

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 2024

Lecture #/Date	Topic	Details	Seminar tasks
1/ 12.09	General Introduction	Aims of the course, expectations, tasks and assessments General proceeding	Watch Elisabeth Holmes Documentary (Theranos story)
2/ 19.09	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/ 26.09	Market analysis	Market size, competitors, customer models, growth and scalability,	Introduction into GlobalData, Find market data on your business example & group innovation
4/ 03.10	Corporate planning	Business models, exit strategies, website & visibility,	Define business example of your group innovation, define markets and competitors
5/ 10.10	Business examples	Business examples 1-4 , detailed feedback	
6/ 17.10	Timelines & initial steps – work plan	Business examples 5-8 Milestones and finance plan from idea to startup/product	Find & analyze patents in your field
24.10 – no lecture!			
7/ 31.10	Intellectual property and other legal issues	Business examples 9-12 Patents – facts, data bases, examples Concept of freedom to operate, regulatory hurdles, etc.	Prepare milestones and financial plan for your startup idea
8/ 07.11	How to secure funding	Business examples 13-16 Public funding programs, investments, venture capital, EPFL programs	Finalize pitch deck
9/ 14.11	Finalizing the pitch deck	Business examples 17-20 Final feedback on individual case studies, last year’s best group pitch, time for questions	
11/ 21.11	Guest speaker Daniel Alpern (EPFL entrepreneur)	Business examples 21-24 Introducing Catlyze4Life	Prepare Executive Summary and commercial potential in C4Lformat
12/ 28.11	Guest speakers Gautam Maitra (EPFL C4L)	Introducing EPFL Launchpad Initiative	
13/ 05.12	Pitches Groups A (e.g. 4-6) Feedback Groups B (e.g. 1-3)	10min pitches with non-presenting students to provide written feedback, Submission of Executive Summary and commercial potential in C4Lformat	Prepare written feedback on other group’s pitches
14/ 12.12	Pitches Groups B (e.g. 1-3) Feedback Groups A (e.g. 4-6)	10min pitches with non-presenting students to provide written feedback, Submission of Executive Summary and commercial potential in C4Lformat	
15/ 19.12	Trophy Award & Feedback		

Group	Students	Date Business Example	Company	Date Group Pitch
1	Jakob Behler	2024.10.10	KetoSwiss AG	2024.12.12
	Danja Zengaffinen		Impli	
	Marguerite Derwael			
	Nestor Melissargos			
2	Gian Maria Velardi	2024.10.17		2024.12.12
	Daniel Selmin			
	Alice Canuti			
	Léo Cusumano			
3	Viola Renne	2024.10.31	SelfDecode	2024.12.12
	Marija Zelic			
	Berta Céspedes			
	Sarra Chaabane			
4	Paloma Aubert	2024.11.07		2024.12.05
	Carlota Imbert			
	Nouchine Bouchiat			
	Laura-Rose Hassan			
5	Kamil Lahlou	2024.11.14		2024.12.05
	Ali Mekki Berrada			
	Benjamin Aouzir			
	Camille Pittet			
6	Sara Vannay	2024.11.21	Notable Labs	2024.12.05
	Aygul Bayramova			
	Zhibo Zhao			
	Ruike Yan			

How do we grade case studies?

- Are problem and solution nicely presented (clear need, USPs)?
- Does the business model become clear (who pays whom for what)?
- Have specific challenges or opportunities been recognized?
- Are the questions properly answered?
- Are the slides nice and clear (e.g. not too crowded or text-heavy)?

In case of doubt, contact us (but it should become clear anyway!)

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?

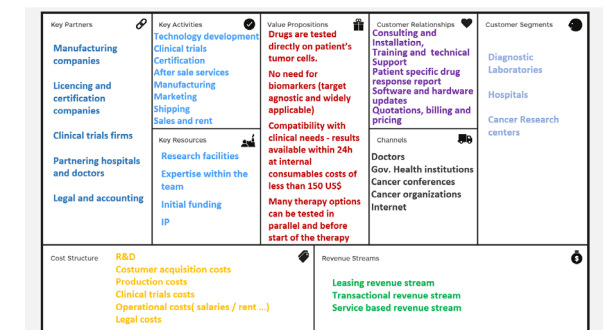
Let's get the money to start!

Pre-launch

- What is my homework for developing a product?

Post-launch (operating on the market)

Roadmap, timelines, milestones & financial plan



Homework for developing a product

Commercialization

1. What is the **USP**? Is there a **market** and how big is it?
2. How do I address my **customers**, what is the **business model**, is it **scalable**?
3. What is needed (**time, budget and resources**) to develop a minimal marketable product (**MMP**)?
4. Do I have **patent protection** and **freedom to operate**? Any other **legal or regulatory hurdles**?
5. How to secure **funding**?

What is the technology readiness level of my innovation?

How does a first product look like?

Which steps are necessary to develop a product?

