

## **THERAPEUTICAL AREA AND PROBLEM TARGETED**

**Describe the problem you solve: Position of the problem, novel approach, achievements to date...**

The problem we aim to solve is to ensure the access to early diagnosis through urinalysis. Traditional approaches to urinalysis, such as urine dipsticks and laboratory automation, present limits in terms of accuracy, accessibility, and cost-effectiveness. These methods often provide either limited information (in the case of the dipstick) or require complex and time-consuming processes, limiting the timely diagnosis and monitoring of various medical conditions.

Our novel device revolutionizes the landscape of urine diagnostics by introducing an innovative device that combines the best features of urine dipsticks and laboratory automation, bringing significant changes:

1. Bringing the medical laboratory closer to the patient: by moving the traditional medical laboratory closer to the point of care, improving the overall healthcare journey and patient experience.
2. Transitioning towards predictive and preventive medicine: Usense aims to be a leader player of this paradigm change in healthcare with the help of our device providing routine health information to take early action.
3. Enhancing access to diagnostics in underserved areas: One of our core missions is to improve access to diagnostics in underserved and vulnerable regions. By leveraging our innovative solutions, we are breaking down geographical barriers and bridging the gap in healthcare services. Our technologies enable the delivery of accurate and timely diagnostics, even in remote or resource-constrained areas, thereby improving healthcare equity and reducing health disparities.

Since the inception of our project, we have achieved significant milestones and garnered recognition within the medical community. We have successfully developed a functional prototype of our device, validating its proof-of-concept for the detection of biomarkers in urine. Building upon this success, we have obtained patents to protect our technology, product ecosystem, and overall approach. Furthermore, we have achieved important regulatory milestones, with the CE marking of our device and the implementation of robust quality management systems.

## **DESCRIBE YOUR TARGET MARKET CHARACTERISTICS**

**What are your targeted markets and their size? Describe other relevant attributes: growth, strengths, weaknesses, trends, disruptions. Who are your competitors on the market?**

### **Market size**

Usense operates in the urine analysis market, which is estimated to reach nearly \$5 billion by 2024, compared to \$3.2 billion in 2019. This market is experiencing significant growth, with a CAGR of 7%, driven by the increasing prevalence of chronic kidney diseases and urinary tract infections.

The urine analysis market is complex and segmented, involving multiple stakeholders such as diagnostic laboratories, hospitals, clinics, research institutions, and healthcare facilities. Various users, including biologists, physicians, nurses, and technicians, rely on urine analysis for early diagnosis and patient management. For instance, in France alone, approximately 380 million urine test strips are used annually.

Usense can fit into the existing use cases of urine test strips but can go beyond by also offering the potential to replace certain laboratory automation systems. The market's focus on early diagnosis and patient management presents significant opportunities for Usense. By providing a comprehensive and user-friendly urine analysis device, we can address the needs of various stakeholders and offer a quick



and efficient alternative to traditional urine analysis methods. Our solution has the potential to improve diagnostic accuracy, reduce turnaround times, and enhance patient care. Furthermore, our device's versatility allows it to be utilized in different healthcare settings, from point-of-care environments to diagnostic laboratories, enabling seamless integration into existing workflows.

### **Targeted clients**

Our main targeted clients segments are:

- Private biological analysis laboratories: These laboratories currently perform urine assessments in their technical center. Usense improves the logistics of routine analysis by enabling faster and more accurate screening of samples with infections. This potentially eliminates the need for culture testing for many samples (as 90% of infection-related measurements yield negative results), resulting in significant cost savings for the laboratories.
- Hospitals and clinics within internal biological laboratories: Our device allows these laboratories to generate rapid and systematic biological monitoring during consultations. This greatly simplifies the patient care journey as urine analysis and medical consultations can be conducted in the same location.
- Hospitals and clinics within the services (emergency departments, nephrology, gynecology, etc.): Under the supervision of a biologist, our solution offers a user-friendly tool at the patient bedside, similar to urine test strips while providing real-time, reliable, and relevant quantitative information to physicians. This enables better patient management and orientation.
- Other healthcare facilities (nursing homes, immediate medical care centers, home care, etc.) through decentralized biology: To support evolving trends in rapid patient care and increased service levels offered by biology professionals, our device integrates into a care package that facilitates admission and discharge assessments, as well as health monitoring by facilitating screening and referral for additional analyses or treatments. To address these use cases, our primary stakeholders are the biologists, who are the key decision-makers and central actors in urine analysis. The laboratories, as purchasers of the Usense product, will have the freedom to choose the use cases and device implementation that best align with their needs and objectives.

