic (growing and ageing population) and macro-economic trends (growing middle-classes)
- ▶ Products particularly well-suited for emerging countries and sales through distributors:
  - High proportion of trauma surgeries
  - Strong issue with the availability of instrument sets for many surgeons and hospitals (sterilization and logistical issues)
  - Quest for efficiency with OR schedules very packed
  - Low WCR for distributors



### ... with potential short-term achievements

	Short-term opportunities	Middle-term opportunities	Other opportunities	
•	Chile (4M\$): Sales ramp-up with first surgeries started in June	Russia: high-potential distributor in registration phase	▶ Japan, Brazil, China (+2B\$)	
•	Mexico (33M\$): registration in process	Taiwan (15M\$)		
•	South Africa, Greece, Israël			

# Focus on trauma and certain sub-segments of degenerative

	TRAUMA	DEGENERATIVE
Minimally invasive surgery (MIS)		
Open surgery		Non-priority segment
		Efficient solutions to treat thoracolumbar and cervical degenerative pathologies
Smart solution	Always available to deal with emergencies  OAK: Unique screw to straighten and fix vertebral thoracolumbar fractures in one step by percutaneous approach	Cemented screw* for ageing, osteoporotic or metastasis patients  (*Pre-assembled instrumentation avoids the risk of leakage of the cement and facilitates the injection by passing
		directly through the disposable screwdriver)

## Tangible arguments to quickly ramp up the uptake of surgeons

Short term: capitalize on Safe Orthopaedics strenghtsLong term: expand opportunities to degenerative segments

# **Strengthen Marketing Work Towards Surgeons**

- ▶ Ongoing recruitment of a marketing manager to complete the current team of 2 product specialists
- Strengthening the scientific notoriety of SO with surgeons:
  - Establishment of a SAB consisting of 4 European KOLs
  - Enhanced presence at EuroSpine, SFCR, DWG with interventions by surgeons
  - Initiation of clinical and medico-economic studies:
    - Oak: Higher clinical outcome for fracture type A compared to other screws
    - Infection: Reduced infection rate for metastasis patient
- Accelerating the number of training sessions:
  - Cadaver lab per month: x2 versus 2016 in France, Germany and Spain
- ► Redesigning communication tools
  - New website, brochures, products names

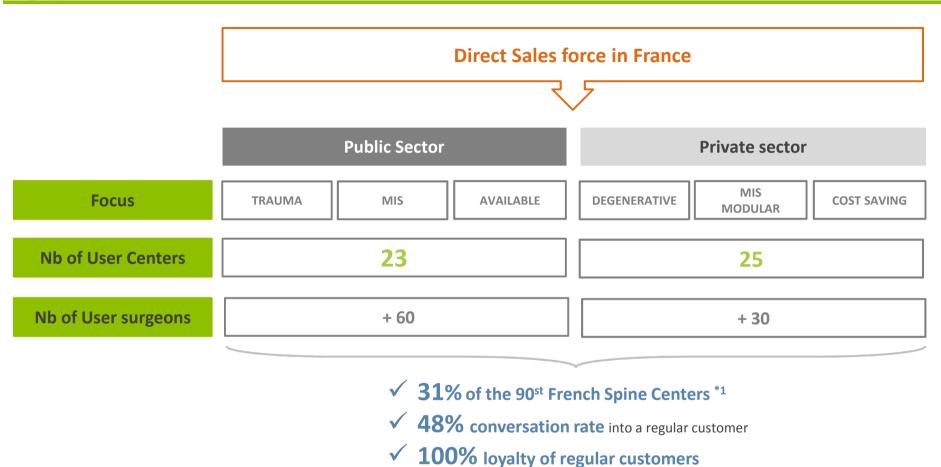
Strengthenting of surgeon support to ramp up SO product uptake





# Replicate France successes in Germany





An excellent conversion and loyalty rates / An average use rate progressing strongly

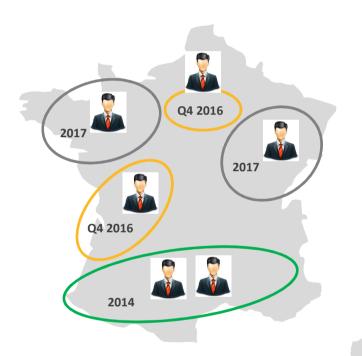
<sup>\*1</sup> Source: LePoint: List of the Top50 public hospital & Top40 Private Hospital



