ANNUAL REPORT

(includes financial report)

2024

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CHAPTER 1: BUSINESS OVERVIEW

1.1 Business overview

1.1.1. Executive summary

Founded in 2000, Mauna Kea Technologies is a global medical device company that develops, manufactures and markets an innovative imaging platform for visualizing tissue at the cellular level, in real time, during standard procedures, with the mission of eliminating uncertainties in diagnosis and treatment through direct visualization of tissue in vivo at the microscopic level.

The Group's flagship product, Cellvizio®, is the world's smallest microscope, designed for direct use during minimally invasive procedures. The Cellvizio consists of a central unit housing the visualization unit, to which a miniprobe is connected, designed specifically for each medical indication. Thanks to the extreme miniaturization of mini-probes, Cellvizio® can be positioned directly in the patient's body. In vivo visualization enables the practitioner to obtain real-time information on the tissue, enabling better-targeted sampling of tissue fragments; to increase diagnostic yield by performing biopsies on tissues with previously identified abnormalities, thus avoiding a large number of biopsies on healthy cells; to monitor the evolution of diseases over time; to assess reactions as they occur; to classify areas of uncertainty; and to guide surgical interventions.

Cellvizio® has received marketing agreements for a wide range of medical applications (of which gastroenterology was the 1st) in over 40 countries, including the United States, Europe, Japan, China, South Korea and several Latin American countries.

Cellvizio® has been extensively validated in a number of international multicenter clinical trials, which have demonstrated that Cellvizio® can help physicians to more accurately characterize or detect early forms of mucosal changes, and to make earlier therapeutic decisions. In particular, this validation contributed to obtaining several reimbursement codes from public and private payers, mainly in the United States and France, for high endoscopy procedures, thus contributing to the adoption of Cellvizio® by numerous hospitals and clinics. With 4 codes obtained in the United States, the American market rapidly became the Group's priority market, where it focused a large part of its sales efforts, while seeking to expand directly into many other countries, notably in Europe, and indirectly via distributors in other regions, including Asia, notably China and Japan.

On the strength of this technological platform, the Group is positioning itself as a key player in the digital transformation of medicine and surgery. The Group's ambition is to move diagnostic practices from an analog paradigm, inefficient and costly, to a fully digital, instantaneous paradigm, bringing doctors and surgeons all the power of real-time cell visualization combined with the best machine learning algorithms.

- **The Cellvizio® benefits from a number of advantages**

A breakthrough innovation protected by an intellectual property portfolio of 266 patents

Cellvizio® is the world's smallest microscope, capable of producing microscopic images of the inside of the human body in real time (9 to 12 images per second) with exceptional stability. Images are magnified by up to 1000 times compared with a traditional camera. They are obtained by simply pressing the Cellvizio® miniprobe against the wall of the target mucosa or organ. The procedure is minimally invasive, and images are perfectly reproducible.

At December 31, 2024, Mauna Kea Technologies' patent portfolio included 266 national and international patents protecting its technologies and methods. This policy of innovation and protection of its intellectual property constitutes an important barrier to entry for potential competitors. The company continues to invest in R&D and will maintain a dynamic patent registration policy.

Cellvizio®, a benefit for patients, doctors and healthcare systems

Cellvizio® has been designed to help doctors reduce diagnostic uncertainties, treat patients more effectively and cut hospital costs.

Cellvizio® provides doctors with real-time, in vivo cellular information during procedures. This information is obtained in a minimally invasive way, without damaging the patient's tissue. The spirit in which Cellvizio® was designed is one of minimal disruption to practices. As a result, a range of probes are available that are compatible with existing practices. For example, in the field of digestive endoscopy, Confocal Miniprobes for this category of applications are compatible with almost all endoscopes on the market, and are naturally used as an endoscopy tool. Cellvizio® can improve practices without radically changing them.

The medical benefits of Cellvizio® have been proven by numerous clinical studies in each of the indications in which it is routinely used today.

For patients, the benefits are significant on several levels. In addition to not having to wait for the results of a physical biopsy, which can sometimes take several weeks, the procedure is non-invasive, repeatable because it does not destroy the areas it inspects, and painless. Above all, it enables faster characterization of precancerous and cancerous lesions.

