

BUSINESS PLAN UVISA

1. Brief Introduction

Uvisa are an ambitious FemTech company working to address the challenge reportedly faced by 138 million women worldwide, of recurrent vaginitis caused by bacterial and fungal infections. Harnessing the antimicrobial effects of long-wave UV radiation within a small, insertable device, the product will treat vaginal infections in a matter of minutes. A substantial decrease in treatment time of traditional solutions. It is a drug free, effective, and safe option in a world where antibiotic resistance is cited as one of the top 10 global threats to humanity by the World Health Organisation (WHO). Additionally, research has shown that 45% of existing over the counter medications (OTC) are not effective in treating the conditionⁱ. It is an innovative solution using technology that is already established within the dermatological sector. We are currently working on product development, regulatory approval, and IP. Uvisa have also already established research agreements with clinicians who have agreed to help trial the product in a clinical environment, and to conduct additional research to further refine the solution and value proposition. Uvisa have recently won the Health category in the Danish Venture Cup's [National Startup Competition](#) and been named a finalist in the Danish Technical University (DTU) [X-Tech](#) competition within Denmark.

Video pitch: https://youtu.be/2562nH_qlBM

2. Product and /or Service Description

2.1 Customer Pain

Vaginitis is a condition characterized as inflammation of the vagina that can result in discharge, itching and painⁱⁱ, and if left untreated can increase the chances of contracting a sexually transmitted infection (STI)ⁱⁱⁱ, and even cause infertility^{iv}. Vulvovaginal candidiasis alone is a problem that is reported to recurrently affect 138 million women worldwide, and this number is expected to reach 158 million by 2030^v. In addition to this, the general prevalence of bacterial vaginosis within the population ranges from 23% to 29% in different regions^{vi}. Evidence suggests that worldwide numbers of people suffering with recurrent vaginitis are much higher than those reported, since many women choose to self-treat rather than visiting a doctor. Currently, the only products available to treat this condition are over the counter pharmaceuticals, applied as a cream or in a pessary, or prescription antibiotics. The OTC products are usually targeted at either bacteria or fungi and can take up to a week to be effective if being used for the correct condition. Antibiotics are effective but have considerable unpleasant side effects. Additionally, many species of bacteria responsible for vaginal infections have shown a propensity for quickly developing antibiotic resistance. There is currently no non-pharmacological option available for the effective treatment of vaginitis.

2.2 Business Idea

Uvisa's minimum viable product (MVP) is a small, cylindrical device containing several battery powered LEDs arranged in such a way to emit light outwardly. It is designed to be inserted into the vagina. The device is reusable and has a shelf-life of 3+ years. We also eventually plan to incorporate a pH sensor to turn the product in to a smart device. Then, the user will be able to monitor their vaginal health via the use of a mobile app, where they can also enter additional information about symptoms of infection and their menstrual cycle. This will help them to begin to identify patterns in their own cycles and treat issues before symptoms become problematic.

Unfortunately, due to currently being in the process of applying for a patent, we are not able to show the device designs.

2.3 Value Proposition

Early research^{vii} indicates that the Uvisa device would remove the problem of vaginitis, regardless of whether it is bacterial or fungal in nature, meaning that the user does not need to know the underlying cause of their condition. Additional research indicates that the micro-organisms will be killed after a single 20 - 30 minute exposure to the light, making it much faster than traditional remedies. Additionally, because the device is reusable it is a more sustainable option. Another advantage of being a non-pharmacological solution is that it is in line with WHO directives to find suitable alternatives to antimicrobial drugs in the fight against antibiotic resistance^{viii}. It also means that sufferers of chronic bacterial vaginosis finally have an effective treatment that is side-effect free, whilst saving GPs time assessing conditions and writing prescriptions. Adding the health tracking element will eventually give women a deeper insight into the intimate workings of their own bodies. Wearable health monitoring technologies are already growing in popular demand^{ix} and we expect this trend to continue.

