pdmeds

BUSINESS PLAN

Designing devices for pulmonary rehabilitation

MARKET NEED

SHORTAGES IN MEDICAL STAFF

In Poland, there is a **tenfold shortage** of medical staff and patients receive, on average, twice less physiotherapy than in Europe. They also have to wait more than three months to begin pulmonary physiotherapy when they need it immediately. As an alternative, they could exercise themselves in their houses, but most do not follow the given prescriptions and abandon the therapy due to the lack of engagement, not visible progress and misunderstanding of the methods of exercising.

USERS

Our devices are dedicated to helping people with pneumonia, COVID-19, severe COPD, lung cancers, after surgeries or with posture defects. This group is globally estimated as more than **70 million** new cases yearly, with at least **220 thousand** new cases reported just in Poland. Severe respiratory diseases remain one of the most common **mortality factors** and account for over **7%** of all the deaths.

POTENTIAL CUSTOMERS

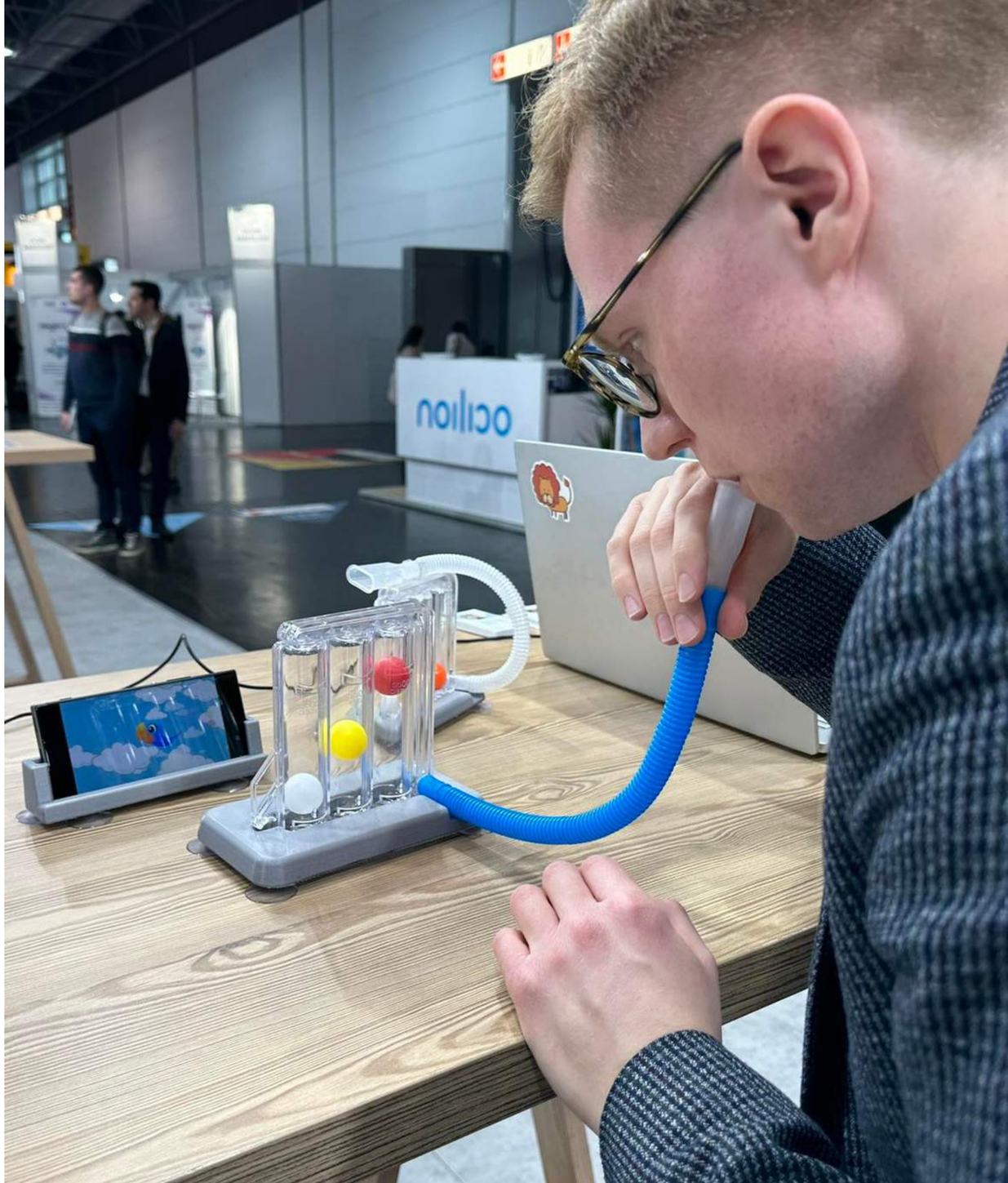
We know that the best results come from the combination of supervised rehabilitation in medical facilities and self-training in houses. This is why we developed two products - one advanced trainer, which can fully automatise resistive treatment with minimal physician supervision, and the second, which can enable entertaining home therapy with minimal costs. The former is dedicated to **hospitals** and **clinics**, while the latter - to **individual users**.