For healthcare systems, microscopic visualization in vivo and in real time reduces the number of unnecessary physical biopsies, as the vast majority of physical biopsies are negative (e.g. prostate: 75%[1] , Barrett's esophagus: 58%[2]), and reduces the number of endoscopic procedures through better characterization of precancerous or cancerous lesions. Cellvizio® also avoids unnecessary surgery, notably of the pancreas.

Cellvizio®, a multi-indication platform

The Cellvizio® has been designed as a platform potentially capable of providing solutions for a wide range of medical and surgical fields in which tissue characterization is systematically required, thanks to miniprobes adapted to each medical indication. Among these, gastroenterology, urology, interventional pulmonology and surgery are priority candidates. With the advent of its < 1 mm diameter miniprobe, capable of penetrating a puncture needle, Cellvizio® can now access the interior of the human body's organs, opening up new possibilities for improved diagnosis of major pathologies such as pancreatic cancer or lung cancer.

To date, the Group has a range of 10 mini-probes that can be reused 10 or 20 times, depending on the model (see section 1.1.2 of this document).

Numerous marketing authorizations

To date, Cellvizio® has marketing agreements for a wide range of applications in numerous countries, including the United States, Europe, Japan, China and Korea. Details of marketing and reimbursement approvals are given in section 1.1.3 of this document.

Several reimbursement codes already obtained

The adoption of Cellvizio® technology is also largely dependent on obtaining reimbursement codes from paying agents (public health systems and private insurers) to enable patients to be reimbursed for all or part of a procedure performed by Cellvizio®. As of the date of this document, the Group has mainly obtained 4 reimbursement codes in the United States, and other codes in France, South Korea and Croatia (see details in paragraph 1.1.3 of this document).

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[1] Presence Of High-risk Prostate Cancer Can Be Predicted Without A Biopsy, New Study Says." ScienceDaily. ScienceDaily, May 22, 2005.

[2] Bertani H. et al. Improved Detection of Incident Dysplasia by probe-based confocal laser endomicroscopy in a Barrett's esophagus Surveillance Program. Dig Dis Sci 2013; 58(1):188-93.

Through these marketing authorizations and reimbursement codes, the Group has demonstrated its ability to successfully complete regulatory processes that are often lengthy and evolving, as well as specific to each geographical area concerned. It is continuing its work in this area, with the aim of obtaining codes in the fields of pneumology and urology in particular.

▯ A rich and statistically significant clinical validation

Imposing a disruptive technology in the medical world today requires scientific and medical proof of the contribution of the proposed innovation. A vast program of international multicenter clinical trials has been underway since 2005, focusing on applications in the digestive tract, pneumology and urology. All the studies completed to date have produced convincing results in terms of Cellvizio®'s contribution to traditional endoscopy, particularly in terms of the quality of the diagnosis it provides. There are over 1,000 published references on endomicroscopy in the PubMed database, queried on the keyword "endomicroscopy". The results of the Company's clinical trial programs are described in sections 1.1.3 and 1.2.3 of this document, including those published in prestigious journals in 2023, whether in the field of lung cancer, esophageal cancer or pancreatic cysts.

▯ An agile business model to adapt to local conditions

The Company's business model is based on the sale of equipment (or systems) and consumables (called miniprobes) adapted to each procedure according to the indication concerned and reusable a limited number of times, as well as a range of services including maintenance contracts to help develop recurring sales, and user training.

The systems are also available for rental in some European countries.

In the United States, the Company also offers a specific business model based on a "pay per use" program. This program is proving its worth thanks to US reimbursement rates, which make the use of endomicroscopy a highly profitable clinical practice for hospitals. Pay-per-use revenues invoiced by the Group are booked under "consumables" sales, while the systems made available are booked under property, plant and equipment and depreciated.

In order to fully exploit its technological platform in indications or markets where the Company does not wish, or cannot, invest directly, it enters into licensing agreements with other players. With this in mind, a strategic partnership was signed in July 2022 with the Chinese company Tasly Pharmaceuticals, leading to the creation of a joint venture in China (see paragraph 1.2.3 of this document). These partnerships generate additional revenues, notably in the form of milestone payments and future royalties.

▯ An operational equipment base of around 250 units capable of generating recurring sales.