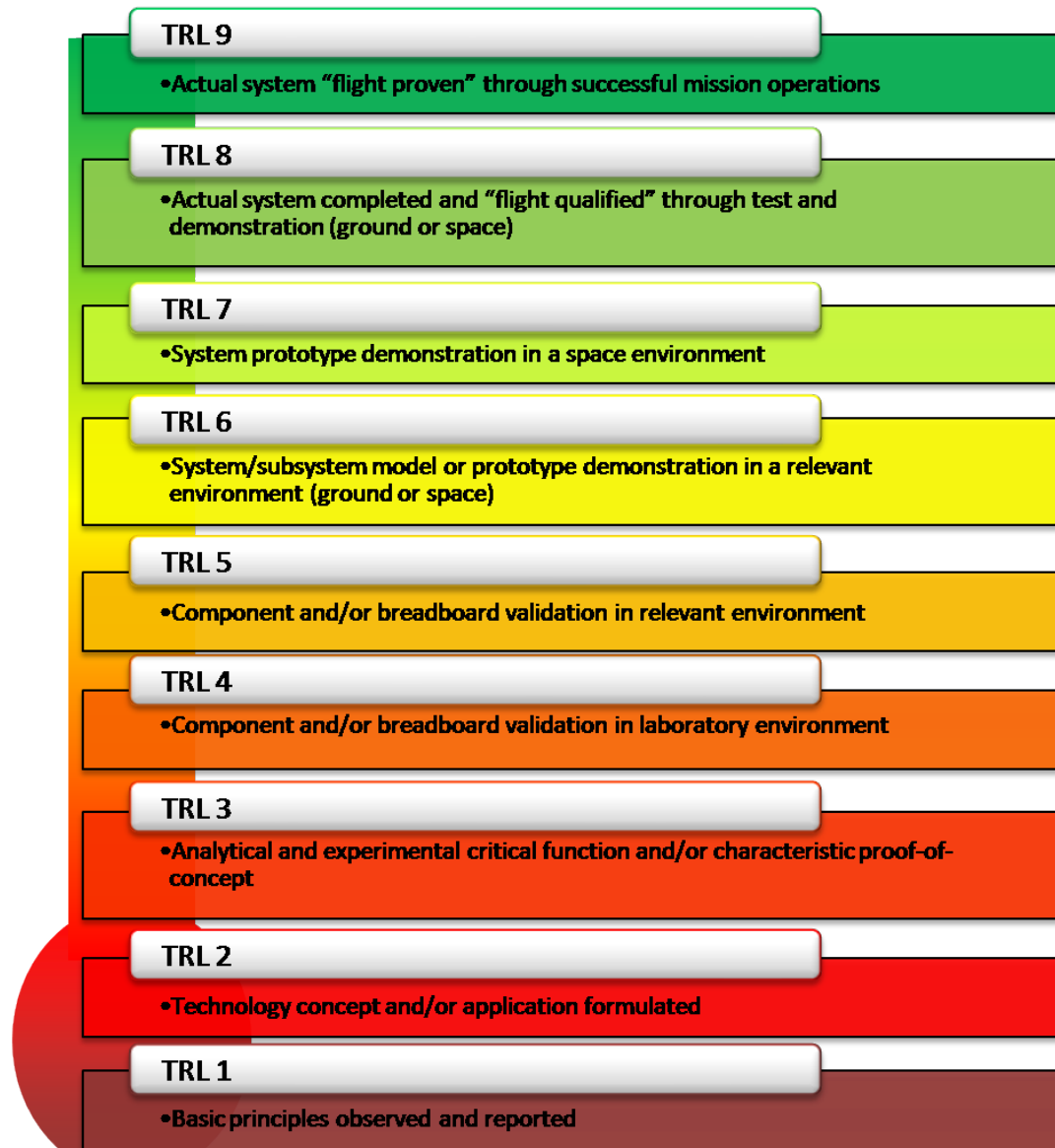


=> today's Lecture on Timelines, initial steps and financial planning

Define your starting and end points - Technology readiness level (TRL)