3. Impact

Whilst vaginitis is typically not life threatening to the person suffering with the condition, it can severely impact quality of life^x and can even lead to infertility in women of reproductive age. However, for many years this condition has been considered little more than an inconvenience. Uvisa will create a social and environmental impact, as we are a female-founded organisation working to develop a scientifically researched and innovative solution to this issue. We will normalise discussions about sexual health and wellbeing, by helping to educate people about the less publicly discussed parts of their bodies. Uvisa will also create sustainable products that can be reused for many years. We are predominantly driven by SDG 3 - Good Health & Wellbeing, and SDG 5 - Gender Equality, though do also contribute towards SDG 12 -Responsible Consumption and Production.

4. Business Plan Feasibility

4.1 Customer Profile

Our initial target market consists of women and those with vulvas in the age range of 20 – 50. They are people that suffer with vaginitis on a relatively frequent basis, likely due to changes in vaginal pH caused by a phenotypic disposition within their own microflora, monthly hormonal changes, hormonal changes due to menopause, or by sexual intercourse. They are dissatisfied with the current OTC remedies and are seeking a solution that is more effective, easier to use, and that is better for the environment. We have validated this user persona by conducting surveys and user interviews with approx. 250 women.

4.2 Market

The global vaginitis therapeutics market size was estimated at USD 2.5 billion in 2019 and is expected to reach USD 4.4 billion (DKK 27 billion) by 2027^{xi}. Furthermore, the global femtech market size was valued at USD 18.75 Billion in 2019 and is anticipated to reach USD 60.01 Billion by 2027^{xii}.

We initially plan to target customers in Denmark, but plan to quickly scale to the rest of Scandinavia and the UK, followed quickly by Germany. Looking at the WHO population data for women in the target age range, the prevalence of these infections in these geographical areas, and the recurrence rate; the addressable market within these territories is approximately 13.59 million potential customers. We have also conducted a small-scale market research study of our own where 81% of respondents said that they would be interested in such a product. However, we know that 81% is extremely optimistic and so assume that we may be able to target 50% of those women already purchasing over the counter antifungals or being prescribed antibiotics. This gives us a servicable obtainable market (SOM) of 6.8 million possible customers in Scandinavia, the UK and Germany alone.

However, this is a highly scalable solution that can have global impact. We intend to reach the global market eventually by utilising channel partners and distributors. The global SOM could be as large as 1.9 billion customers (based on WHO population data from 2020^{xiii}).

4.3 Competition

The main competitor within Europe is the Canesten brand owned by Bayer Healthcare and which predominantly contains antifungal medications to treat vulvovaginal candidiasis (svampe/thrush). Though, one study^{xiv} revealed that 2 out of 3 women who self-diagnose and use OTC antifungals, do not have this, but rather bacterial vaginosis or another type of infection.

Prescription drugs used to treat bacterial vaginosis include metronidazole, clindamycin and tinidazole most commonly, with metronidazole holding the largest market share in this category at just under 50%^{xv}. However, this is a particularly potent antibiotic that has several known side-effects. For people with recurrent bacterial vaginosis, they are

often required to take this drug every month for a week, during which they are not permitted to drink alcohol and often experience unpleasant side-effects such as vomiting, headaches and an upset stomach. There is currently no effective non-pharmacological option available for the treatment of vaginitis, which gives Uvisa an immediate and huge competitive advantage.

4.4 Business Model

We will primarily have a B2C business model and plan to make initial sales directly through our own website. However, to compete with existing OTC medications we need our products to be stocked in physical pharmacy stores. Therefore, we will eventually sell to these retailers through distributors.

We are also investigating the possibility of subsidising the cost of the solution for the end user, by being an approved treatment by insurers or healthcare providers; though this is a long way in the future and not yet thoroughly examined or well understood. Finally, a Robin Hood type model is also being considered, where we sell at a higher price in developed countries so that we can then provide our solution to lesser developed countries where women's access to medication and healthcare is poor, at a very small or no cost.

5. Team Structure

Our core team is made up of the following individuals.