Since its creation, the Group has installed over 700 systems, including those sold and those made available. However, the Group estimates that, to date, the truly operational installed base is around 250 systems, 60% of which are in the United States, 40% in Europe and the rest of the world. A number of systems have been marketed to academic centers for occasional use in clinical trials, for example, or to small animal research and imaging centers from which the Group has withdrawn in 2021, as well as to hospitals and clinics where adoption of the technology has not gone as initially planned, for a variety of reasons (changes in the medical team, unobtainable or unsatisfactory reimbursement rates for certain procedures, etc.).

The operating base should generate recurring sales based on the sale of consumables (minisondes) and a range of services including maintenance contracts.

▯ Market size

The Group's existing range of probes opens up very significant commercial prospects in many medical fields, in addition to its traditional market of gastroenterology.

The number of establishments with endoscopy rooms is estimated at around 60,000 in the 3 main target zones, i.e. 14,700 in the United States, 15,000 in Europe and around 30,000 in China and Japan (see paragraph 1.1.4 below on the market).

Given its financial resources, the Group has so far focused much of its efforts on the US market, specifically identifying and targeting around 1,100 hospitals (1,500 doctors) specializing in digestive endoscopy, whether they be local hospitals with a high level of activity around gastro-oesophageal reflux disease, or Ambulatory Surgery Centers (ASCs) which treat a very large number of these patients.

In the United States alone, this represents a total equipment market of around $200 million, to which can be added a potential recurrent market estimated at over $220 million a year, given the number of procedures performed on the upper digestive tract alone, for which Cellvizio® is particularly well suited and has reimbursement and coverage codes. In addition to chronic GERD, the Group also targets interventional endoscopy centers for the exploration of pancreatic cysts. The Group estimates that there are over 500 centers of this type in the United States, representing an equipment market of the order of $100 million and recurring revenues of $50 to $75 million, based on a number of procedures of 50,000 (i.e. 40% of the number of pancreatic cysts identified per year).

Since 2024, the Group has been deploying CellTolerance®, a program dedicated to the in vivo assessment of intestinal barrier permeability during food challenge tests during standard gastroscopy. This approach meets a major medical need, since food intolerances are thought to be involved in almost 50% of cases of irritable bowel syndrome (IBS), a condition that affects 10-15% of the world's population.

In addition, the Group considers that it could benefit from many other possible outlets, given the large number of fields in which Cellvizio® could be used, such as :

- interventional pulmonology, with a total of almost 60,000 care facilities worldwide, and a very large number of procedures performed (500,000 bronchoscopies per year in the United States alone, including over 240,000 diagnostic bronchoscopies with biopsies); or even

- endo-urology, where the continuous, lifelong follow-up of bladder cancer patients generates a multiplicity of rigid and flexible endoscopic cystoscopy procedures (diagnostic and therapeutic) totaling over 420,000 procedures per year in the United States alone; and

- neurosurgery, a field that the Chinese joint venture intends to develop and market worldwide.

▯ A team of 68 multi-expertise employees

At the end of 2024, the Group had a multi-disciplinary team of 65 employees supervised by experienced top management, including Alexandre (Sacha) Loiseau, the company's founder and current Chairman and CEO. The sales team also benefits from a network of international distributors.

♦ **A strategic repositioning based on hybrid commercial deployment, with priority given to partnerships with leading players**

Building on this decade of experience and significant, capital-intensive investment, by the end of 2021, the Company had adopted a new strategy, shifting from a sales approach based largely on direct marketing to an indirect approach based on strategic partnerships with leading biopharmaceutical, pharmaceutical and medtech companies selling oncology-focused solutions, for whom the advanced imaging technology offered by Cellvizio® is a key performance differentiator. Nevertheless, the Company continues to support its installed base and to target high-volume users, particularly in the United States.

This strategic repositioning offers several advantages:

- ✓ Optimization of financial resources through a more capital-efficient business model based on upfront and/or milestone payments as well as royalties;
- ✓ A robust and stable gross margin profile ;
- ✓ Access to vast markets at a pace that the Group could not achieve on its own;
- ✓ An acceleration in the monetization of intellectual property ;
- ✓ Better visibility of financial results.

The announcement of this new strategy was accompanied by a major plan to reduce operating expenses (headcount cuts, reduced sales efforts in the historical gastroenterology market, particularly in the United States, very limited use of external service providers), which was gradually implemented in 2022 and continued in 2023 and 2024.

The relevance of this approach for both Mauna Kea Technologies and potential partners has been demonstrated by the rapid completion of a 1st strategic partnership with Tasly Phamaceutical, which involves major and multiple challenges (see details in paragraph 1.2.3 of this document).