NASA

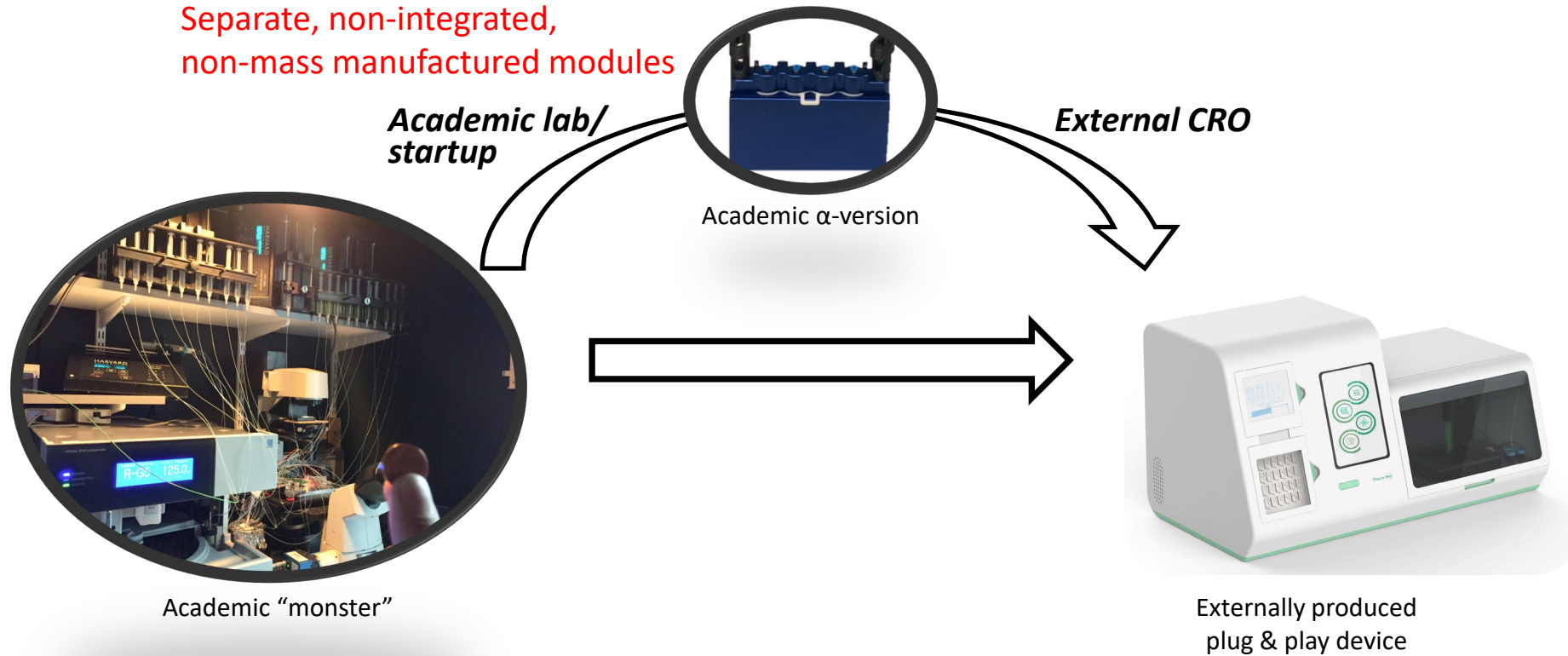
EU



- TRL 9 – Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)
- 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

Technology big picture milestones and product planning

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



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

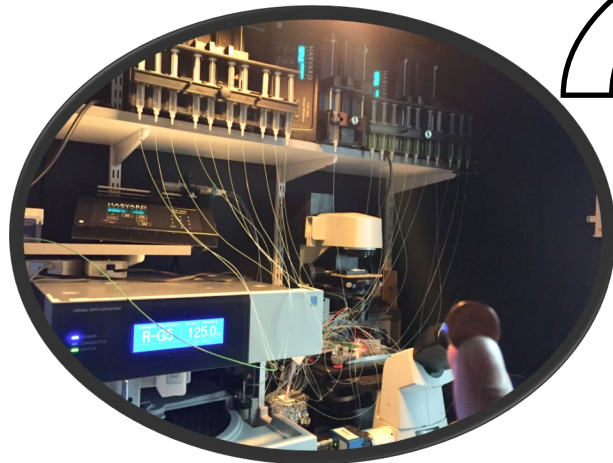
Syringes have to be filled with drugs manually
Non-integrated "wild" multi-component system
Braille valve that have to be aligned manually

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; or in space)

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

Technology big picture milestones and product planning

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



Academic "monster"

*Academic lab/
startup*

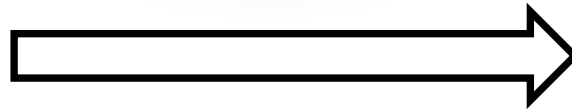


Academic α -version

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!

External CRO



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, 2 years

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

Milstones	Cost	In-house /out-sourced	2021	2022	2023	2024	2025
Industry prototype	2.5M	Mixed: involving external CROs					
							
			(inhouse)		(external)		
First clinical trials	1.5M	Outsourced: IKF Frankfurt (now ZKS Freiburg)					
Iso certification	200K	Outsourced: Johner institute (now dTIP & SQL)					

Translation into a finance table

Pre-market launch financial statement in 1000 CHF scale					
Year	2021	2022	2023	2024	2025
Industry Prototype					
Innosuisse salaries	300	300	0	0	0
Outsourcing and materials	50	50	0	0	0
Product development					
Product development	0	0	500	2000	0
First clinical trials					
Patient recruitment & monitoring, center care, ethics, sample shipments	0	0	1500		
salaries (lab and clinical)	0	0	400	750	750
Certification	0	0	100	100	0
IP	51	7	8	200	10
Legal cost (company launch and tax)	100	15	200	25	25
Total costs	873		6568		
Revenue stream					
Innosuisse grant	600	0	0		
Additional grant	0	700	0		
Intramural funding	100	50	0		
Sponsor's investments	0		2500		
Serie's A investments	0			10000	
Total revenue	1450		12500		
P&L Net 5 year balance	6509				

