Thursdays 8am, Room AAC 1 32

Lecture #5

Work plan

Aims:

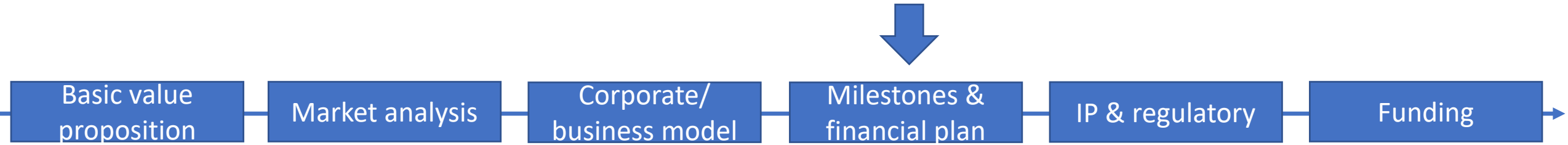
- Define what is happening (R&D, costs, revenue, business development) **until the launch of your startup** and for the **first years operating on the market**

Course content and schedule 2025

Lecture #/Date	Topic	Details	Seminar tasks
1/ 11.09	**General Introduction**	Aims of the course, expectations, tasks and assessments General proceeding	Watch Elisabeth Holmes Documentary (Theranos story)
2/ 18.09	**Roadmap from academic idea to startup**	template business example, Learn about all the steps needed to translate a scientific idea into a startup and what your pitch deck should include => Focus on Value proposition and Business model	Define customer value proposition, USPs and business model (= business example) of Theranos Grouping and assignment of individual presentations
3/ 25.09	**Market analysis**	Market size, competitors, customer models, growth and scalability,	Introduction into (GlobalData), Find market data on your business example & group innovation
4/ 02.10	**Corporate planning**	Business models, exit strategies, website & visibility,	Define business example of your group innovation, define markets and competitors
5/ 9.10	**Business examples**	Business examples 1-4, detailed feedback	
6/ 16.10	**Timelines & initial steps, finance plan**	Business examples 5-8 Milestones and finance plan from idea to startup/product	Prepare milestones and financial plan for your startup idea
23.10 – no lecture!			
7/ 30.10	**Intellectual property and other legal issues**	Business examples 9-12 Patents – facts, data bases, examples Concept of freedom to operate, regulatory hurdles, etc.	Find & analyze patents in your field
8/ 06.11	**Finalizing the pitch deck**	Business examples 13-16 Recap: Detailed analysis of individual case studies, last year's best group pitch and TheraMe pitch	Finalize pitch deck
9/ 13.11	**How to secure funding**	Business examples 17-20 Public funding programs, investments, venture capital, EPFL programs	
11/ 20.11	**Guest speaker Daniel Alpern (Alithea)**	Business examples 21-24 Real-world EPFL startup insight	Prepare Executive Summary and commercial potential in C4Lformat.
12/ 27.11	**Guest speaker Luc Henry (Limula)**	Real-world EPFL startup insight	
13/ 04.12	**Pitches Groups A (e.g. 4-6)** **Feedback Groups B (e.g. 1-3)**	10min pitches with non-presenting students to provide written feedback	Prepare written feedback on other group's pitches
14/ 11.12	**Pitches Groups B (e.g. 1-3)** **Feedback Groups A (e.g. 4-6)**	10min pitches with non-presenting students to provide written feedback	
11.12 at 10:15 am	**Trophy Award & Feedback**		

Timelines and further proceeding of course BIO-490

Today



Idea

Can I sell it?

How do I address customers, what are my costs and how do I generate revenue?

Translate market analysis and corporate planning into projected milestones, timelines & financial figures

Any hurdles before going live?

Let's get the money to start!

How do you get this for your service/product?

Pre-launch
(founding company and developing product)