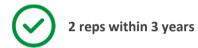
# A gradual ramp-up that will be further accentuated with the strengthening of sales teams







### **CURRENT PERFORMANCES**



3,5% of French addressable market

### PURSUE DEVELOPMENT STRATEGY IN FRANCE



**Penetrate** new centers & Recruit new surgeons

**Continue** to improve conversion rate

**Increase** the average usage rate



Leveraging to go further

France: a model to replicate in Germany

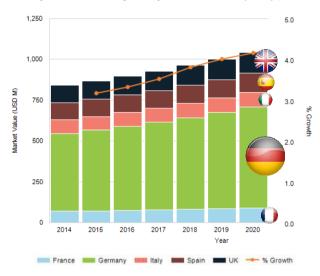


# Germany: the most important and growing market in Europe



### First market in Europe...

### Spinal Implant Market by European Countries (USD) / 2014-2020



- Spinal implant: 443 M€ in 2015¹
- ► First market in Europe Vs. France at 64,7 M€¹
- ► The strongest growth potential: CAGR 2014-24 expected at +4,7%



### ... with lucrative specificities

	France	Germany
Market size	64 M€¹	443,1 M€¹
Number of centers	2,700 <sup>1</sup>	3,300 <sup>1</sup>
Spine Trauma Centers	100	600
Spine University Hospitals	32	36

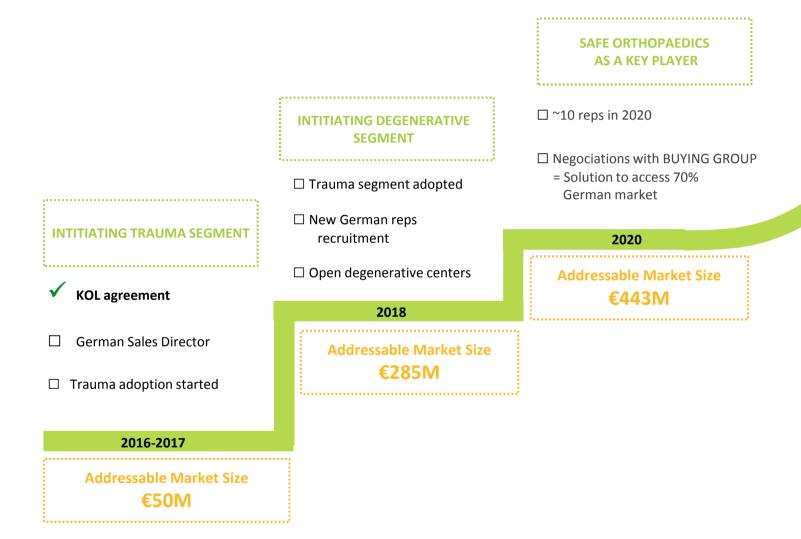
### **Germany priority targets:**

- Trauma Centers
- University Hospitals



# A realistic and synchronized action plan





**Strong penetration of German market in 2020** 



# **Appendix**









# A game changer to push the inevitable market trends towards Single Use & MIS



# Our Technology: Modular instruments with Innovative Implants

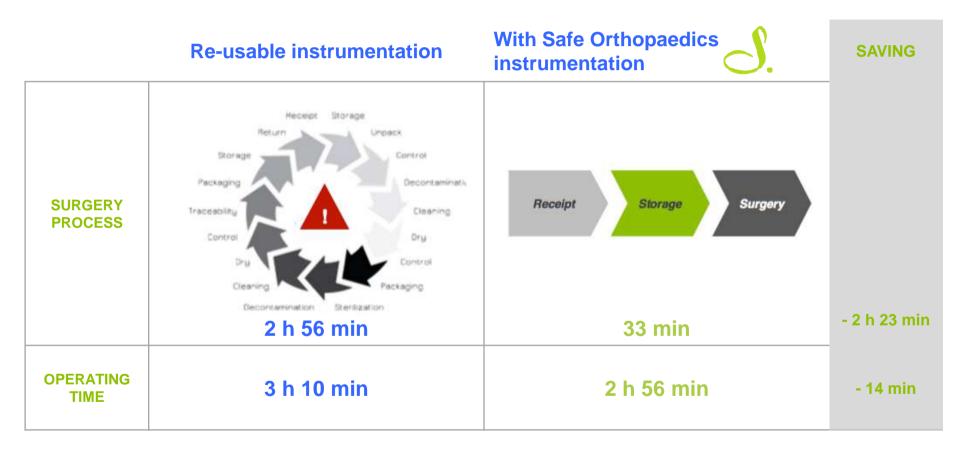
	Mod	<b>ular</b> Instruments	Implant
<u>Trauma</u> <u>Lumbar</u>	SteriSpine PS  Mini Invasive & Open	SteriSpine PS SteriSpine Sterior Steri	Oak.  "Percutaneous Correction screw"
<u>Degenerative</u>	Surgeries Used with all screws	Control Contro	Cypress.  "Modular Anchorage screw"
<u>Lumbar</u>	SteriSpine LC	SteriSpine LC  SteriSpine LC  SteriSpine LC	
	Used with all cages		Sedar.  "Modular Position Cage"
<u>Cervical</u>	SteriSpine CC	SteriSpine CC	"Modular fixation cage" (when ceramic and plate will be available)