2. Define the most important post-launch operating costs

Key Partners Manufacturing companies Licencing and certification companies Clinical trials firms Partnering hospitals and doctors Legal and accounting	Key Activities Technology development Clinical trials Certification After sale services Manufacturing Marketing Shipping Sales and rent Key Resources Research facilities Expertise within the team Initial funding IP	Value Propositions Drugs are tested directly on patient's tumor cells. No need for biomarkers (target agnostic and widely applicable) Compatibility with clinical needs - results available within 24h at internal consumables costs of less than 150 US\$ Many therapy options can be tested in parallel and before start of the therapy	Customer Relationships Consulting and Installation, Training and technical Support Patient specific drug response report Software and hardware updates Quotations, billing and pricing Channels Doctors Gov. Health institutions Cancer conferences Cancer organizations Internet	Customer Segments Diagnostic Laboratories Hospitals Cancer Research centers
Cost Structure R&D Costumer acquisition costs Production costs Clinical trials costs Operational costs(salaries / rent ...) Legal costs	Revenue Streams Leasing revenue stream Transactional revenue stream Service based revenue stream			

...color coding your BC according to different sections of your finance plan might help!

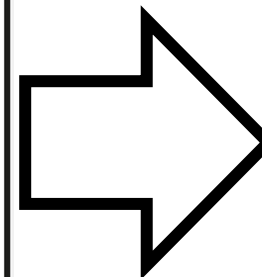
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Translation into a finance table

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Position	Cost/Revenue Year X
Technology development	
Second clinical trial	
Production cost	
Manufacturing	
storage	
shipping	
sales and rent related costs	
Marketing	
Public relations	
Website, server and marketing content	
Customer acquisition cost	
Operational costs	
Salaries	
Rent	
Documentation	
Certification	
Regulatory affairs	
IP	
Legal cost (company registration and tax)	
Total costs	
Revenue stream	
2022-2026 balance	
Number of WS rented	
kits sales	
WS rents	
Service fees	
Total revenue	

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 + annual ~10k, additional ~ 10k for each new patent filing

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

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

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

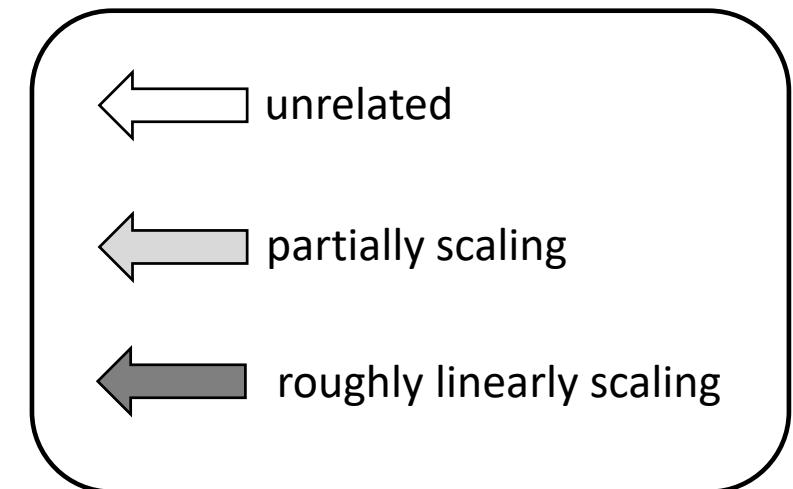
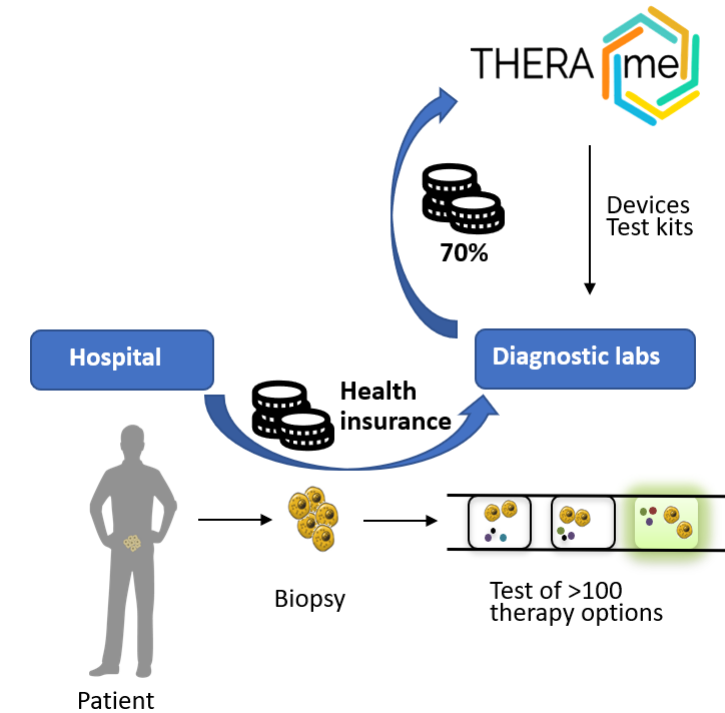
“The average cost of phase 1, 2, and 3 clinical trials across therapeutic areas is \$4, 13, and 20 million respectively. Pivotal (phase 3) studies for new drugs approved by the Food and Drug Administration of the United States cost a median of \$41,117 per patient.” (<https://www.sofpromed.com/how-much-does-a-clinical-trial-cost>)