OUR PRODUCTS

NOTOS

THE SYSTEM FOR SELF-EXERCISING

Notos is a simple system combining a **smartphone** and a mechanical **pulmonary trainer** with three elevating balls only with the image from the front camera. Thanks to this simplicity, it can be used at home by hardly anyone and remains relatively **inexpensive**. The design enables registration of the balls' motion during respiratory treatment and uses an estimation of the inspiration speed, based on these, as the control signal for a mobile game. The therapy is **gamified** as the mobile application analyses the user's breathing patterns and **motivates** them to prolong inspiration and keep the desired inspiration-to-expiration ratio. At the end of the rehabilitation session, the graph of inspiration speed and results compared to the historical collected are presented.



OUR PRODUCTS

BOREAS
THE SYSTEM FOR USE IN HOSPITALS

Boreas is an advanced system for pulmonary rehabilitation. It **controls** the **resistance** of the treatment, **measures** its parameters**, visualises** the desired breathing patterns, and sends the data measured to the physician. The therapy is **gamified** and can be realised with a virtual trainer or an arcade game. Training starts with strong inspiration, and then the patient needs to keep the natural breathing rhythm under changing flow limitations. The resistance settings are changed automatically while exercising based on patients' performance. At the end of the rehabilitation session, the results are presented and can be analysed remotely by the medical expert. The next exercising session is generated **automatically**. The device contains an exchangeable **sterile** filter and an inlet tube. Hence, it can be used by numerous patients.

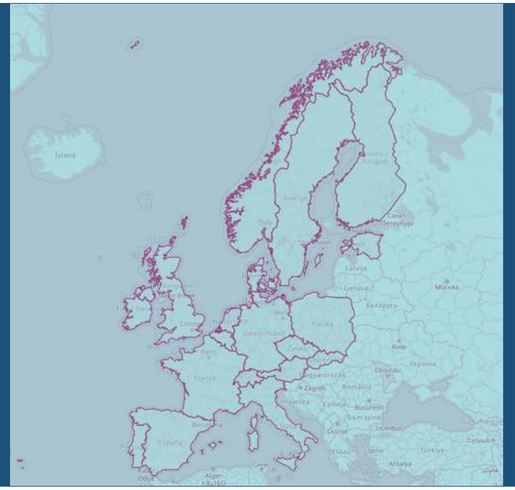
MARKET OPPORTUNITY

TARGETTED MARKET

We initially plan to start with the **Polish** market and continue with the **European markets with significant investments in medical technologies**. These include Germany, Austria, Denmark, Norway, Sweden, Finland, Estonia, Switzerland, Netherlands, Belgium, France, United Kingdom, Ireland, Portugal, Czech Republic, Slovakia, Italy and Spain. We are also considering reaching the Israeli and the USA markets, depending on early European interest and the profile of investors.
The market extension for the Notos device is planned for South-Central Asia, as many regions do not require its strict certification. The first talks with local distributors have been initiated.

MARKET GROWTH

The total market of respiratory rehabilitation devices is estimated to be worth **8.5B USD** and to grow up to **16.3B USD** by **2033**, but is not penetrated yet well enough besides systems dedicated to COPD, asthma, and cystic fibrosis .*
However, both systems are dedicated to telerehabilitation. This sector is estimated to grow with a **CAGR** of **15.3%**, with a large potential in South-Central Asia.**



*https://www.futuremarketinsights.com/reports/home-respiratory-therapy-market
**https://www.grandviewresearch.com/industry-analysis/telerehabilitation-market-report