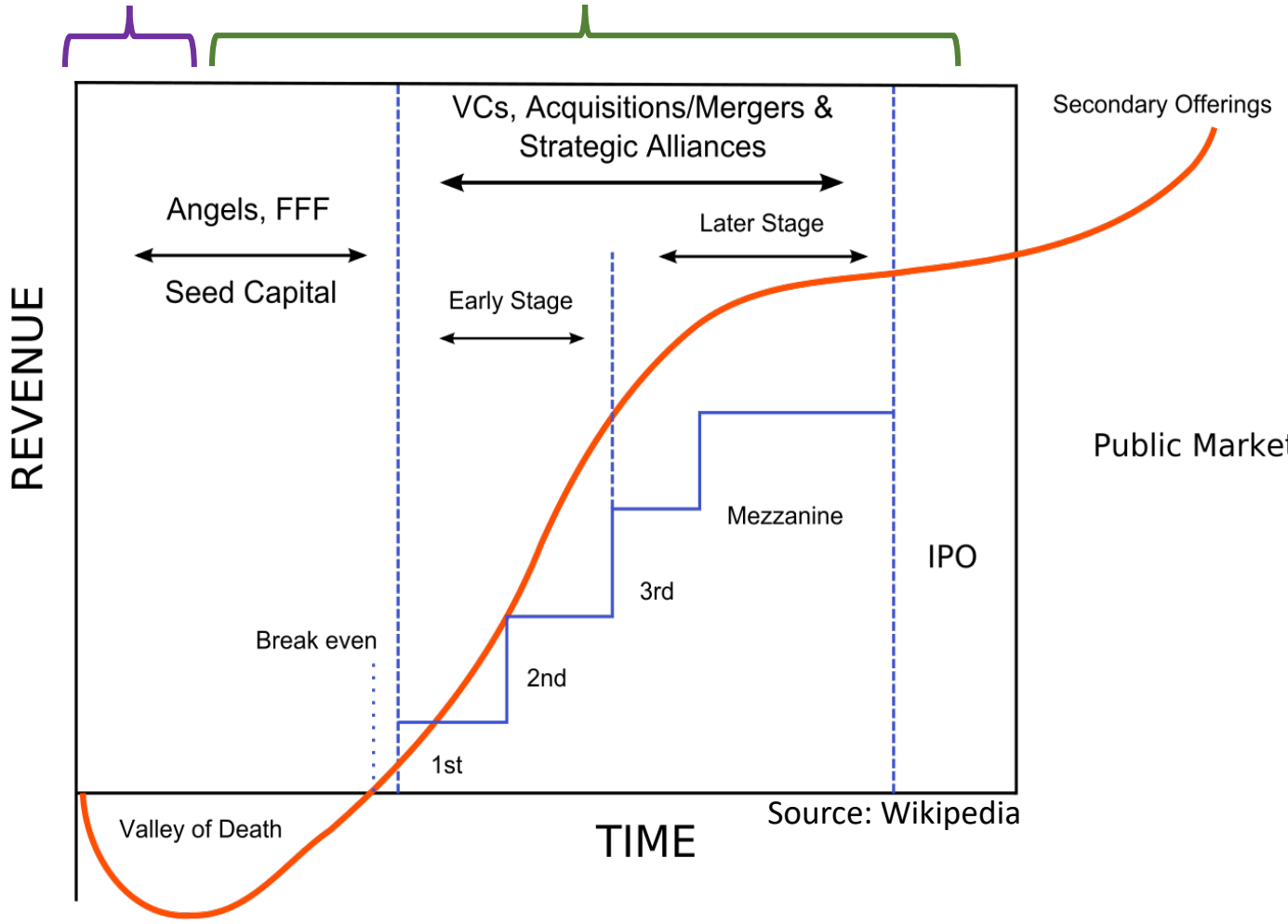
What is my homework for developing a product?

⇩

Finance table

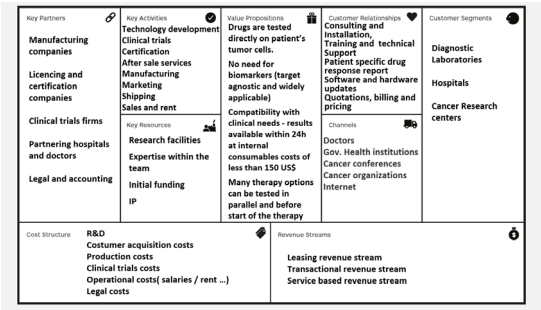
Timeline (years)

cost/budget categories



Public Market

Post-launch
(operating on the market)