Discussions are underway with other potential partners, bearing in mind that the Group is targeting several high-potential application markets, including neurosurgery, pulmonology, gastroenterology and urology, for which it already has marketing approvals and clinical validations.

The Group has therefore set in motion a new dynamic over the last few years, and believes that it now has very tangible assets at its disposal to step up the commercial deployment of Cellvizio® technology and thus accelerate the digital transformation of medicine and surgery.

1.1.2. A breakthrough technology offering

♦ **Integrated technological expertise**

▯ A strong capacity for innovation

All innovation begins with an analysis of application needs, and in the case of medical devices, with an analysis of clinical needs and constraints linked to medical practices.

Mauna Kea Technologies' strength has always been its belief that the most effective way to design new equipment is to start with a blank sheet of paper and rethink the whole concept before modeling it.

Building on this approach, at the end of 2003, the first Cellvizio® was born, after a team of experts had taken up a variety of challenges in an iterative process:

- The design of a high-resolution "plug and play" confocal microscope, i.e. one that requires no adjustment during installation or use,
- Extreme miniaturization of the microscope and its mini-probe objectives,
- Optimized image processing to compensate for the physical limitations of optical components,
- High integration capacity in standard equipment,
- Every component is designed to be as easy as possible to manufacture in the future.

The quality of the thinking that went into the design of the Cellvizio® means that Mauna Kea Technologies now has a technical platform that can be used for a wide range of applications, with only marginal additional investment in research and development.

This approach has been repeated in recent years and has led to the development of the new-generation Cellvizio® platform, known as "GEN 3", which was commercially launched in the United States in Europe on October 1, 2021 and enables:

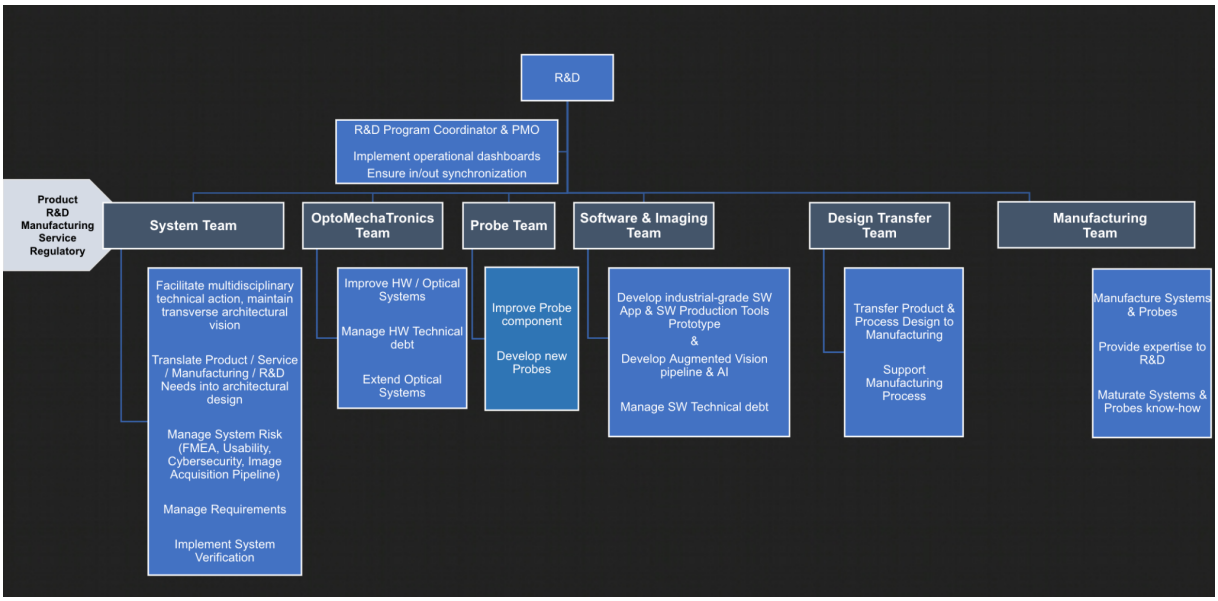
- To offer a mobile, lightweight, space-saving system, with accelerated, optimized set-up in operating theatres,
- A new touchscreen interface and revised ergonomics, based on feedback from users
- Introduce new products and services, including decision-support tools and new business functions,
- Offer functional and ergonomic improvements more quickly, in the form of software or hardware updates,
- Include intra-procedural images in hospital information systems and video capture systems for clinical reporting and patient follow-up,
- Leverage internal modularity to integrate easily with laparoscopic, advanced navigation and robotic systems, enabling the development of potential new market access channels,
- Leverage in-house computing power and scalability to develop advanced visualization tools in the future.