COMPETITION ANALYSIS

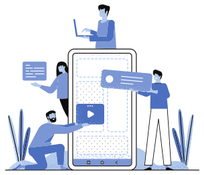
COMPETITION FOR HOME USE

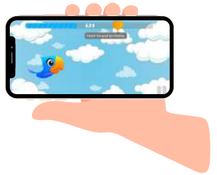
Notos can be compared with three main types of competitors - simple pulmonary trainers, mobile applications for breathing training with voice recognition, and advanced mechanical trainers. Notos, as a combination of a simple trainer and the app, gives comparable functionality for home treatment. It enables **resistance treatment** with **automation** and **gamification** of the treatment. However, the therapy with it can be **up to 30 times cheaper** than with the advanced trainer. Therefore, it is an effective solution affordable to almost anyone.

COMPETITION FOR HOSPITAL USE

Boreas is the only tool which combines all the most desired factors for automatic therapy. It **automates** and **gamifies** the treatment, including the **continuous adjustment of the resistance**, **monitors** the patient's health, and provides a connection with a medical professional. Hence, the fleets of these can serve numerous patients, even **remotely**.

COMPETITION ANALYSIS




Solution	Mechanical Trainers*	Mobile Apps**	Advanced Trainers***	Notos	Boreas
Gamification	✗	✓	✓	✓	✓
Resistance Treatment	✓	✗	✓ / ✗	✓	✓
Remote Connection	✗	✗	✗	✗	✓
Training Automation	●●●	●●●	●●●	●●●	●●●
Price	5-40 €	0-50 €	200-2500 €	20 €	2000 €

*Tri-ball breathing exercisers, Kit PipeP, Pulmotrainer, Flutter, PowerBreathe
** Breathwrk, Lungy, Breathesimple
***AiroFit, Breather One, play.air

REACHING OUR CUSTOMERS

REACHING PATIENTS VIA PHYSICIANS

Distribution of both products will begin with building awareness among **physicians**. They will impact both hospital **managers to purchase Boreas** and their **patients to purchase Notos**.

ORGANIC REACH FROM MEDIA PRESENCE AND MEDICAL FAIRS

During the R&D phase, we are using our media presence to build awareness of the project. This contributes to the increasing number of **professionals reaching us** to test our devices.

R&D COOPERATION WITH HOSPITALS

We plan to combine the R&D of the products with acquiring customers in the most natural way - by shaping the developed technologies with their involvement. For this reason, we are establishing cooperation with the leading pulmonary hospitals, including the Center for Pulmonary Diseases in Olsztyn, and applying for **research joint projects**.

MEDICAL DEVICES' DISTRIBUTORS

We plan to distribute our systems via medical device suppliers - particularly outside Europe. In our business model, we assumed that the acceptable price abroad can include up to a **30%** commission fee.

BUSINESS MODEL

MANUFACTURING	PRODUCT	DISTRIBUTION	CUSTOMER
MANUFACTURING AND ASSEMBLING COMPANY	BOREAS	DIRECT B2B	HOSPITAL
pdmeds	EXCHANGEABLE COMPONENTS	MEDICAL DISTRIBUTORS	
	NOTOS HARDWARE	ONLINE B2B	
	NOTOS APP	ONLINE B2C	PATIENT
		MEDICAL DISTRIBUTORS	
		SUBSCRIPTION	

BUSINESS ROADMAP

INVESTMENT ROUND OF 2,700,000 PLN REQUIRED

1

Design

Development of the Notos and Boreas systems and adjustment of their parameters

2

Tests

Testing the performance of the systems in medical facilities to prove their effectiveness

3

IP protection

Applying for IP protection in Poland and extending the application into selected European countries in a year (2 months)

INVESTMENT ROUND OF 5,900,000 PLN REQUIRED

4

ISO certification

ISO certification of the start-up (5 months)

5

Technology Adjustments

Adjusting the technology to manufacturing requirements, selecting available components and planning assembly; manufacturing the first batch (9 months)

6

Non-clinical trials

Tests of devices' compliance with the requirements of medical devices and electronic devices in general; preparing documentation (11 months)

INVESTMENT ROUND OF 1,300,000 PLN REQUIRED

7

Clinical trials

Clinical analysis of the devices' impact on patients' condition with controlled trials (10 months)