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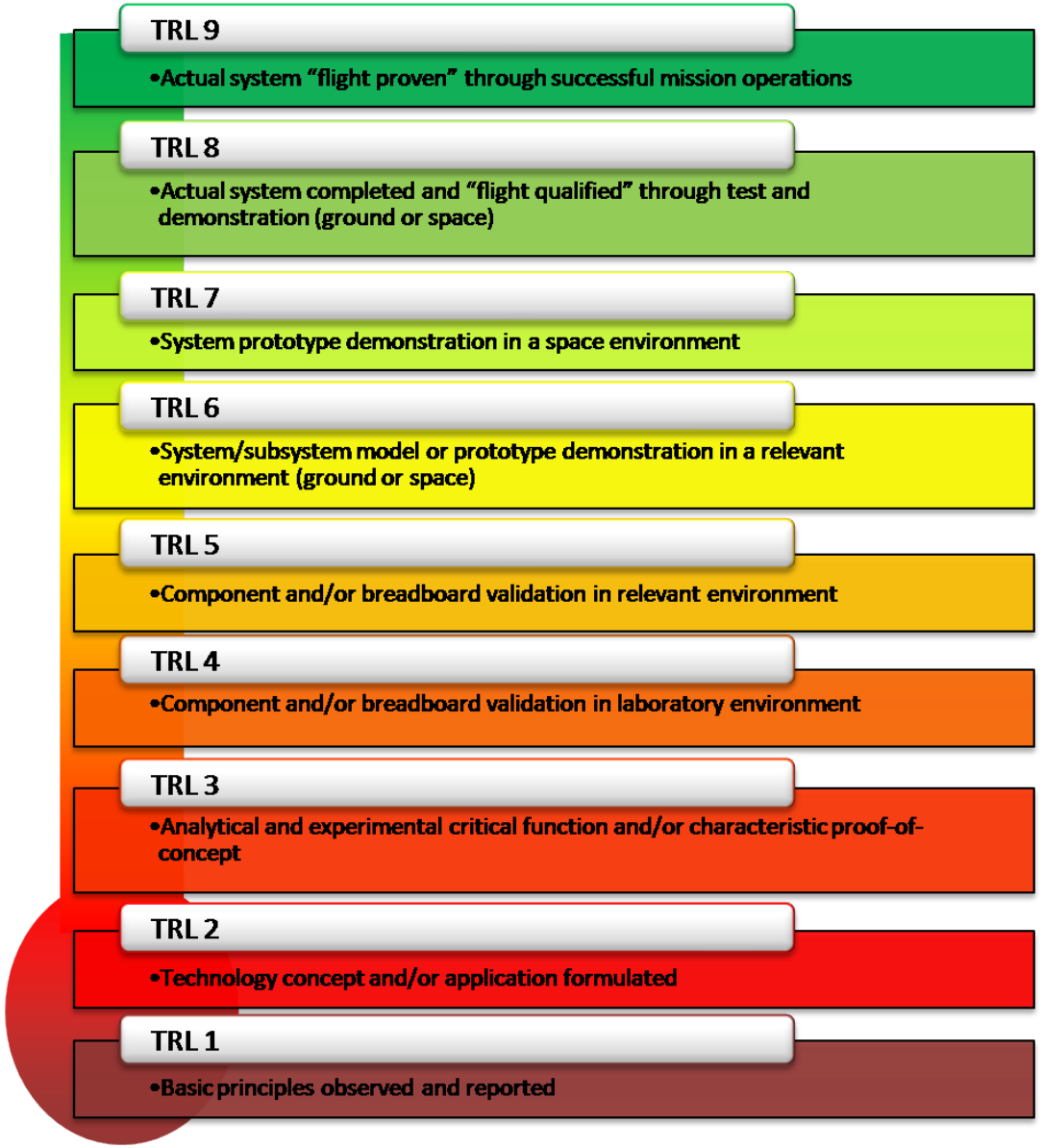
Finance table

Timeline (years)

cost/revenue categories

Pre-launch starting point - Technology readiness level (TRL)

NASA



https://www.nasa.gov/directorates/heo/scan/engineering/technology/technology_readiness_level

EU

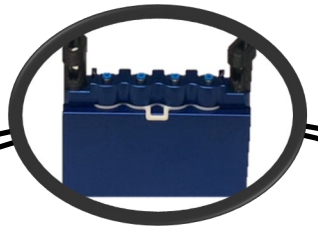
- TRL 9 – Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies)
- TRL 8 – System complete and qualified
- TRL 7 – System prototype demonstration in operational environment
- TRL 6 – Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 5 – Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 4 – Technology validated in lab
- TRL 3 – Experimental proof of concept
- TRL 2 – Technology concept formulated
- TRL 1 – Basic principles observed

https://enspire.science/trl-scale-horizon-europe-erc-explained/

Technology big picture milestones and product planning

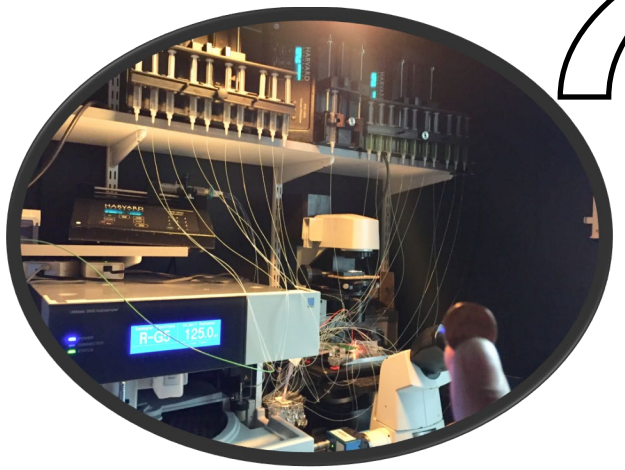
final working principle
Separate, non-integrated,
non-mass manufactured modules