IND studies are required for getting approval as an Investigational New Drug 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\$

**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!**

How do costs scale with sales?

Position	Cost/Revenue Year X	
Technology development		←
Second clinical trial		←
Production cost		
Manufacturing		←
storage		
shipping		
sales and rent related costs		
Marketing		←
Public relations		←
Website, server and marketing content		←
Customer acquisition cost		←
Operational costs		←
Salaries		←
Rent		
Documentation		
Certification		
Regulatory affairs		←
IP		
Legal cost (company registration and tax)		
Total costs		
Revenue stream		
2022-2026 balance		
Number of WS rented		←
kits sales		
WS rents		
Service fees		
Total revenue		



Year	2026	2027	2028	2029	2030
Technology development					
	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					
2022-2025 balance	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

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

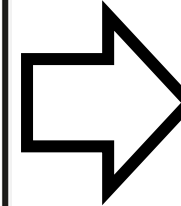
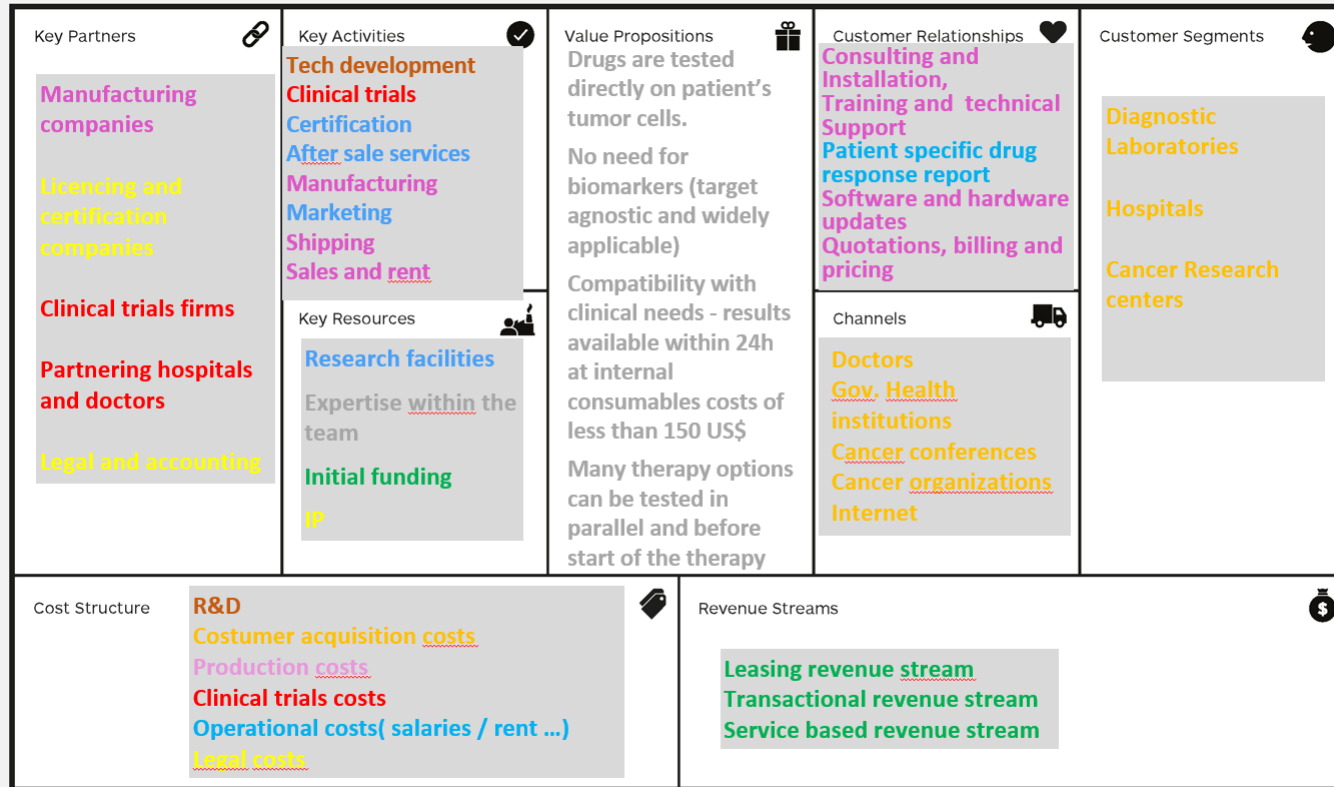
not linear, scales with new markets

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

cummulative number!

