Managing innovative Biotech corporations and creating start ups

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Agenda
Main topics of today

1. Desired Deliverables
2. You have an idea!
3. The business plan
4. Considering support!
5. Create the activity
6. Ramp-up plan
7. Managing risks
8. Case Study
9. Lessons learnt
1. Deliverables

*What do WE expect from this session of the Crash Course*

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**Why are you here today?** (take a note ....)

---

**No explanation of the tools**

*How to steer the process*

*Share experience*

*Indicate some traps*

*Encourage you to move ... and convert you to MTB*
1. Deliverables

*What do WE expect from this session of the Crash Course*
2. You have an idea!

Your idea and the environment

Articulate your vision/concept, write it down, think about who will benefit, how may it create sustainable value.
Keep it simple to get a first feeling

Attractiveness of Vision  Sanity check  Ability to Execute

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<td></td>
<td>Ability to Execute</td>
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Business Case Scorecard
© simplicable.com
3. The business plan

How to proceed?

The «Plan»

Challenge and get challenged!
Idea & Plan

Get help!

Help!
3. The business plan

*Why help is needed?*

**Your Dreamspace**

Help small children with diabetes to live a good life

**Your Idea & Concept:**
Put a nano insulin pumping concept in a wearable RC - no tube Med Device
3. The business plan

Why help is needed?

Being a highly qualified engineer/specialist you are able to realize this concept technically

IP & Legal?
Operations?
Regulatory?
Financing?
Negotiation & Managing?
Communication?

Plan for help early, ideally as starting to develop the business plan
3. Make a proper business plan

Standard elements to consider for your business plan

- Executive Summary
- Mission Statement
- Company Background
- Product Description
- Marketing Plan
- SWOT Analysis
- Competitor Analysis
- Operations
- Financial planning
- Timeline
- Selling skills
- Sense of reality
- Ability to anticipate
- Credibility
3. Make a proper business plan
*Sanity check – again!*

---

Attractiveness of Vision  
Ability to Execute

---

Balanced scorecards to evaluate  
Mentor & Challenger

---

Target group(s) for the plan
4. Considering support!

*How to <sell> the business plan*

**Target audience**
- Investors
  (Seed/Angels/Banks/Shareholders/Funds/VC)
- Organizations / NGOs / etc
- Partners
- Customers

**Personal presentation**

**Pitch the Business Plan**
4. Considering support!

*Selling the Idea - the first seconds to success*

- 500 mio persons suffer from serious back pain
- The spine market is worth € 20 billion
- Med Tech Industry & HCP have not yet solved the problem

![CSS kinematic solution vertaplant](image)
5. Considering support!

_Selling the Idea - the first seconds to success_

500 mio persons / market € 20 billion

x years to market

y years to break even

€zz mio EBIT in year 5
4. Considering support!

*Selling the Idea - the first seconds to success*

500 mio persons / market € 20 billion

Ready to market: x yrs / BE: y yrs / EBIT yr 5: €zz mio

*spontech*

spine intelligence

invites to share the success
4. Considering support!

_Selling the Idea - the first seconds to success_

Old but good ...

**AIDA** initially presented in 1898 by Elias St. Elmo Lewis

*(same year as *<Quattro pezzi sacri>* from Giuseppe Verdi)*
5. Create the activity!

*What is the appropriate form to <materialize> the activity*

Own legal entity
Organized start-up programmes /Tech parks
Co-operation (add / in)

... get help
### 6. Looking into details

**The Ramp-Up plan**

Once the frame Business Plan is done, the detail preparation starts. This takes time and many modifications as going ahead. This tool is flexible – challenge it and get challenged.

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7. Managing risks

Alternatives and fall-back position

- Accept that risks do exist or will appear
- Define the known risks
- Likelihood
- Severity of impact
- Outline CAPA
- Plan for reserves
7. Managing risks

Alternatives and fall-back position

Foresee CAPAs for the individual risk classes
7. Managing risks

*Alternatives and fall-back position*

Foresee CAPAs for the individual risk classes

- Alternate strategy
- Product/concept modifications
- Revised timelines
- Revised financials
- Partnerships
- Revised IP strategy
- Exit strategy
8. The case «Spontech Spine Intelligence AG»

Focus on:
1. Selling the idea
2. Strategic CAPA
8. The case
The technical and the business model in a nutshell

Now the phase Incubation & Phase 1

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8. The case
The technical and the business model in a nutshell

Now the phase Incubation & Phase 1
Mission and Medical Business Model

The Issue:

Each person has their own personal motion profile and his or her own individual coordination between head, shoulders and pelvis. The individual spine is formed by this unique motion profile.