As the urine analysis market continues to grow, Usense's innovative approach and technological advancements position us as a competitive player in the industry. Our goal is to provide healthcare professionals with a reliable and convenient tool for urine analysis, ultimately improving patient outcomes and contributing to the advancement of personalized healthcare.

### **Market trends**

The urinalysis market is expected to grow through several drivers:

- Increasing prevalence of chronic diseases: The rising prevalence of chronic diseases such as diabetes and kidney diseases has led to an increased demand for urine analysis tests to monitor disease progression and adjust treatments accordingly.
- Adoption of advanced technologies: Technological advancements in urine analysis, including the use of wearable devices and artificial intelligence, can enhance the accuracy and reliability of test results while reducing costs.
- Growing demand for non-invasive tests: Patients prefer non-invasive tests like urine analysis over other analytical methods such as biopsies, leading to an increased demand for these services.

### **WHAT IS YOUR VALUE PROPOSITION?**



**What is your solution / program name?**

JIMINI Urinalysis Solution

**Please describe your solution and highlight its performance/benefits. Describe Preclinical & Clinical aspects of the product?**

Our solution, JIMINI, is an innovative diagnostic device that revolutionizes urinalysis by providing instant and accurate measurements of various biomarkers. The device combines ultra miniaturized optical and electro-analytical sensing technologies, enabling quantitative analysis of biomarkers in urine samples in a matter of seconds.

Usense underwent an analytical validation to ensure its performance and reliability. Extensive laboratory experiments were conducted using a diverse range of urine samples to establish correlation and accuracy with gold-standard laboratory methods. The results demonstrated excellent concordance between JIMINI and usual laboratory techniques, showcasing its precision and diagnostic capabilities.

**What is your competitive edge? How does your solution compare to competition (existing solutions on the market or solutions being developed by competitors)?**

In the urinalysis market there are currently 2 main types of solutions: "Reference" methods: These are laboratory automation devices (spectrometers, osmometers, etc.) that allow for precise measurement of biological markers but are stationary, bulky, and costly. We differentiate ourselves from these actors by:

- Our diagnostic speed: providing results in a matter of seconds.
- Our mobility: our device can be used directly at the point of care.
- Our cost-effectiveness: both in terms of acquisition cost and the fact that we do not require consumables.

Urine test strips: These strips provide a qualitative analysis (colorimetric system) with a maximum of 8-12 parameters using chemical reagents. While these tools offer a quick initial analysis, they are highly imprecise, limiting their clinical decision-making value. We differentiate ourselves from these actors by:

- Our diagnostic accuracy: providing precise quantitative measurements.
- Our cost-effectiveness: our device is reusable and becomes more cost-effective than urine test strips after a certain volume.
- Reduction in interpretation errors: as the interpretation of urine test strips is often operator-dependent.

In addition to our advantages that set us apart from existing solutions, Usense has implemented several barriers to entry (both structural and strategic) to maintain our competitive edge:

- The use of complex and cutting-edge technologies.
- Proprietary algorithms developed in-house.
- An unprecedented database of over several thousands urine samples created internally with our strategic partners.
- Preferred access to urine samples for research and development.
- Robust and validated patent strategy.
- Regulatory milestones achieved, including CE marking and certification of internal quality systems.
- Partnerships established with domain experts. Guidance and support from industry leaders.



## BUSINESS MODEL

**What will be your marketing and sales strategy (prospection, distribution channels, etc.)? How do you acquire customers? What does a typical sales cycle look like?**

Our marketing and sales strategy is designed to reach users, decision-makers, and purchasers through identified distribution channels.

Our initial approach will focus on the B2B market, targeting analysis laboratories, hospitals, and clinics. By establishing partnerships and collaborations with key players in the healthcare industry, such as Biogroup and Eurobio Scientific, we aim to penetrate these B2B channels and make our innovative device widely available to healthcare professionals. This B2B strategy allows us to gain market traction, build credibility, and refine our product based on user feedback.