▯ A highly qualified multidisciplinary team

At the end of December 2024, the Research and Development team consisted of 18 employees (PhDs, engineers or technicians) covering the areas of expertise required for the development of the Group's products and technologies:

- Optics and opto-mechatronics,
- Applied mathematics for image processing,
- Digital and analog electronics,
- Software development,
- Systems engineering,
- Biomechanics and instrumentation,
- Micro-mechanics, materials and precision assembly processes.

The R&D team shares medical and biological knowledge of product applications and use with specialists from the Clinical Affairs team and Product Managers.



Front-end R&D: Innovation

The Company has set itself the means to directly inspire the technological innovations that will enable it to develop its market and conquer new ones, by studying all proposals likely to foster the development of any innovative solution capable of improving patient care.

Scientific and technological watch is carried out on an ongoing basis under the supervision of the Innovation Department. The aim is to identify and validate the benefits of emerging technologies and components, so as to remain at the cutting edge of technology, while limiting the risk of obsolescence of key components by identifying alternative technical solutions at an early stage.

The upstream studies resulting from this watch are carried out by R&D department teams, either in-house or through external collaborations. They may constitute the preliminary phase of feasibility assessment, enabling the decision to launch a product development project.

On the clinical front, the Company is working with various hospitals to assess the potential interest and usability of Cellvizio® technology in new indications.

Upstream studies carried out in collaboration with academic laboratories are often co-financed to optimize research costs through grants or doctoral thesis scholarships.

- **Development of current products and optimization of manufacturing processes**

In October 2021, Mauna Kea Technologies launched its Cellvizio® IVE product (known as "GEN 3"), which brings two important benefits:

- A scalable medical platform for endomicroscopy,
- Greater ease of use, miniaturization and mobility for the many specialties addressed.

The launch of this platform has been accompanied by major organizational changes in R&D, in order to capitalize on Cellvizio® IVE's scalability:

- The implementation of development cycles - or iterations - allowing the device to be updated twice a year, in compliance with medical standards, device safety and performance;

- Structuring the entry point for these iterations around requests from the Product, Customer Support and Regulatory teams;

- Continuous integration of system and probe technical debt management: improve maintainability, optimize manufacturing costs, increase robustness and reliability.

These organizational changes combine classic "V-cycle" techniques with more up-to-date and proven "Agile" approaches. R&D, Marketing, Clinical and Regulatory teams synchronize during each iteration to achieve the set objective.

This iterative approach creates a virtuous loop of valorization:

- Continuous delivery of value to the market,

- Increased interest from customers who see a return on their investment through an evolving offer,

- A close loop enabling rapid capitalization on field feedback and implementation of improvements to optimize the effort/value delivered ratio ("minimum viable product").

-

♦ Technological pillars of innovation

From 2022 onwards, the R&D team has put in place a 4-pronged technological strategy to enhance its technological value and develop its business model. These 4 axes are based on a medium- to long-term strategy:

- "XPLore": agnostic instrumentation compatible with the largest number of minimally invasive devices on the market (endoscopes, needles, etc.);

- "AI": system-integrated physician assistance to democratize practice;

- "Multimodal Vision": the provision of multi-wavelength imaging on the new platform, in particular to address the molecular imaging market;

- "Core Components": the supply of a "Cellvizio® Development Kit" enabling the integration of in vivo CLE technology into third-party devices such as surgical robots, endoscopes, and any minimally invasive device for monitoring, diagnosis or treatment. The kit includes technology and services to open up an OEM integration market.

♦ How the technology works and its benefits

□ Principles of biopsy

Based on a minimally invasive visual approach to the body's natural pathways, endoscopy is a recognized screening and treatment method. Since 90% of cancers develop in mucous membranes (source: Year 2000 Surveillance Research from the American Cancer Society), endoscopic access to these (located in hollow organs such as the esophagus or colon) has led to a major improvement in patient comfort and diagnosis in general. If all people aged 50 and over followed screening recommendations, in particular colonoscopy, 60% of colorectal cancer deaths could be avoided.