Academic lab/ startup



Academic α-version

External CRO



Academic “monster”

Externally produced
plug & play device

TRL 5/6 (based on successful processing of clinical samples in the lab – only by specialists and NOT in the operational environment)

TRL 7 – System prototype demonstration in operational environment
TRL 8 – System complete and qualified
TRL 9 – Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies)

Syringes have to be filled with drugs manually
Non-integrated “wild” multi-component system
Braille valve that have to be aligned manually

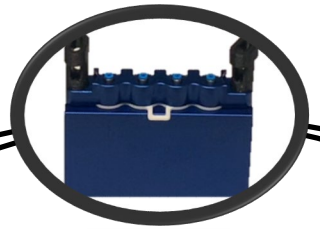
Pre-filled drug reservoirs that can be pressurized
Fully integrated device
Mass manufactured valving system

Technology big picture milestones and product planning

Get quotes and timelines from CROs such as CSEM, TTP, Fusion Bio, Stratec, etc.
500k CHF initial development costs (up to an alpha-prototype) and another 1-2M CHF to translate this into a mass manufacturable solution at a unit price of about 70k CHF – total duration for this about 2 years!

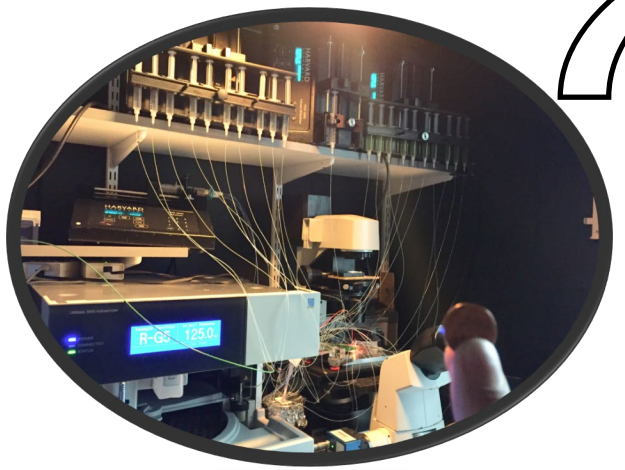
1-2 years, senior engineer + consumables & equipment 200k

Academic lab/ startup



Academic α-version

External CRO



Academic "monster"

Externally produced plug & play device

9 years and almost 3M!

Note: Costs and timelines are usually chronically *UNDER*estimated!

1. Define the most important pre-launch milestones, their timelines and cost

1. Minimum Marketable Product (MMP). The most simple (e.g. small number of features) product that provides a use or service to the customer for which he/she would be willing to pay for. **2.5M CHF, 3 years**

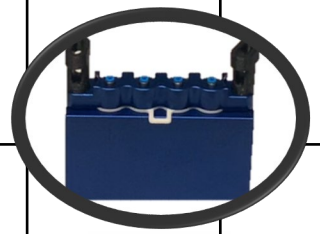
Unfortunately, nobody will buy this unless….

…**2.** some **clinical patient benefit** has been shown
1.5M CHF, 3 years

…**3.** the **device** ultimately gets **certified** (note that this is not required for initial market launch in diagnostic labs)
200K CHF, +1 year

1. Define the most important pre-launch milestones, their timelines and cost

Milstones	Cost	In-house /out-sourced	2021	2022	2023	2024	2025	2026
Industry prototype	2.5M	Mixed: involving external CROs						
Clinical performance study	1.5M	Outsourced: Clinical network & Veranex						
Iso & CE certification	200K	Outsourced: Veranex						