- Ella Harris. CEO & Founder. Life science background and 11+ years of experience working in business development and product management. Currently taking the MSc Technology Entrepreneurship at DTU.
- Nick Jones. CTO & Founder. Background in product design engineering, mechanical and manufacturing engineering, and well versed in quality management systems, finance, and consumer law. Also taking the MSc Technology Entrepreneurship at DTU.
- Ourania Pappa. Product Development. Physics background with practical hands-on experience in engineering electronic devices, and additional expertise in computer programming.
- Gizem Simsek. Scientific Officer. Biology background now undertaking a master's in microbiology. Passionate feminist with first-hand experience of the issue.

In addition to the core team and to the strategic partners listed above, we have a carefully selected board of advisors consisting of:

- Dr. Paul-Michael Petersen, Group Lead & Professor, DTU Photonics
- Jimmy Bak, Founder & CEO, UV Clinical Apps
- Sofia Wareham Mathiassen, STAR industrial PhD Fellow, NovoNordisk
- Scott Young, Head of Manufacturing, Elvie
- Jan Dombernowsky, CEO, Intellex Healthcare
- Thorbjørn Hjarndal, Head of Commercial, Aspen Pharma (Nordic)
- Jørgen Skov Jensen, Head of Research Unit for Reproductive Tract Microbiology, Statens Serum Institut

6. Current Status and Plan

6.1 Prototyping and Testing

Uvisa conducted the first proof of concept testing with their first technical prototype in May 2021, the results of which were very encouraging. It was a rudimentary lab test using only candida albicans (the fungus responsible for svampe / thrush), whereby live candida was plated on to two agar plates. One plate was then exposed to the device prototype and the other was not, and then both plates were placed in an incubator for 24 hours. The plate exposed to the device had no growth, meaning all microorganisms were killed by the exposure. (see Appendix 1) Uvisa will begin more extensive lab trials from November as Gizem will be making it her master's thesis, and ahead of then the rest of the team will be working on iterating on the technical and visual prototypes.

6.2 Traction

Uvisa have conducted several user surveys and interviews (see Appendices 2 - 4). The first was a very small social media poll to gauge initial interest in the idea. As this was encouraging, we then conducted a small survey of 35 anonymous respondents, of

which 69% said they would be interested in using a product such as ours. To validate this further we conducted another survey of almost 150 people where most respondents were aged 21 – 40 and 62.5% of them had experienced recurrent vaginitis throughout their lives. Of this group, > 80% expressed a keen interest in purchasing our product. They informed us that they would pay in the region of 400 DKK (≈50 EUR) for the MVP. In addition to this, we have been pitching the idea frequently to over 50 relevant experts and have consistently expressed with interest and encouragement. As described previously, many of these experts have now agreed to either be research partners with us or have taken a seat on our advisory board. Furthermore, we have already secured soft funding of 76,000 DKK through a Skylab Funding grant in partnership with their associated foundations. Finally, we have recently been named as a finalists in the DTU X-Tech start-up competition taking place in December 2021, winning a further 20,000 DKK. We were also awarded best Health startup at Venture Cup Denmark's National Student Startup Competition, winning a further 10,000 DKK and a place in the Student Startup World Cup set to take place in November 2021.

6.3 Marketing and Sales

As we are in the process of creating a medical device which requires regulatory approval we are still at the very start of our sales and marketing journey. We are however in the process of establishing our brand identity and are developing a website to accompany this. We have also just signed a contract with a consulting firm to extend our market research, including conducting focus groups with potential customers, and to devise a marketing strategy that includes a plan for PR and social media for our initial target markets. We want our customers to know that we are experts in the vaginal microbiome and in female related issues, and so we will create meaningful and educational content about these topics to open a dialogue. This content will be driven by the peer-reviewed scientific publications we plan to produce as Gizem conducts her master's thesis, and as we begin to move forward with clinical trials. We also plan to attend and speak at relevant conferences, events, and exhibitions where we can build brand awareness and exhibit the product. Events such as MedTech Live, The MedTech Forum, TechBBQ and so on. By being a knowledge provider and expert, we will gain sufficient support to start making direct sales through our own website, something we are already implementing using a preliminary sign-up page. By doing this we will show sufficient traction to demonstrate to relevant retailers that our product would add significant value in their portfolio of women's health products.

