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New perspectives for patients with pancreatic cancer

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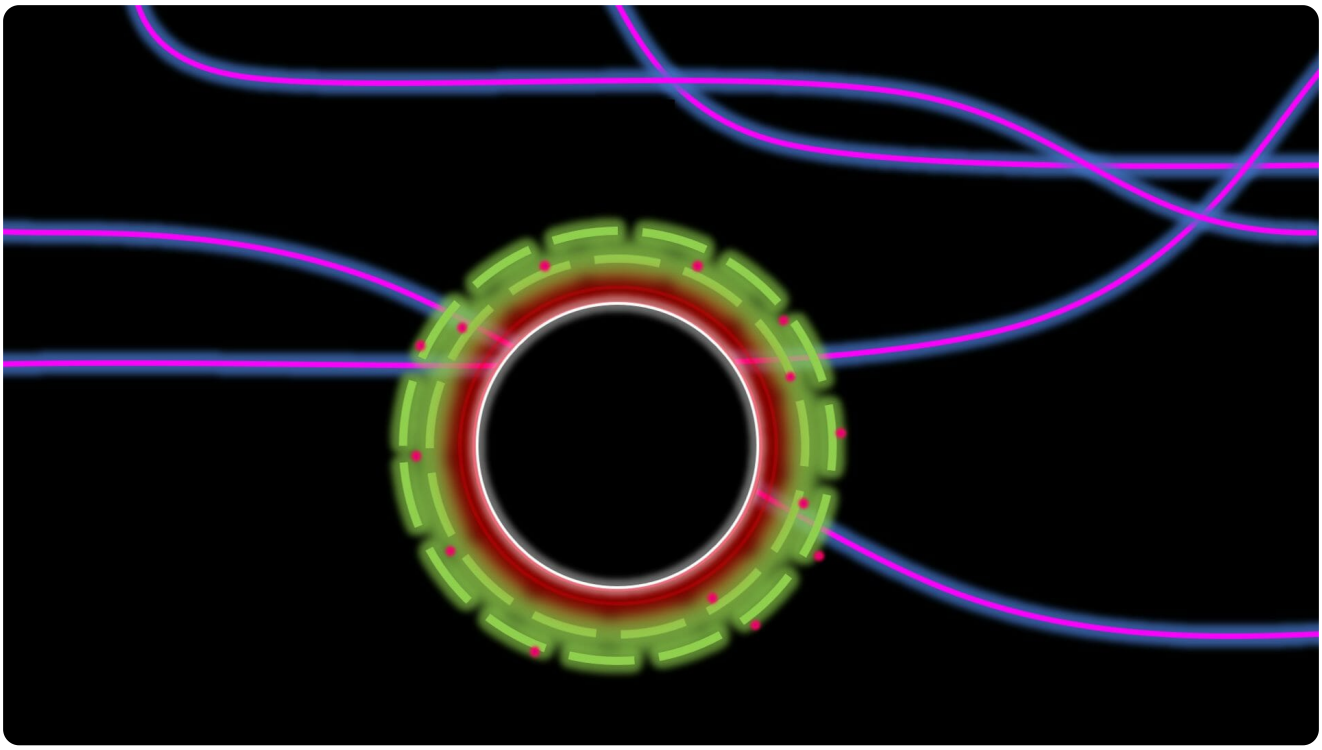

Type Klant	B2B
Gewenst Type Investeerder	Angel Investor, Venture Capital, Incubator-Accelerator, Strategic-Investor
Benodigd Kapitaal	€ 350.000,-
Reeds toegezegde financiering	€ 0,-
Minimale Ticketsize	€ 50.000,-
Sector	Health

Bedrijfsfase	Pre-Seed
Land geregistreerd	Netherlands
Aantal Founders	3
Aantal Huidige Werknemers	0
Maandelijkse Omzet	€ 0,-
Omzet (prognose) komende 12 maanden	€ 0,-
Omzet (prognose) maand 13 - 24	€ 0,-
Huidige Kosten (maandelijks)	€1.000,-

Bedrijfsbeschrijving

Each year in the US alone, we estimate that approximately 40,000 patients with pancreatic, liver, and bile-duct cancer are told they are inoperable because the tumor is growing around major blood vessels, making it unlikely for surgeons to operate successfully.

There is a need for a treatment that could clear blood vessels from tumor involvement. That is why we are developing an innovative perivascular ablation solution aimed at creating clean margins around blood vessels, clearing the way for surgeons to operate and ultimately improving the patient’s chances for survival.