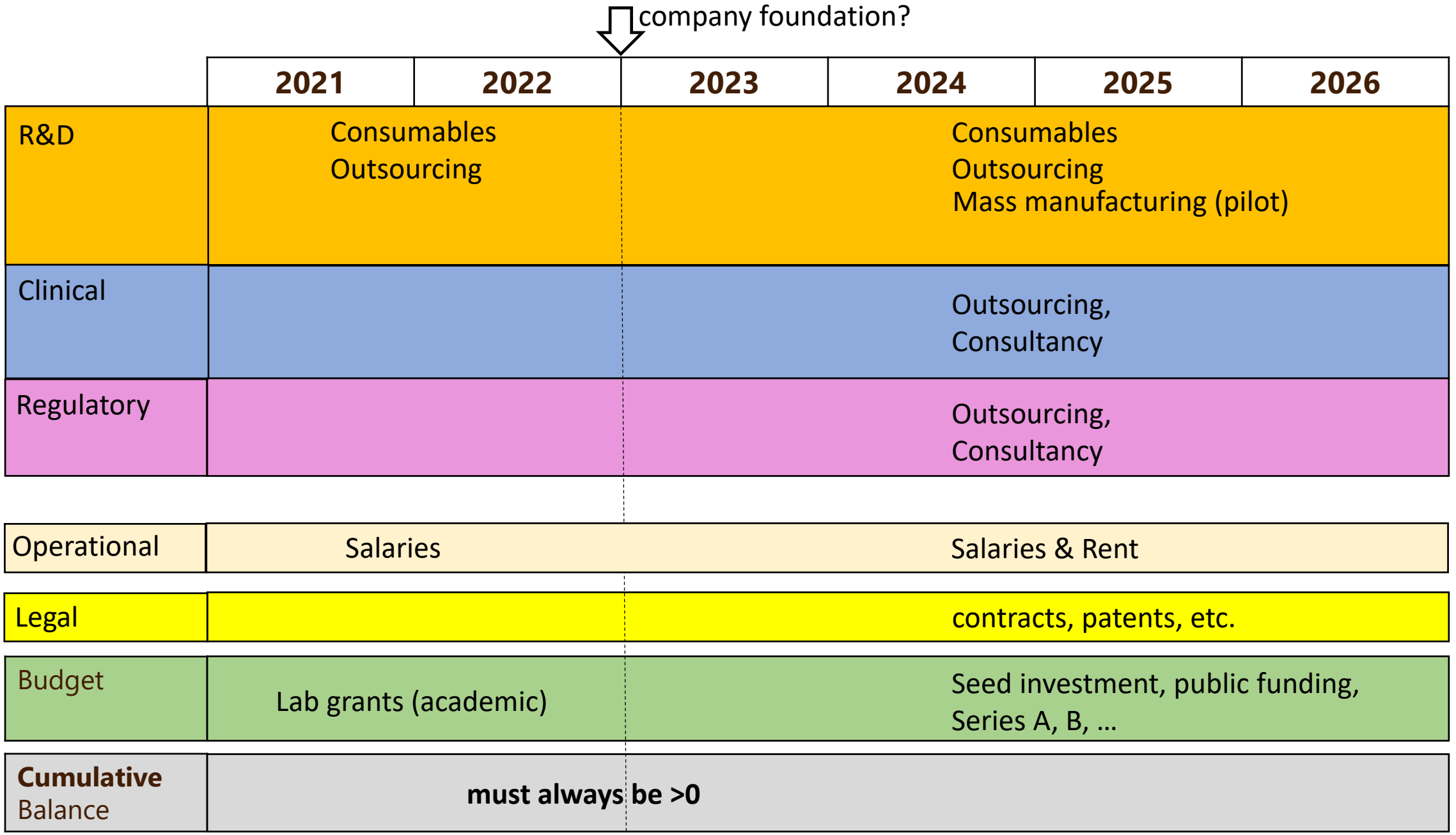


(inhouse)

(external)

company foundation?