6.4 Financial Strategy & Budget

Uvisa have devised a 6 year Income Statement factoring in all anticipated costs with some contingency, making realistic forecasts about market capture, and pricing the product based on manufacturing costs and price point consumers would be willing to pay (see Appendix 5). Given the long development and approval time, this would give a break-even in operation year 6, one year after releasing the product to market. To finance this we have a relatively straightforward strategy of running on soft-funding and bootstrapping to begin with, then turning to accelerator programmes that come

with finance, before seeking venture capital in the third operating year. Operation year one began in April 2021 when the company was formally incorporated.

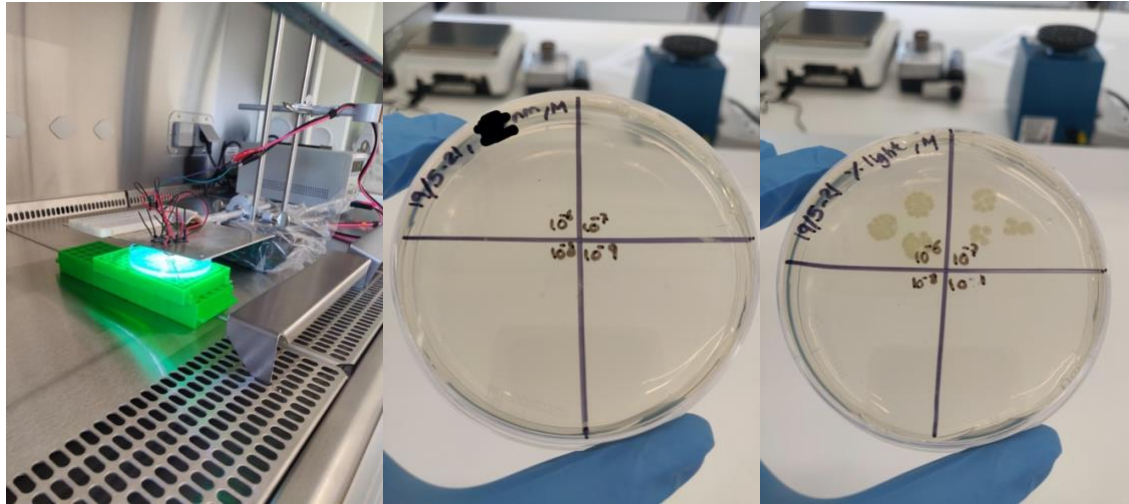
A caveat to the financial plan and strategy is that it was written under several assumptions. The first being, that Uvisa will focus on a single MVP product only in this timeframe and will operate with the minimum financing possible. Secondly, that Uvisa can obtain a patent for their MVP device and will continue to operate for the next 5 years. Finally, we have also made some very conservative estimates about market capture so that we are not presenting a wildly imaginative expected revenue. However, we believe that with additional funding and budget allocated to strategic marketing and PR we may be able to scale even quicker, addressing markets not included in these projections. We also hope to develop an R&D and product pipeline, so that before 2026 Uvisa have developed a Phase 2 product at the very minimum. Our vision is to ultimately offer a variety of products and services in the global women's health space, but at this stage of the company formation we have not factored this in.

6.5 Risk Analysis

A risk matrix was compiled, considering financial, technical, social, and legal risks (see Appendix 6). Potential risks in each of these categories were analysed and a mitigation strategy was outlined. The two biggest threats to the success of Uvisa are the long time to revenue and the dependency on successful clinical trials. Uvisa's long time to revenue is largely due to the regulatory process. This is a risk that is unavoidable, however Uvisa plans to mitigate this by recruiting a microbiologist to the founding team, to avoid contracting out work by conducting high fidelity lab tests in-house. This will also allow us to iterate faster. Furthermore, we will utilise our strong relationships with experts in the field to decrease uncertainty prior to clinical trials. Long term, Uvisa will consider partnering with an established medical device company, decreasing financial pressure by providing facilities, personnel, and wages.