### **Evident benefits**



## **Study performed in CHU Bicêtre:**



### TIME SAVING = COST SAVING



# A highly protected technology



### **Patents**

### Smart technical solutions

### An international patents policy

United States, Europe, Japan, China, South Africa, Australia, Brasil, Russia, etc.

### 17 patents families:

- Implant-instruments pairing
- Instruments design
- Tracability / Logistics
- Implants

# Very performing bender



- Fonctionality and efficiency are adapted to different surgical techniques
- Finished product with a competitive price

# One unique handle... Instead of 5!



the number of instruments to benefit from significant volume effects.

## **Our innovation is highly protected = Company value**



# Scientific Advisory Board - Q4 2016



Pr Le Huec, France. Oral agreement



Dr Van Gaalen, Netherland. Oral agreement



Dr Faundez, Switzerland. Oral agreement



Dr Franke, Germany. Agreement pending

### **SAB MISSIONS:**

- Identify and assess the spine MIS trends
- 2. Define the SO strategic technical plan
- 3. Define the SO study program

### **FUNCTIONING:**

- 3 meetings per year
- 1st meeting around Eurospine (Oct 2016)



### **Board of directors**

Dr. Alain Coudray Executive Chairman of the Board for Safe Orthopaedics, SAS



**Dr. Alain Coudray**, is an international veteran of the Medical device industry with more than 20 years of experience. In Medtronic he has held various positions of responsibilities since June 2006, to become in 2014 the Vice President of Global Corporate Clinical Affairs. Before this assignment, he was European Vice President of the Cardiac Rhythm Disease Management business unit. Before joining Medtronic, Alain held the position of Vice President Central and Eastern Europe & Distributors for Guidant, based in Vienna (Austria). Alain is an active participant on the advisory board of MD Start, a MedTech incubator based in Paris, and was a Board Member of EUCOMED (European Medical Devices Industry association). Alain received his medical degree from Grenoble University, graduated from HEC Paris MBA and completed a Business executive program at Kellogg's.

Pierre Dumouchel Founder and CEO



Pierre Dumouchel is the co-founder of Safe Orthopaedics. He has 11 years' experience in spinal medical devices industry. He began his career in the automotive industry, before joining SpineVision in 2005 as Industrialization project leader for the PediGuard. In 2008, he took over responsibility for SpineVision's industrialization department. In 2010, he co-founded Safe Orthopaedics and led the Industrialisation, Operations and Quality/Regulatory Affairs departments. Pierre holds a master's degree in both advanced materials engineering and in management from the Conservatoire des Arts et Métiers and Institut Supérieur de Technologie et Management.

Dominique Petit Founder Scientific advisor



**Dominique Petit** is the founder of Safe Orthopaedics. He started his career at Sofamor, a pioneer in this medical field. He was primarily responsible for the CD Horizon (Legacy) product line, still a largely marketed product by Medtronic these days. He co-founded SpineVision SA (Paris) in 1999, serving the company 10 years as Chief Technical Officer. Having developed more than 30 spine products, Dominique is a veteran spinal device engineer who worked collaboratively with the world's most innovative and respected spine surgeons. He also has been engaged in collaboration with world renowned surgeons.

Michael DeMane Executive



Michael DeMane is Executive Chairman of Nevro, a Silicon Valley based leader in the medical device field. Michael led the company as Chief Executive Officer from March 2011 until June, 2016, from scrappy start-up with negligible revenue to a leading global player in the spinal cord stimulation market. An engineer by training, Mr. DeMane has established a consistent record of strategic and operational success leading large and mid-size global medtech organizations. Over the past 35 years, he has held executive leadership roles in the US, Europe and Australasia. Prior to Nevro, Michael held a variety of positions at Medtronic, Inc., Michael has served as a senior advisor to Thomas McNerney & Partners, and Oak Hill Capital and serves on several Boards of Directors including: Cardionomic,Rotation Medical. Safe Orthopaedics Mr. DeMane has completed the Advanced Management Program at INSEAD in Fontainebleau, France and holds an M.S. in Bioengineering from Clemson University and a B.S in Chemistry from St. Lawrence University in Canton, New York.