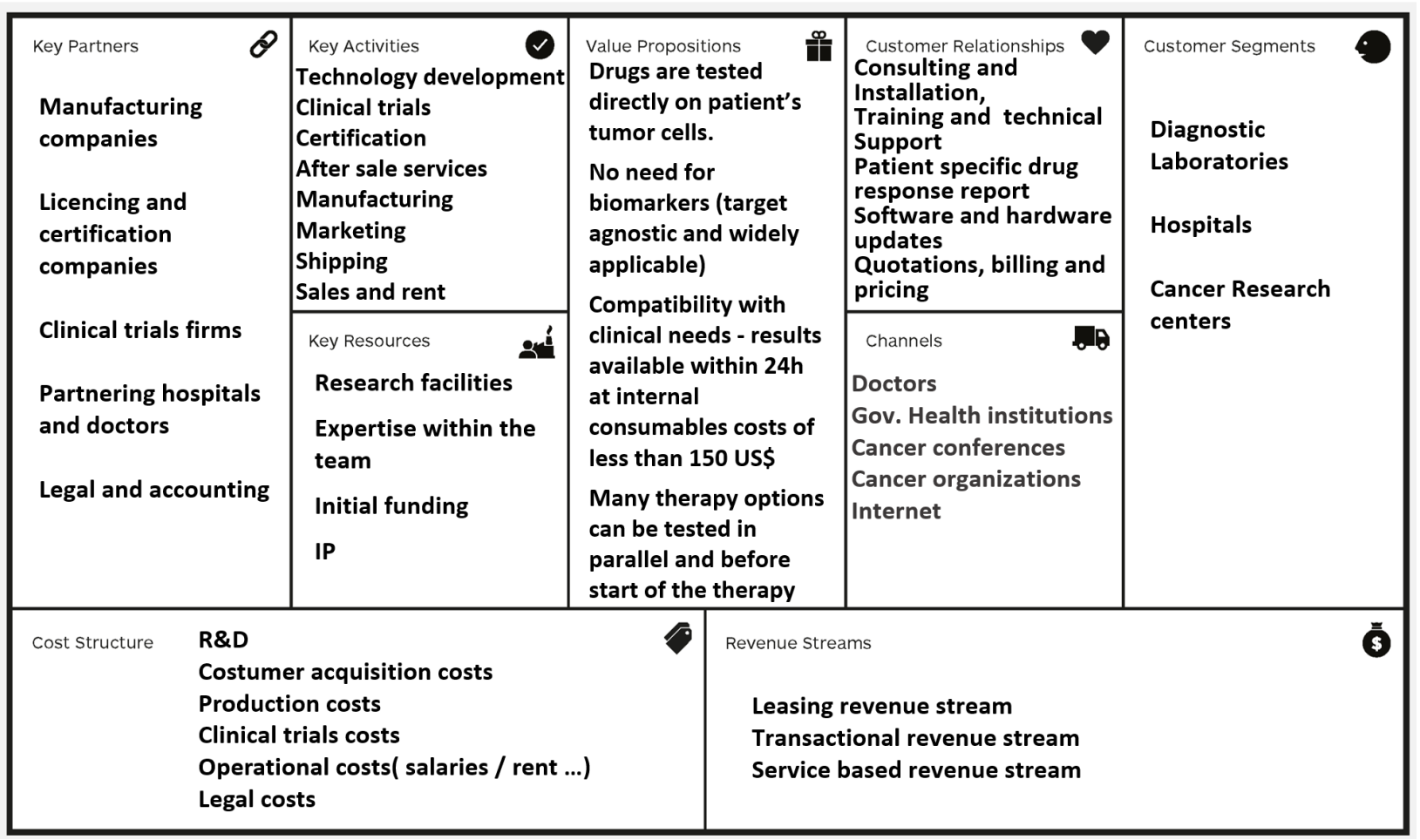
Translation into a finance table



2. Define the most important post-launch operating costs

Pre-launch

- R&D
- Clinical
- Regulatory
- Operational
- Legal
- Budget
- Balance



Post-launch

- R&D
- Clinical
- Regulatory
- Operational

Production cost, marketing, customer support

Revenue/Sales
Investments

- Balance

A few ballpark figures for YOU to start with…

Benchspace ~1750 CHF per person per month in a fully equipped Biopole lab**.** Alternatively ~320 CHF per square meter per year (empty lab)

Salary costs = ~750k CHF per 5 people per year

Consumables costs ~ 5-50k CHF per person per year (depending on application and discipline – anything requiring sequencing gets crazily expensive)

Legal counselling and FTO analysis for establishing a startup ~100k CHF, then at least 10K CHF/ year

Required stock capital to found a Swiss "Aktiengesellschaft" (= stock company) ~100K CHF

IP costs = royalties of at least 5% on total revenue + ~500k CHF milestone payments + ann
10k, additional ~ 10k for each new patent filing

Certification of an IVD device ~ 250k CHF for a complete certification service (e.

Clinical trial for an IVD device ~ 1.5M CHF (e.g. IKF)

Clinical trials for drugs = only affordable for Phase 1 and ADME, pla
age and then partner with big pharma:

*"The average cost of phase 1, 2, and 3 clinical trials across therapeu
4, 13, and 20 million respectively. Pivotal (phase 3) studies for new drugs approved by the Food and Drug Adminis
of the United States cost a median of $41,117 per patient." (https://www.sofpromed.com/how-much-does-a-clinical-trial*

In case of doubt or for things not listed here: Ask suppliers, service providers or partners how much it costs and how long it takes!