APPENDICES

Appendix 1: Photos of preliminary POC tests. (Left to right: setup, plate that was exposed, plate that wasn't.)



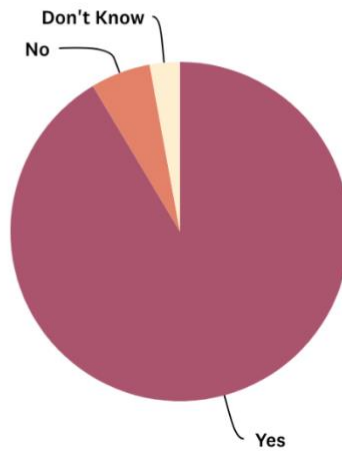
Appendix 2: SoMe Poll (October 2020)



Appendix 3: First User Survey (November 2020)

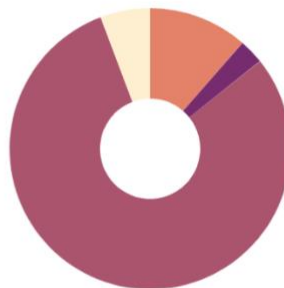
Have you ever experienced itching and discomfort in the vagina caused by some kind of yeast or bacterial infection?

Answered: 35 Skipped: 0



How do you typically treat this problem?

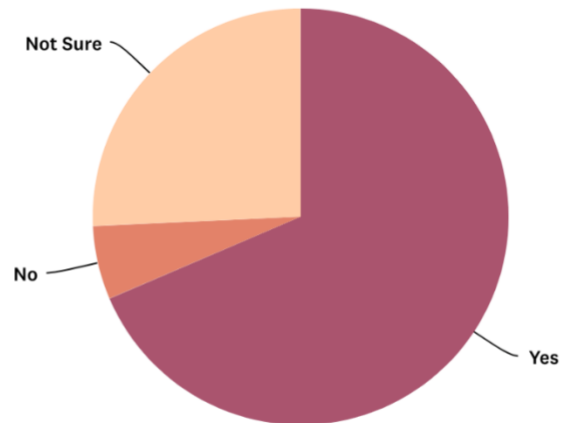
Answered: 35 Skipped: 0



■ Visit the GP ■ Visit the Gynecologist
■ Buy Canesten (or similar) from local pharmacy or drug store with no need for prescription
■ Use natural herbal products ■ Other (please specify)

If you could purchase a product as described above (reusable, insertable device, using only light to kill bacteria/yeast in a single 20 min session) would you buy it?

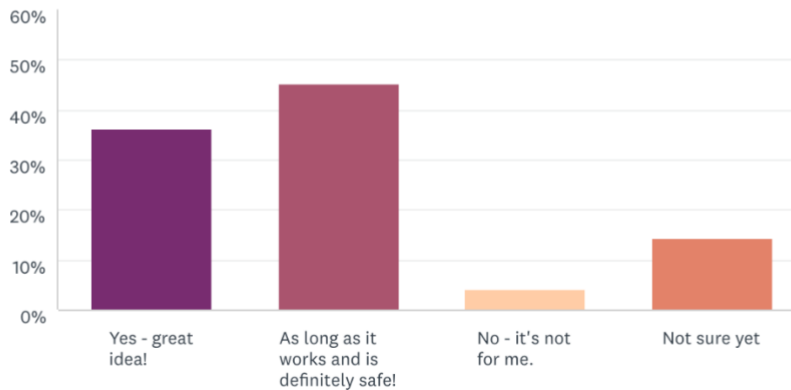
Answered: 35 Skipped: 0



Appendix 4: Second User Survey (March 2021)