Unlike competing approaches, our perivascular ablation is potentially effective in more patients and becomes quickly visible on CT scans as soon as 48 hours after ablation, allowing for rapid surgery within a week.

Our target customers are abdominal surgeons and interventional radiologists at top cancer centers with high volumes of hepato-pancreato-biliary (HPB) surgeries. Our geographic markets include the US, Canada, Europe, Japan, and South Korea. We estimate the market sizes as follows: a global TAM of €2.3 billion, a US-CA SAM of €760 million, and a US-CA-JP-KR SOM of 10-80 million over years 1-3 after approval.

We have previously conducted successful simulation studies at UHN in Toronto and recently completed a dose-escalating proof-of-concept study on a large animal model at IHU in Strasbourg. The results are encouraging to such a degree that we are now initiating a multi-center Phase II clinical study involving 6-12 pancreatic cancer patients at Radboud UMC in Nijmegen, Amsterdam UMC, and UMC Groningen. First patient enrollment is planned for early 2024, with trial completion expected in the same year.

Business Model

The platform comprises the following drugs and devices:

- Ablation treatment planning and verification software (software-as-a-service)
- An energy-activatable drug (consumable)
- A diode laser emitting near-infrared energy (capital expenditure)
- An infrared energy-emitting endovascular balloon catheter (disposable device)

It provides an attractive business model with several revenue streams at attractive profit margins.

In the first years, we aim to stay small and focused and consciously avoid building up a large sales force. Instead, we plan to utilize our existing relationships with the top cancer centers, focusing solely on them and selling directly to them. They have access to the highest volume of pancreatic cancer patients and will influence and drive adoption by smaller hospitals.

- In year 1 after approval, we will start in the US with only 10 customers, generating €10-20 million in revenue.
- In year 2, we will expand to 20 customers in the US and Europe, generating €20-40 million in revenue.
- Moving into year 3, we will target 40 customers in the US, EU, and Japan, generating €40-80 million in revenue.

After that, we will seek an exit to a large device company, such as Medtronic, Boston Scientific, Abbott, etc.

Our price point per treatment is estimated at €20k, benchmarked against similar interventional treatments such as stroke thrombectomy or TAVI, which may affect the quality of life and survival.

USP's

Unlike competing approaches, our perivascular ablation is potentially effective in a larger number of patients and becomes quickly visible on CT scans as soon as 48 hours after ablation. This allows for rapid surgery within a week.

Competition:

Several competing approaches are currently being evaluated. One category includes technologies attempting to enhance chemotherapy. Generally, this approach takes several months and cycles of chemotherapy, and it does not downstage all patients effectively. In contrast, our approach is competitive due to its faster response time (48 hours after treatment) and our aim to effectively downstage a higher proportion of patients.

Another category is locoregional ablation, such as irreversible electroporation. This method requires a highly skilled expert team to accurately place needles into the pancreas and is associated with complications. In comparison, we believe our technology platform is competitive as it is likely easier to perform, requires less skill, and potentially has lower complication rates.

Investeringsbehoefte

We are requesting a pre-seed investment of €350K to initiate the Phase II clinical study and begin treating the first patients. This significant milestone will transform and mature our company from a pre-clinical to a clinic-stage start-up. It will also substantially increase our company valuation and enhance our chances of attracting future investors for seed funding. In line with this goal, we have already started discussions with Angels, Family Offices, and Venture Capital firms. Importantly, we have received a ‘Letter of Intent to Invest’ from a Strategic Partner, conditional upon ethics approval and the commencement of the clinical study.

The breakdown of expenses for the Phase II clinical study is as follows:

- Regulatory Agent fees: €10k
- Quality Management System Agent fees: €10k
- Travel expenses: €7k
- Clinical study insurance fees: €8k
- Transferring the patent application from the PCT into the regional phases: €45k
- CDMO for product (4x) development: €210k
- Trial site set up and enrollment fees: €60k

Ervaring Founder(s)

The company is managed by a passionate team of three senior founders (CSO, CMO, CEO). Our team has several decades of combined medical, scientific, and business experience with the development of drug-device combination products such as these and have direct experience taking these through Phase I/II clinical studies.

Overige Relevante Informatie

At present, our company is bootstrapped and financed by its founders. We estimate **660k EUR has been invested to date**.

Samenvatting

Datum: 8 September 2023

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Contact & Site