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

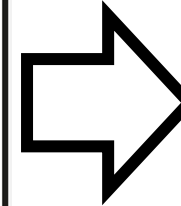
15min exercise: Define YOUR cost and revenue categories (post-launch) and populate with numbers at least for the first year of product sales



Year	2026	2027	2028	2029	2030
Technology development					
	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 acquisition 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
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Homework: Define YOUR cost and revenue categories (pre- and post-launch) and populate with numbers

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Cost Structure  - R&D - Customer acquisition costs - Production costs - Clinical trials costs - Operational costs(salaries / rent ...) - Legal costs	Key Resources  - Research facilities - Expertise within the team - Initial funding - IP	Channels  - Doctors - Gov. Health institutions - Cancer conferences - Cancer organizations - Internet	Revenue Streams  - Leasing revenue stream - Transactional revenue stream - Service based revenue stream	



Year	2026	2027	2028	2029	2030
Technology development	0	2000	0	0	0
Second clinical trials					
Recruitment, ethics approval and sample shipments	1500			0	0
Production cost					
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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 product 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?

Milestones	Cost	In-house /out-sourced	2021	2022	2023	2024	2025
Industry prototype	2.5M	Mixed: involving external CROs					
First clinical trials	1.5M	Outsourced: IKF Frankfurt					
Iso certification	200K	Outsourced: Johner institute					

Timeline annotations:

- An orange arrow points from 2021 to 2023, labeled "(inhouse)" and "(external)".
- A blue arrow points from 2023 to 2025.
- A red oval highlights the 2023-2024 period.

Year	2026	2027	2028	2029	2030
Technology development	0	2000	0	0	0
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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					
2022-2025 balance	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

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?

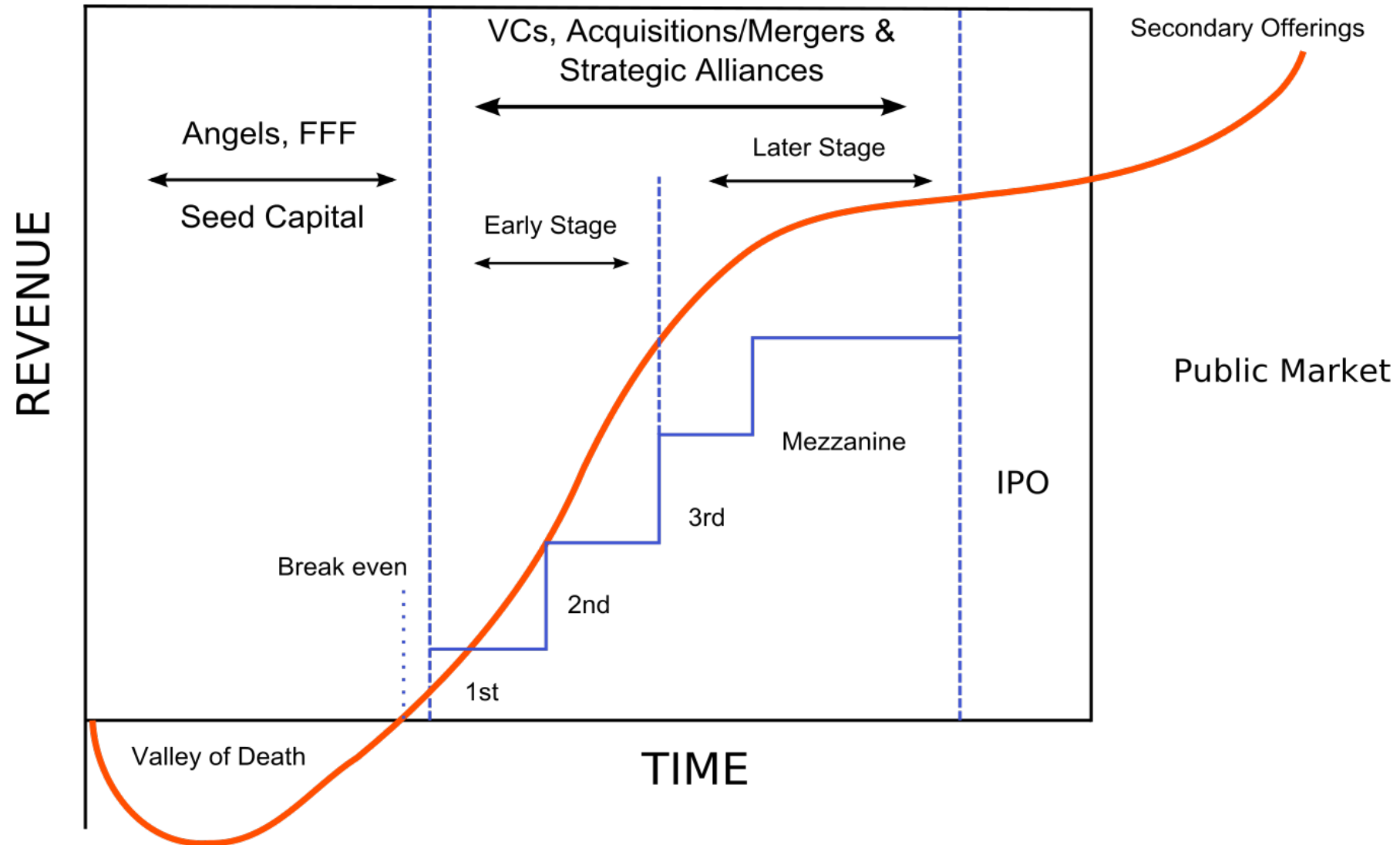
<u>Operational costs</u>					
Number of R&D employees	2	2	3	3	4
Number of management employees	3	3	3	3	5
Number of sales and services employees	1	1	10	10	20
Salaries	900	900	2700	2700	4350
Rent	90	90	270	270	435
<u>Documentation</u>					
Certification	10	10	200	10	10
<u>Regulatory affairs</u>	200	10	200	10	10
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<u>Revenue stream</u>					
2022-2025 balance	0				
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kits sales	1250	2500	12500	25000	62500
<u>WS rental</u>	50	100	4000	5000	15000
Service fees	0	0	150	300	750