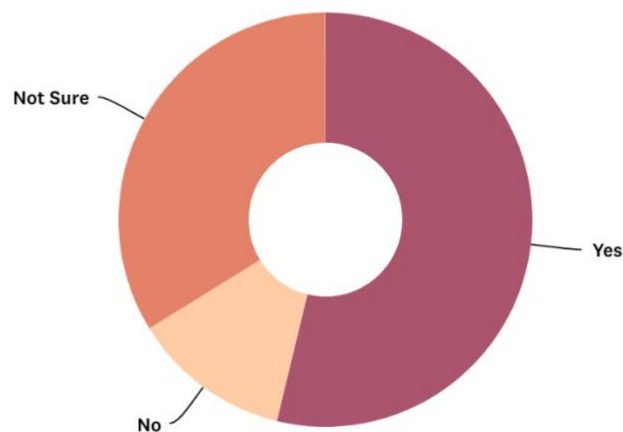
If you could purchase a product as described above (reusable, insertable device, using only light to kill bacteria/yeast in a single 20 min session) would you buy it?

Answered: 146 Skipped: 0



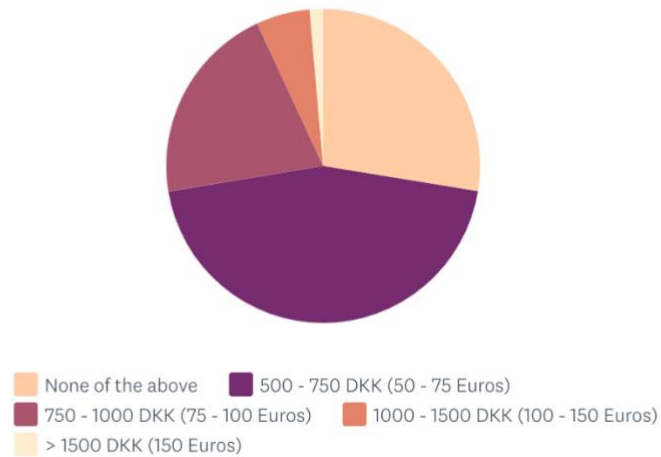
Would you like the device to be a "smart" device? (aka. be able to monitor certain levels within the vagina.)

Answered: 145 Skipped: 1



What would you pay for a "smart" device that personalises treatment duration and tracks overall vaginal health?