As the individual matures, the human spine is adapting exactly to these movement pattern and therefore it becomes virtually unique to that single person.

It is a multi functional very complex joint organ which needs to be understood as a chain of joints depending on each other.

Today's surgical spine therapies in Degenerative Disease do not or only marginally allow to individualize the required treatment.
Mission and Medical Business Model

The Challenge:

Spine surgery needs to use effectively a systematic approach ranging from advanced diagnostics over standardized planning and calculating using software modules, specialized instruments and a wide range of intelligent implants in order to provide individualized solutions to spine problems.

This is the novel approach to individualized surgical spine therapy

Therefore was founded in 2008!

spontech spine intelligence AG has set itself the goal of enabling people suffering from spinal conditions and diseases directly into the development of our products
Mission and Medical Business Model
The Innovation:

Closely cooperating with our near-by partner Galenus Clinic, spontech AG is translating their extensive accumulated diagnostic and clinic expertise into integrated and comprehensive product- and process innovations.

spontech: Innovation to revolution
With the revolutionary CSS system we have developed a new systemic approach for the best possible patient-specific treatment of the spine. The CSS comprises the diagnostic procedure, implants, special instrumentation and software for calculating to the exact degree and millimeter the precise adjustment of the spine geometry, software which to this date is xxxxxxxxx.

All systems are developed and manufactured in Germany with highest quality standards.
Mission and Medical Business Model

The components of CSS (Vertaplan)

- Advanced software
- Modular implant system
- Components of the CSS
- Intra-surgery measurement tool
- Specific support tools
The *spontech* CSS Surgery:
Step 1: Software for Diagnose & Plan

Run CSS Software

Diagnose Images

Plan Surgery

More …
The sponotech CSS Surgery:
Step 2: Surgery

The Surgery Process is Computer supported

The Implant has unique features

Specific Tools allow for unseen precision

April, 2011
The spontech CSS Surgery:
Step 3: Result

The CSS PLIF Implants are placed with perfect precision and rest exactly where they should:

*On both sides of the cortical ring.*

This helps to avoid one of the historical problems of Lumbar Interbody Fusion:
The sintering-in of the spacer/implant.
spontech spine intelligence

What makes spontech unique?
Patents and Innovations

Wide scale of patents and applications by numbers

· 18

Wide scale of patents by coverage

· Cages and fixation systems,
· Instruments and surgical tools,
· Non fusion technology – prothesis,
· Diagnostic and planning software.

Wide scale of patents by prospected sales

· On the basis of past spine innovations sales by exploiting the patent pipeline should easily reach an amount of US$ 1 bn.

Wide scale of patents by future innovations

· All future innovations of Dr. Copf in the area of spine technologies are to be transferred to spontech spine group AG free of charge.

Big Medtech firms are already infringing the patent rights...
Management and Board

Experienced Management Board with international background

- Thomas F, CEO (3M, Medtronic) DE, AT, CH
- Peter Georg Haag, Fin & M&S (Roche, Abbott) CH, RSA, CZ, SK, IT, LUX
- Dr. Thomas P, R&D (CeramTech) DE, FR, CH
- Dr. med. Roland S MD M.Sc., QA/RA (University of Hamburg) DE, CH

Highly reputed Medical Advisory Board

- Dr. Dr. med. Franz C
- Prof. Dr. med. Claus C
- Prof. Dr. med. Hans-Joachim W
- Prof. Dr. med. Kai S
- Pr. Doz. Dr. med. M. R

Experienced and connected Strategic Consultants

- Prof. Erich S: R&D Software & Corp. Communications
- Dipl.-Ing. Gerhard K: Strategy (HP, Fresenius, Medtronic)
- Dr. Gerhard P: R&D Hardware (Philips)
- Dr. R, IP&Patents (Fed. Patent Office)
spontech spine intelligence

The Market Overview

April, 2011
The World Spine Market is attractive

The global recession has slowed down the continuous growth of the spine market only for approx 2 years.

More ...
spontech spine intelligence
Financial and Business Case
Planned Market Shares (Fusion and Non-Fusion)

The Share is calculated ex Distributors + direct sales in the referenced markets Fusion and Non-Fusion Medical Devices

More …
Imagine…

In 20xx, the current Business Plan goes for % Market Share in Non Fusion (artificial discs and other devices to keep mobility)

....that means 1 out of 27 patients with a Non-Fusion Spine Surgery will benefit from the CSS Spine System ..... 