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

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

Revenue stream					
2022-2025 balance	6509				
Number of WS	5	10	50	100	250
kits sales	1250	2500	12500	25000	62500
WS rental	50	100	4000	5000	15000
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P&L Net balance before investment	-3313	-2983	711	4498	20995.5
Cumulative profits and investments	3196	213	924	5422	26417

You should end up with something like this!



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

- Are your initial budget requirements realistic? Do you always have cash?

Revenue stream					
2022-2025 balance	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

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\$

	2026	2027	2028	2029	2030
Number of WS	5	10	50	100	250
kits sales	1250	2500	12500	25000	62500
WS rental	50	100	4000	5000	15000

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)!

Questions?



Supplementary Slides

Technology big picture milestones and product planning

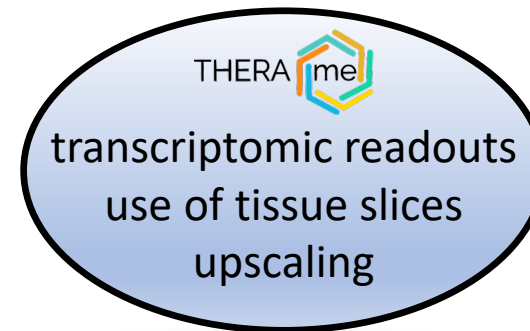
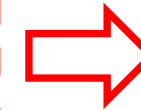
Minimal Viable Product (MVP). Basically a mockup of the product or service, allowing the provider to get real world feedback/data on what the customer will use the product/service for. Could e.g. be a non-scalable platform that is still fully manually operated, without disclosing this to the customer.

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.

Second generation product. After the initial product launch, further product generations can be introduced to the market that have additional features (which were potentially already known but purposely excluded when designing the MMP).