Fred Goad Co-founder and current partner of Voyent Partners, LLC



Fred Goad is a co-founder and current partner of Voyent Partners, LLC, a private investment firm focused on early stage investments across a variety of sectors including healthcare.

Mr. Goad served as President and Chief Executive Officer of ENVOY Corporation (1985 - 1996), a leading provider of electronic data interchange services, and as Co-Chief Executive Officer and Chairman of ENVOY Corporation from June 1996 until March 1999 after the company was acquired by Quintiles Transnational Corporation.

From March 1999 through May 2000, Mr. Goad served as a member of the board of directors of Quintiles (1999 – 2000). Mr. Goad's career also includes positions with UCCEL Corporation, Financial Institution Services, Inc. (now CompuCard International), Docutel (now Olivetti USA), and IBM Corporation. Mr. Goad currently serves on the Board of Directors of a number of companies including Luminex Corporation.

Mr. Goad holds a Bachelor of Science degree from the University of Virginia.

Vanessa Malier Associate Director of Kurma Partners



Vanessa Malier joined Kurma Partners in September 2013 after 15 years working in the biotechnology and pharmacy markets. She started her career in venture capital in 1998 as an analyst at CDC Innovation. In 2003, she joined Ipsen as Strategic Advisor of the CEO. She then advanced on various positions in the company.

Mrs Malier is graduated in Biology from the Ecole Normale Supérieure in Cachan, and in Immunology from the Institut Pasteur. Kurma Partners is shareholder of the company since 2010.

Marie Landel, Founder of Marie Landel & Associates



Marie Landel is a certified accountant who has been based in Boston since 1990, with extensive experience in helping French and European medtech companies in the United States, where she has large networks in financial and healthcare circles.



In €K	31/12/2014	31/12/2015	30/06/2015 6 months	30/06/2016 6 months
Revenues	2,053	2,498	1,307	1,303
Purchases net of stock variations	(1,640)	(2,057)	(894)	(982)
External expenses Staff expenses Others	(2,221) (3,048) (710)	(2,682) (3,903) (1,074)	(1,141) (1,983) (308)	(1,362) (2,010) (361)
	,			
Operating result	(5,566)	(7,218)	(3,019)	(3,412)
Financial result	630	657	292	(158)
Net result	(4,936)	(6,566)	(2,727)	(3,559)

# **Balance Sheet**

In €K	30/06/2016	31/12/2015	In €K	30/06/2016	31/12/2015
NON-CURRENT ASSETS			EQUITY		
			Capital	1,413	1,374
Intangible assets	387	483	Share premium	23,688	23,036
Tangible assets	746	837	Reserves	(548)	(967)
			Other consolidated reserves	(18,274)	(11,785)
Other financial assets	45	44	Profit/Loss	(3,559)	(6,566)
TOTAL NON-CURRENT ASSETS	1,177	1,363	TOTAL EQUITY	2,720	5,092
			NON-CURRENT LIABILITIES		
CURRENT ASSETS	2 000	1.057	Long-term loans and financial liabilities	4,468	3,138
Inventories	2,089	1,957	Non-current deferred tax liabilities		
Receivables	765	546	Non-current deferred tax naplifities	-	-
	260	271	Non-current provisions	228	229
Other current assets	260	271	TOTAL NON-CURRENT LIABILITIES	4,696	3,367
Current tax asset	513	400	CURRENT LIABILITIES		
Cash and cash equivalents	4,315	5,918	Long-term loans and financial liabilities	264	289
			Payables	856	919
			Other current liabilities	583	789
TOTAL CURRENT ASSETS	7,942	9,093	TOTAL CURRENT LIABILITIES	1,703	1,998
TOTAL ASSETS	9,119	10,457	TOTAL LIABILITIES	9,119	10,457



## Stock market information

# Stock market information (at January 11, 2016)

FR0012452746
Euronext Paris
€ 1.30
€ 2.98
€ 1.14
14.5 million
17.7 M€



### Shareholders (at December 31, 2016)