IND studies are required for getting approval as an **I**nvestigantional **N**ew **D**rug enabling first in human clinical trials. These studies typically include determination of Absorption, Distribution, Metabolism, Excretion, and Toxicity (ADMEtox studies) and cost about $2-3M US$

Cost & Revenue

Year	2027	2028	2029	2030	2031
Technology develpoment					
	0	2000	0	0	0
Second clinical trials					
Recruitment, ethics approval and sample shipments	1500			0	0
Production cost					
kits Manufacturing	625	1250	5000	10000	18750
WS Manufacturing	350	350	2800	3500	10500
storage	10	20	50	50	50
shipping	5	10	50	100	250
sales and rent related costs	3	6	30	60	150
Marketing					
Public relations	10	10	10	10	10
Website, server and marketing content	70	7	7	7	7
Customer aquisition cost	375	750	3750	7500	18750
Operational costs					
Number of R&D employees	2	2	3	3	4
Number of management employees	3	3	5	5	5
Number of sales and services employees	1	1	10	10	20
Salaries	900	900	2700	2700	4350
Rent	90	90	270	270	435
Documentation					
Certification	10	10	200	10	10
Regulatory affairs	200	10	200	10	10
IP	445	150	852.5	1535	3932.5
Legal cost (company registration and tax)	20	20	20	50	50
Total costs	4613.00	5583.00	15939.50	25802.00	57254.50
Revenue stream					
Investment carry over	6509				
Number of WS	5	10	50	100	250
kits sales	1250	2500	12500	25000	62500
WS rental	50	100	4000	5000	15000
Service fees	0	0	150	300	750
Total revenue	1300	2600	16650	30300	78250
P&L Net balance before investment	-3313	-2983	711	4498	20995.5
Cumulative profits and investments	3196	213	924	5422	26417

Scaling

not linear, one off investment for new generation, new readout, etc.

not linear, cost per trial and disease indication

mass discount: 1250 CHF per kit up to 1000/yr 1000 per kit up to 100000/yr 750 CHF per kit from 100k+ kits per year

linear 70k per station

not linear, rent 1 or 2 or 3 rooms

linear (1k per WS)

linear (0.6k per WS)

initial investment for design and launch of the website, then constant

linear 30% margin for diagnostic lab

moderate increase with growth

moderate increase with growth

increase with expansion to US market

linear average of salary cost of 150k per employee

linear 15k per employee per year

not linear, scales with new markets

not linear scales with royalties + new inventions, milestones, etc.

cummulative number

first 10 workstations are for rent & demos, then full sales at 100k

Quick reality check: Do your numbers and timelines make sense?

- **Do you start selling products only AFTER you have all regulatory permissions?**
- **Do you start selling products only AFTER you professionally (mass)produce them?**
- **Do you have enough personnel and infrastructure to reach the sales numbers projected for each year?**
- **Are you profitable at some point (or are the annual costs higher than the revenue)?**
- **Are your initial budget requirements realistic?**
- **Are the sales numbers matching the market size?**

Quick reality check: Do your numbers and timelines make sense?

- **Do you start selling products only AFTER you have all regulatory permissions?**

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(inhouse) (external)

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Quick reality check: Do your numbers and timelines make sense?

- **Do you have enough personnel and infrastructure to reach the sales numbers projected for each year?**

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- **Are you profitable at some point (or are the product costs higher than the revenue)?**

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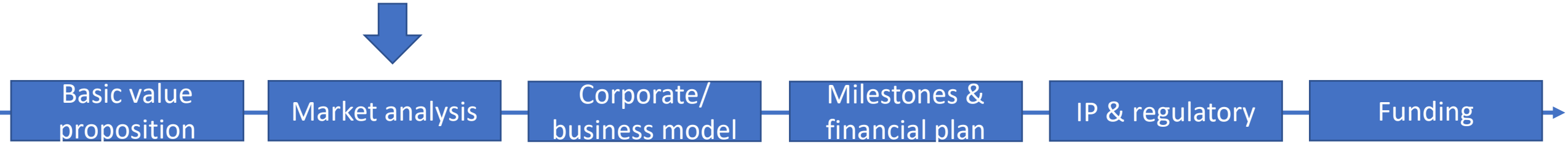
Break-even in 2029

Quick reality check: Do your numbers and timelines make sense?

- **Are the sales numbers matching the market size?**



Country	# new colorectal cancer diagnoses/ year	# of potential tests (6% patient reach)	Potential annual sales
CH	4681	281	1.6mio US$
D	58 047	3483	20 mio US$
US	155 098	9306	54 mio US$

	2027	2028	2029	2030	2031
Number of WS	5	10	50	100	250
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100 Devices serving 10,000 patients per year. To achieve the projected sales numbers, markets beyond CH & D must be served OR a >6% patient reach OR additional indications (requiring additional clinical trials)!