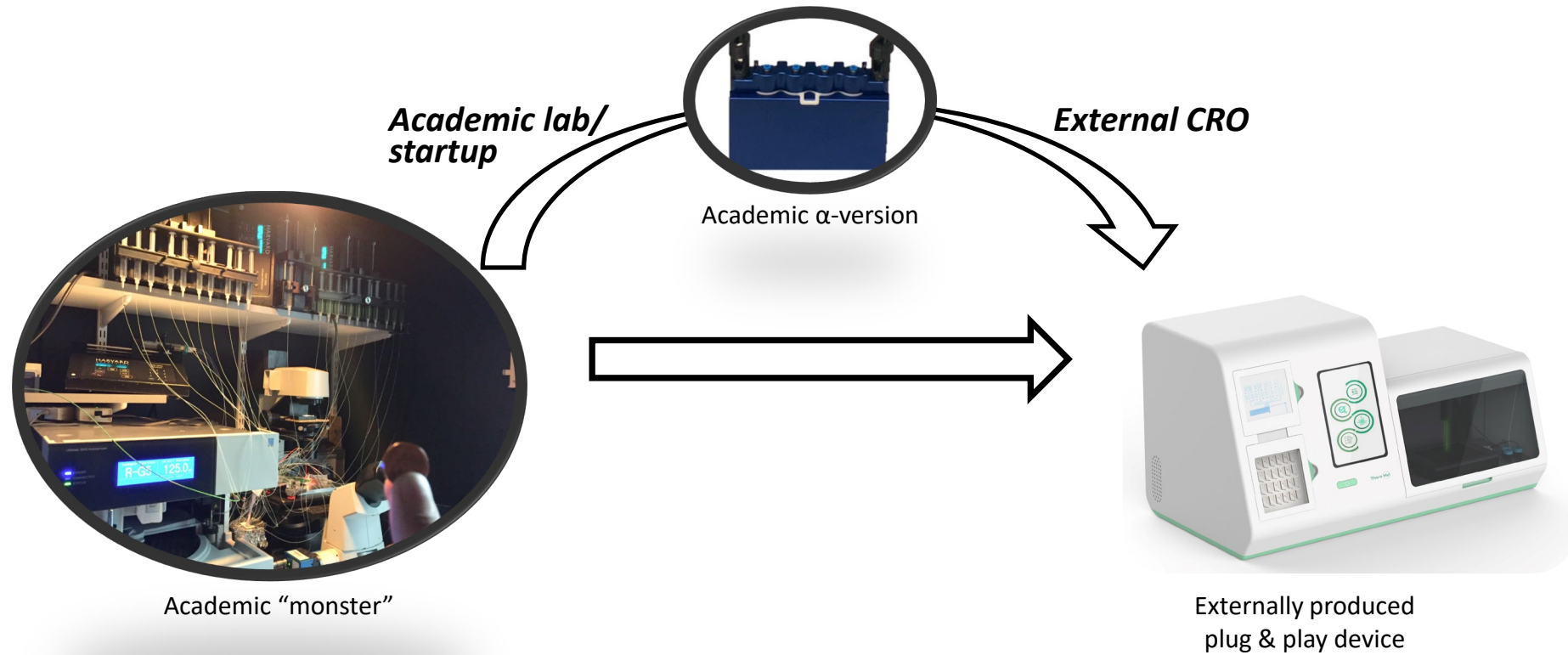


Focus on this to define all milestones and financial needs until your startup is operating on the market!



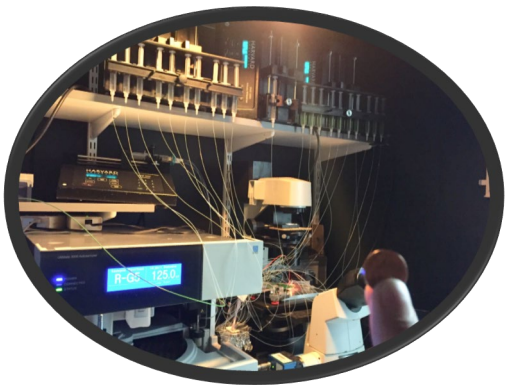
Reserve resources and a budget for this for the time when your startup is operating on the market

Estimates on timelines and cost



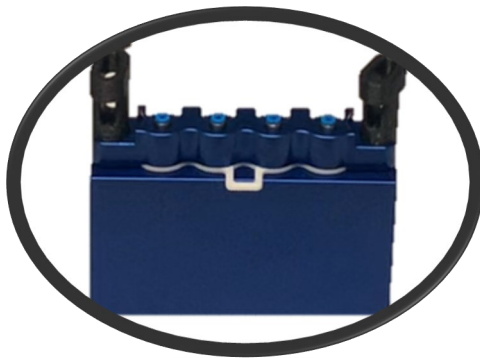
Give 3 answers corresponding to your estimates on timelines and cost

1st answer



Academic “monster”

2nd answer



Academic α -version

3rd answer



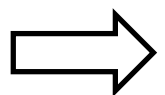
Externally produced
plug & play device

0	0	0	0	0	0	0	0	0	0
Current Status - 3 years and 1M CHF	Current Status - 6 years and 2M CHF	Current Status - 9 years and 3M CHF	Academic Alpha - 1 year and 200k CHF	Academic Alpha - 2 years and 500k CHF	Academic Alpha - 3 years and 1M CHF	Plug & Play - 1-2 years 500k CHF	Plug & Play - 1-2 years 1M CHF	Plug & Play - 1-2 years 2M CHF	Plug & Play - 1-2 years 3M CHF

General roadmap and milestone planning

Why is setting milestones important ?

1. A roadmap guides you towards **accomplishing preset goals within a predetermined period of time.**
2. Helps you defining **your short-term goals** and how to get there?
3. Clarify your **path to launching a product** people need and pay for.
4. **Define customer expectations**, product functionality and customer acquisition and avoid costly mistakes later on.
5. **Determine costs** and show an investor/funder what exactly will be done with his/her money



Prioritize Milestones & prepare backup plans, estimate costs and timelines

Steps to build a strategic financial plan

**1
Step**

Establish a solid roadmap

Estimate Fixed And Variable
Expenses

**2
Step**

**3
Step**

Estimate your revenues or your funding
spread out over the years/months

Create a cash flow statements

**4
Step**

**5
Step**

Use a cost balance sheet to lay
out your estimations