Once we have established a strong presence and achieved success in the B2B market, we plan to expand into the B2B2C segment. This entails collaborating with healthcare providers and practitioners to incorporate our device into their patient care processes. By leveraging their networks and expertise, we can reach a broader customer base and provide patients with direct access to the benefits of our device.

Ultimately, our long-term vision includes a B2C approach, where individuals can directly acquire and utilize our device for personal health monitoring and management. With advancements in technology, growing consumer interest in proactive healthcare, and the shift towards personalized medicine, we believe that offering our device to consumers will empower individuals to take control of their health and well-being.

## FINANCIAL

**What will be your operational costs? Your expected revenue? How will the project be financed (Self-financing, Investors, etc.)? What are the capital requirements? What are the potential risks you may encounter and your contingency plan to address these risks (regulatory, financial, economic, technical, scientific, etc.)? What will be your needs & costs in terms of regulation (FDA accreditation, reimbursement, etc.)?**

### Operational cost

The operational costs of our project encompass various components:

- As a hardware medical device company, a significant portion of these expenses includes the procurement of raw materials and subcontracting services for the production of our devices. We strive to maintain high-quality standards in manufacturing while optimizing costs to ensure the affordability and accessibility of our products.
- As a deeptech healthcare company, continuous research and development efforts are crucial. This entails investment in new technologies, talent acquisition, and ongoing scientific exploration to improve our device and expand its capabilities.

### Expected revenue

The economic model of Usense is a subscription-based business model, providing healthcare professionals with access to our medical device and unlimited diagnostic capabilities. With this subscription-based approach, we aim to offer flexibility and cost-effectiveness to our clients, ensuring they have access to the necessary diagnostic tools without incurring significant upfront costs.



In 2022, Usense generated a revenue close to €100 000 through pre-orders from several of our partner clients. These pre-orders validate the relevance of our approach in the medical field and demonstrate the demand for our innovative solutions. Looking ahead, we have projected sales of €300 000 for the year 2023 and €1,5 millions in 2024 for the first entire year of commercialization. These projected sales reflect the growing market interest in our medical device and the anticipated expansion of our customer base. As we continue to develop and refine our product, we are confident in our ability to capture a larger share of the market and drive significant revenue growth.

### **Project financed**

To finance our project, we have undertaken two funding rounds, securing investments from a venture capital firm, major actors of the biological industry and a foundation. Usense completed a seed round in September 2020, raising €300,000, and a series A round in October 2021, raising €5 million.

- Upperside Capital Partners: A specialized investment fund that supports innovative Medtech and Biotech companies.
- Biogroup: A leading group of medical analysis laboratories in France, holding over 25% of the market share in the country and in Europe. Biogroup operates more than 1,600 medical biology sites, including over 800 in the Île-de-France region, serving 100,000 patients daily. In addition to being a shareholder of Usense, Biogroup is also one of our future clients.
- Eurobio Scientific: An integrated player in in vitro medical diagnostics, supplying diagnostic equipment and tests for healthcare professionals. As a recognized specialized distributor, Eurobio Scientific will facilitate the commercialization of the Usense solution in France and internationally.
- Praesens Partners Management: A Belgian foundation with a strong presence in Africa, dedicated to improving access to healthcare systems for people in low-income areas, including the establishment of mobile laboratories. This investment aligns with Usense's "for good" strategy, focusing on social and environmental impact.

The selection of investors during the series A round (Biogroup, Eurobio Scientific, Praesens Partners Management) was mainly driven by the fact that they are all part of Usense's value chain. Beyond the financial investment, these stakeholders are the primary buyers and ambassadors of the solution, recognizing its potential and actively supporting its growth. In addition to these €5,3 million, Usense has completed by raising over €3 millions in non-dilutive funding by winning prestigious awards and call for projects, such as the French innovation contest led by the Government called i-NOV.

Today, Usense is actively preparing for an international Series B funding round with a target of €25 million. This fundraising round will enable us to accelerate the commercialization of our device and expand internationally, especially in North-America. With the successful validation of our technology and the increasing demand for our solutions, we are confident that this additional investment will fast-track our expansion.