(source: Center for Disease Control and Prevention, 2014:
http://www.cdc.gov/cancer/colorectal/pdf/no_pocket_brochure.pdf).

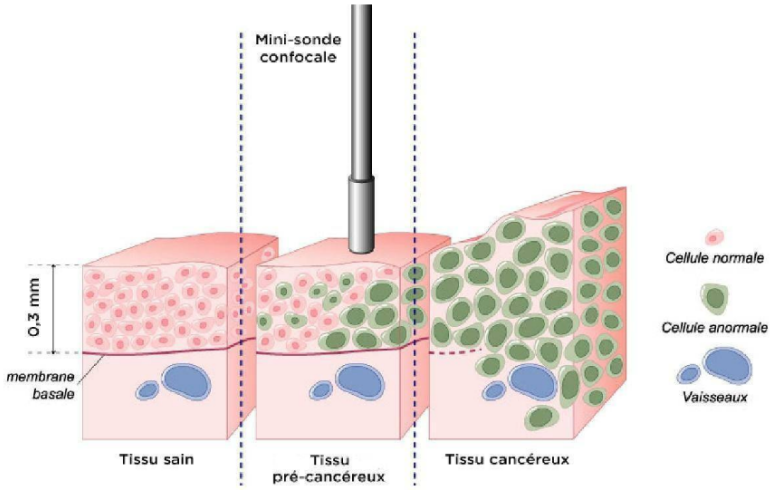


Diagram of the progression of cancer cells from deep in the mucosa to the surface (invisible by endoscopy) and the ability of a Cellvizio® miniprobe to image a precancerous area.

Thanks to a camera on a flexible, articulated tube - the endoscope - the doctor can identify lesions from which samples (biopsies) can be taken to obtain histological confirmation of his or her macroscopic diagnostic impression.

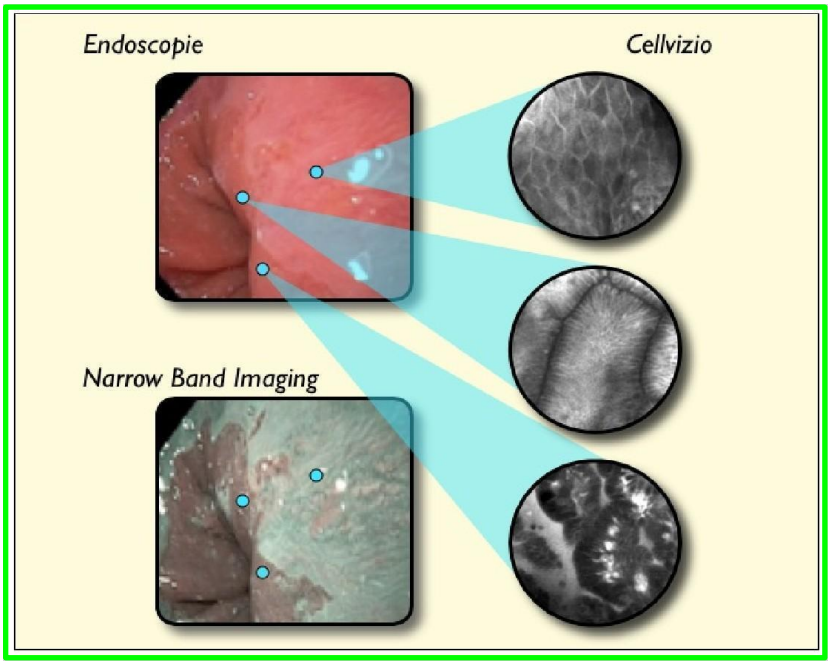
Microscopic analysis of the cellular architecture of the samples is then entrusted to the anatomopathology department, which differentiates and characterizes any alterations. This sampling and study procedure, which is always carried out with a delay - often several weeks - and on dead cells, does not allow the physician to intervene in real time during the same endoscopic procedure. What's more, the biopsy is based on the images received from the endoscope, so the choice of sampling areas is hampered by the microscopic size of the cells and their preferred location beneath the tissue surface, or even in places inaccessible to biopsy forceps. Biopsies, when they can be performed, are therefore "blind" in areas where the physician can only estimate the probability of suspicious lesions. The quality of the sample is therefore not always exploitable for diagnostic purposes, and often necessitates one or more additional endoscopic procedures, further delaying diagnosis and the implementation of therapy in pathologies where early intervention is a determining factor in the cure rate.