BIO-490 students tasks for today/ this week

- **Define a road map with milestones for product development**

1. Minimum Marketable Product (MMP). The most simple (e.g. small number of features) product that provides a use or service to the customer for which he/she would be willing to pay for. **2.5M CHF, 3 years**

Unfortunately, nobody will buy this unless….

…**2.** some **clinical patient benefit** has been shown
1.5M CHF, 3 years

…**3.** the **device** ultimately gets **certified** (note that this is not required for initial market launch in diagnostic labs)
200K CHF, 2 years

Milestone A (task/completion date)
Milestone B (task/completion date)
Milestone C (task/completion date)

- **Prepare a financial plan for the first years of your startup (pre- and post-launch)**

Year	2022	2023	2024	2025	2026
Development					
Research and development	700.000,00	500.000,00 €	1.200.000,00 €	1.000.000,00 €	1.900.000,00 €
Ichner Institute	100.000,00 €	100.000,00 €	50.000,00 €	50.000,00 €	50.000,00 €
Annual certification	18.500,00	15.000,00 €	36.000,00 €	45.000,00	87.000,00
Regulatory affairs	100.000,00	250.000,00	53.000,00	53.000,00	53.000,00
Clinical study	500.000,00 €	60.000,00 €	60.000,00 €	60.000,00 €	60.000,00 €
abor equipment	500.000,00 €	100.000,00 €	100.000,00 €	100.000,00	100.000,00
Production					
Nbr of workstations/kits/peop le/rental cars	5/500/10/1	10/1500/20/1	20/3500/35/2	30/4500/38/2	50/6500/40/3
Workstations	500.000,00 €	1.000.000,00 €	2.000.000,00 €	3.000.000,00 €	5.000.000,00 €
Storage	20.000,00 €	20.000,00 €	22.000,00 €	25.000,00 €	25.000,00 €
Shipping	5.000,00 €	5.000,00 €	10.000,00 €	10.000,00 €	15.000,00 €
Hotel	15.000,00	30.000,00 €	60.000,00 €	90.000,00	150.000,00 €
Taxes	113.335,25€	113.949,50€	199.748,50 €	286.526,50€	350.080,50 €
Repair	3.000,00	6.000,00 €	12.000,00 €	18.000,00	30.000,00 €
Marketing/Sales					
Public relations	100,00 €	100,00 €	100,00 €	100,00 €	100,00 €
Website	10.000,00	3.000,00 €	5.000,00 €	5.000,00	5.000,00 €
Server	60.000,00	600,00 €	600,00 €	600,00	600,00 €
/video materials	1.200,00	1.200,00 €	1.200,00	1.200,00	1.200,00
Shootings	7.200,00 €	7.200,00	7.200,00 €	7.200,00	7.200,00
External Agency	3.300,00 €	6.600,00 €	13.200,00 €	19.800,00 €	66.000,00
External consulting					
Legal advice	101.750,00 €	7.500,00 €	15.000,00€	22.500,00 €	37.500,00 €
Tax consulting	9.600,00 €	12.000,00 €	16.800,00 €	21.000,00	160.000,00 €
Personnel costs					
Recruitment	20.000,00 €	40.000,00 €	140.000,00 €	152.000,00 €	15.000,00
Employees	300.000,00 €	1.000.000,00 €	1.750.000,00 €	1.900.000,00 €	2.000.000,00 €
Other costs					
T Management	5.000,00	10.000,00 €	10.000,00 €	1.000,00	1.000,00 €
Rent	24.000,00	24.000,00 €	48.000,00 €	48.000,00	48.000,00 €
Travel	21.000,00	28.500,00	43.500,00	58.500,00	88.500,00 €
Insurance	3.000,00 €	6.000,00 €	12.000,00	18.000,00	30.000,00 €
Celebrations	500,00	1.000,00 €	1.500,00 €	2.000,00	2.200,00 €
Total costs	3.141.435,25€	3.349.649,50 €	5.866.848,50 €	6.944.426,50 €	10.282.380,50 €
Income					
Number of workstations sold	5,00	10,00	20,00	30,00	50,00
Number of kits sold	500,00	1.500,00	3.500,00	6.500,00	115.000,00
Case 1: Revenue (2500 Euro/kit and 100000 Euro/WS)	1.750.000,00	4.750.000,00	10.750.000,00	19.250.000,00	292.500.000,00
Net	-1.591.485,25€	1.400.350,50€	4.883.151,50€	12.305.573,50 €	282.217.619,50€

When do you break even?

What investments are needed?

Questions?