8

Marketing

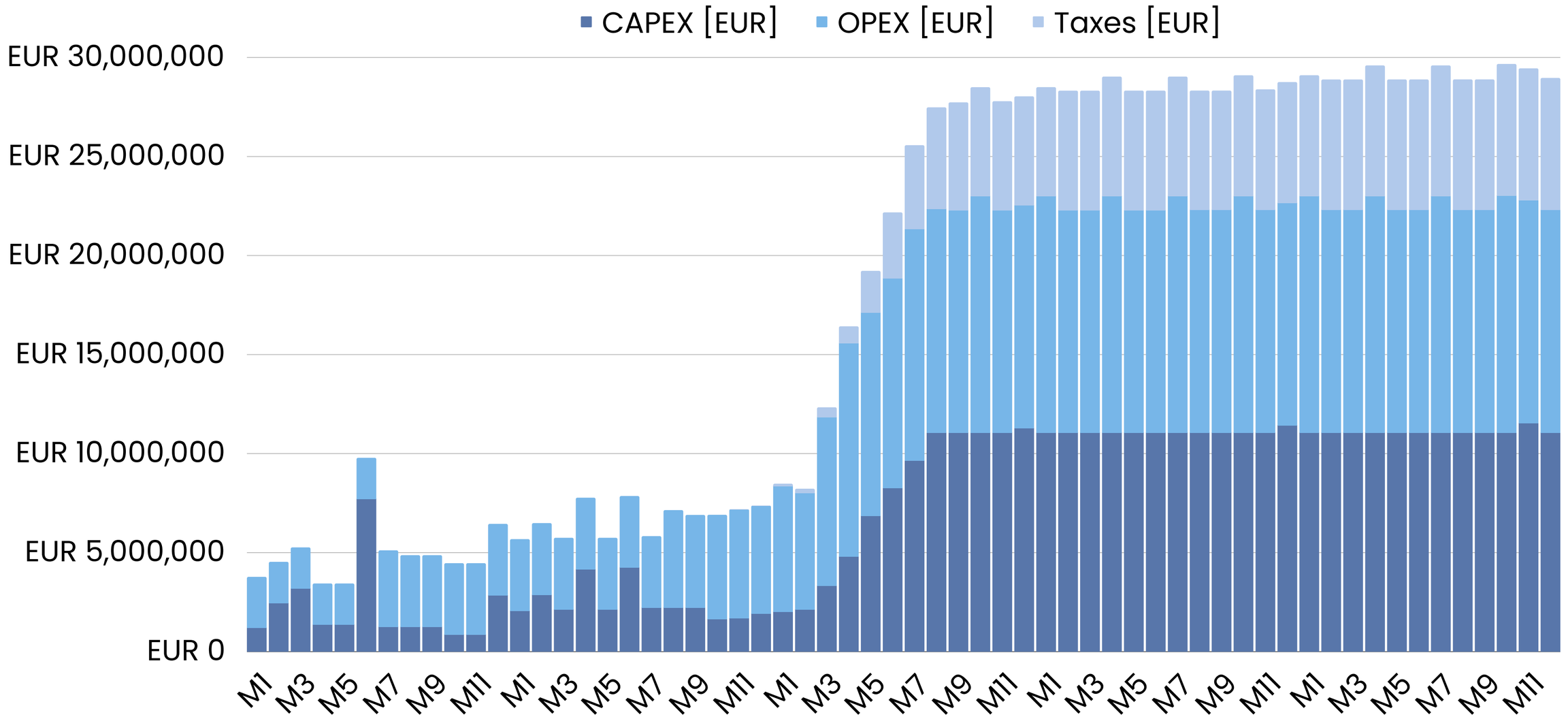
Reaching customers and signing pre-orders to deliver them systems