Imagine we convince 1 out of 10 patients .......
8. Case 1
Get help but keep control

- Medical Advisory Board
- Communication Specialist
- Senior Mentor
- IP
- UNI Tuebingen
- Scientific societies
- UNI Wuerzburg
- Media spec
- HW designer
- UNI Heidelberg
- Accounting Specialist
- Camber of Commerce
- Consulates
- Galeazzi MI
- Humanitas MI
spontech spine intelligence
Market Entry
spontech Growth Phases

- Incubation Phase
  - before 2008
- Development
  - 2008, 2009
- External Trial OP’s at Reference Centres
  - 2010
- First OP
  - Q1
- External Software Useability Trial
- Final CSS System Configuration and CE Mark
  - Q2
- Q3
- Q4
  - Q4
  - Ramp-Up in direct distribution markets D A CH
  - Q4
  - Commercial expansion & International
  - 2011
  - 2012
  - 2013
  - 2014

Public Presentation LAUNCH
8. The case
«Spontech Spine Intelligence AG»

Vision > Sanity Check with professionals
Business Plan Abstract
Round 1 Seed Investment – Innovator+ Bank

Set-up founding Team
Business Plan + Ramp up plan started, 0 series
Selling Concept for Round 2 - Get professional help
Round 2 mid Investment – Regional funds + Angel Investors

Registration of Vertaplan software – full portfolio + OP sets
Create Awareness – leverage awareness
Round 3 big Investment – Private investors / selling equity
First 0 series successful surgery:

The implanted devices are perfectly positioned as previously planned.
8. The case

Use the communication lever to consolidate and multiply interest

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8. The case
«Spontech Spine Intelligence AG»

Phase 3: Become visible + Creating sound interest for the concept
8. The case
«Spontech Spine Intelligence AG»

.... unforeseen Issues comes to our attention:

Cash Burn Rate > CBR by far.

1. Fortunately we had proper accounting
2. Soon we found out it went into CAPEX, not into OR

Quarterly P&L worsent. Reason Increasing depreciation

You remember the complex tools? (OPS-SETS)
Specific Instruments and Tools
Intelligent Inserter device

Controlled insertion of the cage. Measured against dorsal edge of the vertebrae (equals 0 on the scale)
Specific Instruments and Tools
Intelligent Inserter for exact positioning

On the side of the PLIF-cage inserter there is a scale which is used to determine precisely how far the implant has been inserted into the disc space.

The benefits:

• controlled insertion and fixation of the implant
• accurate and very secure positioning for fine adjustment of the spine
• hence minimization of X-ray radiation exposure
Specific Instruments and Tools
Smooth distraction device

- Distractors
- Distractor shafts
- Implantation shaft
- Hammer
- Inserter
- Drill
8. Case 1

Symptoms of an issue

K€ 50-60 / OPS SET
8. Case 1

Addressing the issue

RCA

Symptoms:

- unplanned business critical increase in CAPEX

Problem: TAT

Cause: Actual > Assumption

Assumption 1,5d = approx 18 Ops/month

Actual 2 weeks = approx 2 Ops/month

Consequence:

- Fixed assets up - ROI down
- Liquidity down
- Investment attractiveness down
8. Case 1

Corrective Actions

TAT: Change from resident ops-set concept to travelling ops-set concept

Ops-Set: Significant cost reduction

Products: Anticipate an innovative TLIF concept
Lower costs, Ops-Set more economic.
Higher volumes in the market.

Legal form: Change from SpA/AG to Srl/GmbH

Focus: Key countries & key customers
8. The case

*Where is the start-up now?*
8. The case

Where is the start-up now?
9. Lessons learnt

*Don’t trust the shining stars*

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Forbes

**QUOTE OF THE DAY**

"The only strategy that is guaranteed to fail is not taking risks."

- Mark Zuckerberg
9. Lessons learnt

Genius and luck may be helpful, .....
9. Lessons learnt

Before starting
• Do your own SWOT on yourself related to your project

Starting
• Plan for help early
• Proper Planning (All aspects)
• Do not fall in love with your plan
• Stay critical but convinced
• Challenge everything, even the Challengers and Mentors
• Look deep into details as you start activity
• Document properly
• Accounting and Finance
Deliverables

Did this presentation give you some additional insight?
Further questions? Let me know. Thank you for the attention