At term, we anticipate that the revenue generated from our sales will play a significant role in financing the growth and sustainability of our project. The subscription-based business model of Usense offers a scalable and recurring revenue stream. As we continue to onboard new clients and expand our customer base, we expect our revenue to grow organically. This self-financing model allows us to reduce our reliance on external funding sources and grants us greater control over our financial operations.

### **Potential risks**

Usense has identified several key risks associated with our business.



1. A financial risk, which was addressed by a successful Series A fundraising in 2021, which has provided us with the necessary resources for R&D and early commercialization. The next challenge will be to secure the Serie B fundraising by 2024.
2. In terms of research and development, the development of our solution relies on a comprehensive database of urine samples to train our algorithms. To overcome this challenge, we have established strategic partnerships with reputable healthcare establishments such as the Parisian Hospital Group (AP-HP), ensuring access to a wide range of patient samples.
3. In terms of competition, we can see that the urinalysis sector is becoming more and more active, with many startups entering the market. However, Usense has gained a significant competitive advantage. We possess a strong intellectual property portfolio with patents, deep regulatory knowledge, valuable know-how, and exclusive partnerships that set us apart in the market. These factors contribute to our confidence in maintaining a leading position in the industry and driving the success of our innovative solutions.

### **Needs & costs in term of regulation**

Usense holds a CE marking in accordance with the Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD). Our goal is to achieve compliance with the new Regulation (IVDR) 2017/746, which requires the solution to be classified as a Class B urine test, by 2027. In anticipation, we have already started the transition process for compliance to the new regulation.

In the next-step, Usense is actively working on its FDA compliance roadmap to ensure regulatory approval for the commercialization of our device in the United States. We are collaborating with regulatory experts, including our partner Voisin Consulting Life Science (VCLS). Our roadmap includes the preparation and submission of the necessary documentation, for a 510(k) or 510(k) de novo. The cost will of course vary depending on the pathways that are available, but will imply a budget of several hundred thousand dollars.

### **TEAM AND SUPPORT**

**Please present the dedicated team to the project; Do you have an advisory board? If yes, please describe the members; Does your project have social impacts (job creation, development of new skills and qualification, etc.)?**

Usense is composed of a dedicated team of professionals who are committed to making a positive impact in the field of biology and medical diagnostics. Our team is characterized by its diversity, bringing together individuals from various cultural backgrounds and expertise.

The core team comprises three founding members who each possess over 10-15 years of experience in corporate groups, startups, and strategy and innovation consulting firms. Their combined knowledge and skills in business development, strategy, and entrepreneurship provide a solid foundation for the success of the project.

We have also assembled a talented group of scientists and engineers who are spearheading our research and development efforts. Including PhD within our expertise fields in our Science team, Usense has a deep understanding of the complexities of urine analysis and expertise in areas such as spectroscopy, electroanalysis, and machine learning. They are driving the innovation behind our device and ensuring its scientific and technological validity.

Usense also benefits from a highly skilled and dedicated operational team that plays a crucial role in the successful execution of our project. Composed of experienced professionals with expertise in operations, production, commercialization, and regulatory affairs, this team ensures the seamless coordination of all aspects of our business. Our operations team oversees the day-to-day activities,



including supply chain management, manufacturing processes, quality control, and logistics. They work diligently to optimize production efficiency, maintain product quality, and meet market demand. Their meticulous attention to detail and commitment to excellence ensure that our devices are manufactured to the highest standards and delivered to customers in a timely manner.

To strengthen our strategic decision-making and benefit from a wide range of perspectives, we have established an advisory board comprising seasoned professionals and experts in relevant fields. These advisors bring extensive experience in the healthcare industry, medical research, technology development, and business strategy. Their guidance and insights play a crucial role in shaping our project's direction and ensuring its alignment with market needs and trends.

#### **WHAT IMPACT HAS YOUR PROJECT ON SOCIETY?**

**Please explain how your project benefits to society (product with societal benefit, impact in terms of public health, quality of life, circular economy, etc.)**

At Usense, our project is driven by a strong commitment to creating societal benefits and making a positive impact in healthcare.