9

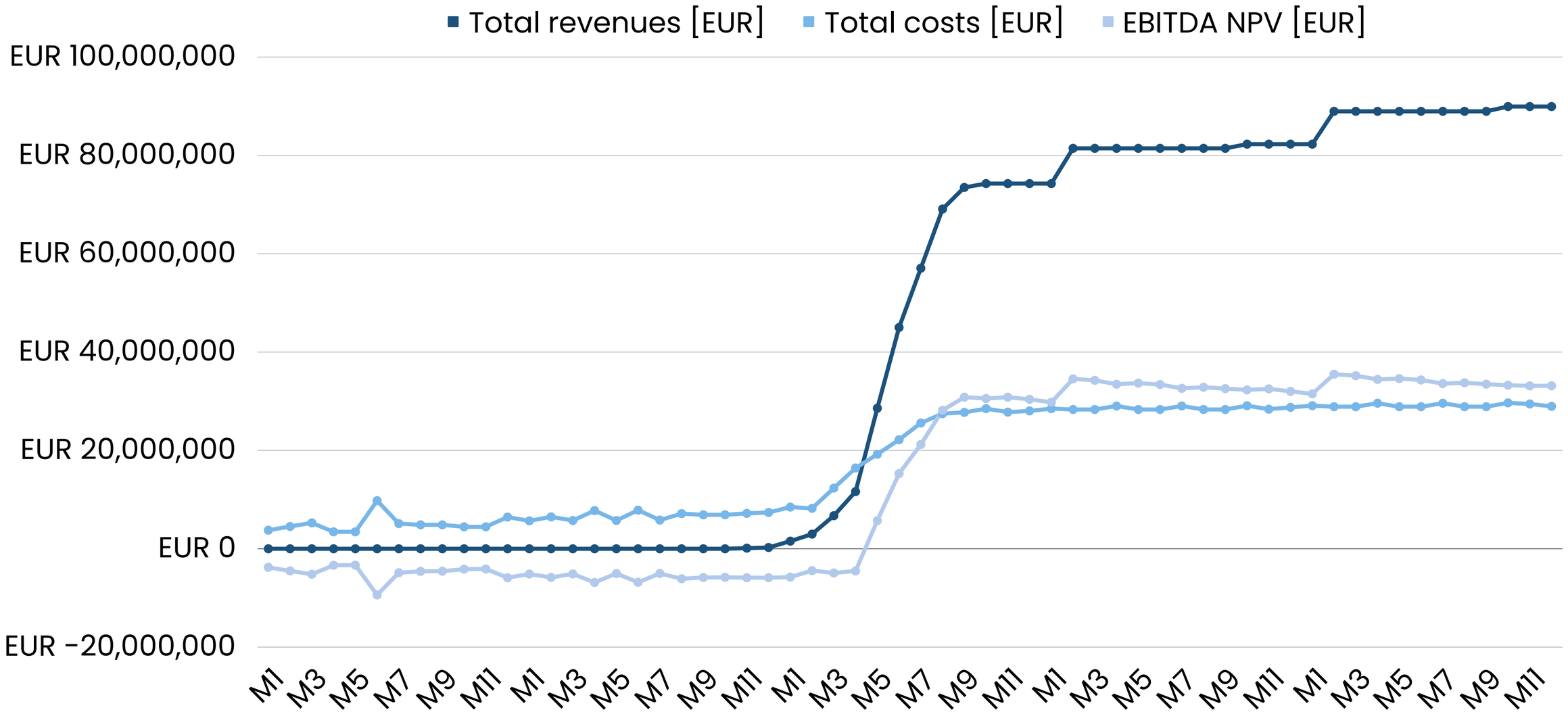
Manufacturing

Manufacturing and delivering the systems to the customers

COST STRUCTURE



FINANCIAL ANALYSIS



SWOT ANALYSIS

Strengths	Weaknesses	Opportunities	Threats
• Ready to test prototypes with the technology missing by the competition • Established collaborations with the Center for Pulmonary Diseases in Olsztyn, which declared to test the devices • Complementary devices for advanced hospital use and affordable home therapy	• Long time and high costs of required certifications • Time-consuming business model which requires decision taking by large institutions	• Rising interest in the pulmonary rehabilitation due to the next COVID-19 and pneumonia waves • Increasing market of telerehabilitation devices (15.3% CAGR) • Continous interest of medias with the project (6 invitations to radios and 2 to television in 2023)	• Risk of cutting down on EU grants for Poland • Risk of changes in medical devices regulations requiring funds

OUR TEAM

Piotr Falkowski
CEO

Maciej Pikuliński
CIO

Anna Pastor
CMO

Bazyli Leczkowski
CTO

Krzysztof Zawalski
Technologist

WHO ARE WE?

We are a team of friends who want to improve the quality of society's living. We develop technologies in-house, as we are all engineers. We have electric, electronic, IT, biorobotics and mechanics experts on board, as well as UX/UI specialists, or even the ones experienced in acquiring funding, IP protection, and conducting research projects.
We are also supported by a team of medical and business experts who consult us in the field out of our speciality.
From September 2023, we collaborate with the Center for Pulmonary Diseases in Olsztyn, which supports us in testing the devices and adjusting them to the real-life patients' needs.

THANK YOU

OUR CONTACT

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