Answered: 145 Skipped: 1



Appendix 5: Forecasted Income Statement

REVENUE	2021	2022	2023	2024	2025	2026
Gross Sales	0 DKK	0 DKK	0 DKK	0 DKK	14,438,847 DKK	42,469,885 DKK
Less Sales Returns and Allowances	0 DKK	0 DKK	0 DKK	0 DKK	0 DKK	0 DKK
NET SALES	0 DKK	0 DKK	0 DKK	0 DKK	14,438,847 DKK	42,469,885 DKK
COST OF SALES	2021	2022	2023	2024	2025	2026
Beginning inventory	0 DKK	0 DKK	0 DKK	0 DKK	7,028,081 DKK	18,364,718 DKK
Plus Goods Purchased or Manufactured	0 DKK	0 DKK	0 DKK	7,028,081 DKK	18,364,718 DKK	20,201,190 DKK
TOTAL GOODS AVAILABLE	0 DKK	0 DKK	0 DKK	7,028,081 DKK	25,392,799 DKK	38,565,908 DKK
Less ending inventory	0 DKK	0 DKK	0 DKK	7,028,081 DKK	18,364,718 DKK	20,201,190 DKK
TOTAL COST OF GOODS SOLD (COGS)	0 DKK	0 DKK	0 DKK	0 DKK	7,028,081 DKK	18,364,718 DKK
GROSS PROFIT (LOSS)	0 DKK	0 DKK	0 DKK	0 DKK	7,410,766 DKK	24,105,167 DKK
OPERATING EXPENSES	2021	2022	2023	2024	2025	2026
SALES & MARKETING						
Salaries and Wages	0 DKK	0 DKK	480,000 DKK	499,200 DKK	999,168 DKK	1,039,135 DKK
Marketing & Advertising	2,000 DKK	89,000 DKK	251,000 DKK	556,000 DKK	756,000 DKK	1,210,000 DKK
Travel	0 DKK	9,000 DKK	42,800 DKK	105,600 DKK	186,000 DKK	125,600 DKK
R&D						
Prototyping	34,970	50,000	200,000	350,000	200,000	200,000
Patent & IP	40,000	10,000	100,000	50,000	50,000	50,000
Regulatory Approval	0 DKK	0 DKK	635,072 DKK	450,000 DKK	0 DKK	0 DKK
GENERAL AND ADMINISTRATION						
Salaries and Wages	0 DKK	220,000 DKK	1,380,000 DKK	4,159,200 DKK	6,843,168 DKK	7,954,495 DKK
Employee Benefits	0 DKK	3,600 DKK	11,400 DKK	116,800 DKK	984,234 DKK	1,148,363 DKK
Payroll & Employee Expenses	0 DKK	98,400 DKK	295,200 DKK	631,008 DKK	1,013,080 DKK	1,151,236 DKK
Accounting, Legal & Auditing	17,000 DKK	26,000 DKK	51,000 DKK	77,000 DKK	92,000 DKK	92,000 DKK
Office & Equipment	0 DKK	7,200 DKK	40,000 DKK	55,000 DKK	641,000 DKK	720,000 DKK
Other Insurances	0 DKK	0 DKK	0 DKK	24,000 DKK	48,000 DKK	72,000 DKK
Depreciation	0 DKK	0 DKK	0 DKK	976,797 DKK	976,797 DKK	976,797 DKK
TOTAL OPERATING EXPENSES	93,970 DKK	513,200 DKK	3,486,472 DKK	8,050,605 DKK	12,789,447 DKK	14,739,625 DKK
EBIT	-93,970 DKK	-513,200 DKK	-3,486,472 DKK	-8,050,605 DKK	-5,378,681 DKK	9,365,542 DKK
Interest	0 DKK	6,000 DKK	6,000 DKK	120,000 DKK	120,000 DKK	0 DKK
Corporation Tax (CIT)	0 DKK	0 DKK	0 DKK	0 DKK	0 DKK	2,060,419 DKK
Net Profit	-93,970 DKK	-519,200 DKK	-3,492,472 DKK	-8,170,605 DKK	-5,498,681 DKK	7,305,123 DKK

Appendix 6: Risk Matrix

Risk Category	Risk	Mitigation Measures
Financial	High cost of regulatory process, including in vivo and in vitro testing, clinical trials and regulatory consulting.	Begin the process early, and plan for all regulatory costs early. Partner with academic institutions as much as possible to cut costs during early testing.
Financial	Long time to revenue, due to development time.	Take advantage of the time which the founders are students and pay no salaries. Apply for soft funding at every opportunity.
Technical	Lack of certainty regarding effectiveness of product. There is yet to be any significant real-world evidence of the effectiveness of UV light treating vaginitis.	Start in vitro testing early and be willing to pivot early if required.
Technical	Wide range of technical disciplines required (microbiology, medicine, thermodynamics, electronics, etc.)	Partner with academic institutions as much as possible, find experienced mentors and start with a diverse team that can develop skills as needed.
Technical	An existing patent for a similar device has been filed, however the claims are different to our device with the exception of the USA, where the patent has relatively broad claims)	Focus on design-around strategy from the beginning and involve regulators early to secure intellectual property that can be FDA approved and CE marked.
Social	Consumers have deep set habits around the way they handle vaginitis. Uvisa found most women do not consult a medical professional for mild cases.	Target younger consumers through clinics. Younger women with less experience with vaginal issues are more likely to seek help and have less deep-set habits.
Legal	Safety issues, with regard to UV exposure, electrical issues or over-heating could lead to legal exposure and damage to reputation.	Develop product to fit ISO standards. Conduct safety tests using human cells, rather than just efficacy tests. Constantly review product safety even after regulatory approval.

Team	Core team does not have experience in the development of medical devices	The team has established relationships with mentors with many years in the field, with experience in all facets of the business.
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ADDITIONAL SOURCES

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