First and foremost, our device revolutionizes the field of urinalysis by providing a fast, accurate, and user-friendly solution for diagnosing and monitoring various health conditions. By enabling healthcare professionals to obtain real-time and reliable information about a patient's health status through urine analysis, our technology enhances early disease detection, facilitates medical and treatment intervention, and improves outcomes. This has a direct impact on public health by enabling timely diagnosis, reducing the progression of diseases, and enhancing patient management. The ease of use and mobility of our device also promote accessibility to healthcare, particularly in underserved regions or remote areas where access to advanced medical facilities may be limited. By bringing the power of urinalysis directly into the hands of practitioners and patients, regardless of their geographic location, we aim to bridge the gap in healthcare disparities and provide equal opportunities for diagnosis and monitoring.

Furthermore, our device contributes to a more sustainable healthcare system by reducing the need for costly diagnostic procedures. Urinalysis is a non-invasive and cost-effective method that can provide valuable insights into a wide range of health conditions. By complementing traditional laboratory-based tests (such as blood tests) we reduce the burden on healthcare facilities and optimize healthcare resource allocation.

In terms of the circular economy, our commitment extends to the entire product life cycle. We prioritize sustainable design principles, ensuring that our device is built with durable materials, optimized for energy efficiency, and designed for ease of maintenance and repair. As our device does not use any consumables and is reusable, we limit the waste of consumables such as urine dipsticks.

At Usense, we are also proud to have a potential impact on developing countries healthcare systems. Our strong partnership with our investor, the Belgium Praesens Foundation as well as our relationships with the UN (thanks to one of our close board advisor) allow us for hope to improve early diagnosis in areas where diagnosis is difficult or to tackle the important subject of nutrition monitoring within the first thousand days of life.

Additionally, our project has the potential to generate economic benefits by creating job opportunities and fostering the development of new skills and qualifications. As we grow, we aim to expand our team, providing employment opportunities in various fields and countries, including research and



development, manufacturing, sales, and customer support. By investing in talent and expertise, we contribute to the development of a skilled workforce and support economic growth.

## ROADMAP

### **What are the midterm and long term next steps for the project?**

In the midterm and long term, Usense has a clear roadmap of next steps to further develop and expand our project, ensuring its success and maximizing its impact in the field of urinalysis.

In the short and midterm, our focus is on the industrialization of our production and commercialization efforts both in France, Europe and North-America. We aim to establish strategic partnerships and collaborations with key stakeholders in the healthcare industry to ensure widespread adoption and distribution of our innovative device. This includes collaborating with renowned laboratories, hospitals, clinics, and healthcare providers to integrate our technology into their diagnostic workflows and improve patient care.

Additionally, we will continue to engage with regulatory bodies to obtain necessary certifications. Although our current CE-Marking allows us to commercialize in Europe, we are currently seeking to obtain the FDA approval, to ensure commercialization in the United States.

Furthermore, we will invest in research and development to continuously enhance the capabilities and features of our device. This includes expanding the range of biomarkers that can be analyzed and improving the accuracy. We have for instance started these R&D efforts with major players in France such as the CNES which is the French Spatial Agency - allowing us to work in the most constraining conditions for testing - and the CEA, a top french public scientific, technologic and industrial research institute, with the aim to develop specific technologies to potentially detect new signature biomarkers. Usense also aims to leverage on the vast biological data it is creating, with its partners, to develop advanced data AI analytics solutions to provide diagnostics and personalized healthcare tools (patient profiling, digital twin, disease risk factors, ...).

Finally, we will focus on integrating our device into telemedicine platforms and digital health ecosystems, enabling remote monitoring and enhancing patient engagement. This will facilitate seamless integration of urinalysis results into electronic health records, enabling healthcare professionals to make informed decisions and provide personalized care to patients regardless of their location.

In the long term, Usense goals address new use cases. One key focus is to extend the application of its technology to new therapeutic areas such as oncology and neurology. Usense aims to contribute to the early detection and monitoring of cancers or neurological disorders, providing valuable insights for better patient outcomes.

In addition to healthcare, Usense recognizes the potential of its innovative approach in other sectors as well. One notable area is water monitoring, where the ability to analyze fluids can provide valuable information about human and environmental health. By detecting the presence of contaminants and markers of water quality, Usense envisions playing a significant role in ensuring the safety and sustainability of water resources.