Vue d'ensemble d'un endoscope flexible standard (à gauche) et vue de la partie distale avec la caméra, les fibres optiques d'illumination et le canal opérateur dans lequel on trouve une pince à biopsie insérée

However, this progress has contributed only marginally to improving the localization of suspicious lesions, and still without providing access to the microscopic level, which remains the sole responsibility of the anatomopathologist.

The diagram below shows the essential difference between a standard or advanced endoscope and Cellvizio®. The image on the left shows a macroscopic view of the esophageal mucosa using standard endoscopy, which corresponds to the actual x4 size, and then, on the lower left, contrast enhancement (Narrow Band Imaging or NBI), which makes no difference to image size, whereas the images on the right show a real-time in situ microscopic view obtained by Cellvizio®, enabling immediate characterization.

The scale is x1000 compared with normal size, corresponding to visualization at cellular level.



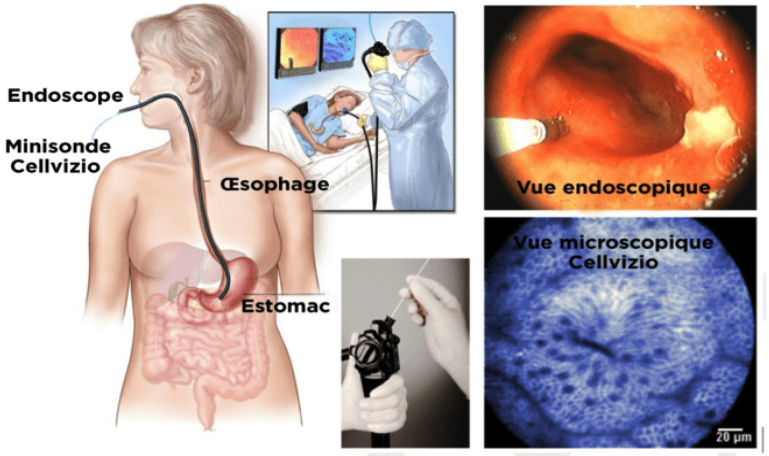
Technology benefits

By bringing the microscope into the patient, instead of taking a sample (biopsy) from the patient and placing it under a microscope, Cellvizio® brings together all the key diagnostic stages of the endoscopy procedure. For the first time, the clinician has access to the relevant cellular information in real time:

- For optimized diagnosis and better diagnostic yield than traditional biopsies,
- For difficult or inaccessible areas where biopsies are compromised, Cellvizio® can provide key microscopic information for diagnosis,
- To decide, if necessary, on immediate endoscopic therapeutic intervention, to send the patient to surgery or, on the contrary, to confirm the absence of disease and limit unnecessary interventions.

Insertion of a confocal miniprobe into the operating channel of a standard endoscope.

Confocal miniprobe emerging from the end of an endoscope's operating channel. All endoscopes have such a channel for passing instruments.



Cellvizio® procedure in an endoscopy room: the endoscopic image (macroscopic, on the left of the image) and Cellvizio® imaging (microscopic, in the center of the image) are simultaneously available to the doctor.

In addition to the in vivo cellular imaging provided by Cellvizio, its confocal video mode, capturing 8 to 12 images per second, enables dynamic sequences to be recorded, revealing pathophysiological processes at cellular level in real time. This high frame rate makes it possible to visualize capillary microcirculation, leukocyte migration, permeability of epithelial junctions or extravasation of fluorescent dye - key parameters for assessing inflammation and food hypersensitivity reactions. In the CellTolerance® protocol, the clinician observes the immediate reaction of the duodenal mucosa a few seconds after the application of a test food: vascular leakage, intercellular dilatation, reversibility after rinsing, and so on. All video sequences are automatically archived in mp4/DICOM format and can be reviewed frame by frame for precise longitudinal monitoring of intestinal barrier integrity, facilitating instant, personalized therapeutic decisions.

Mauna Kea Technologies' value proposition is significant in that it benefits all players in the healthcare chain. Clinical studies conducted with Cellvizio® have demonstrated the following benefits:

For patients

- Real-time clinical information,

- A less invasive procedure than biopsy,
- For certain indications, the reduction of unjustified endoscopic and surgical interventions.

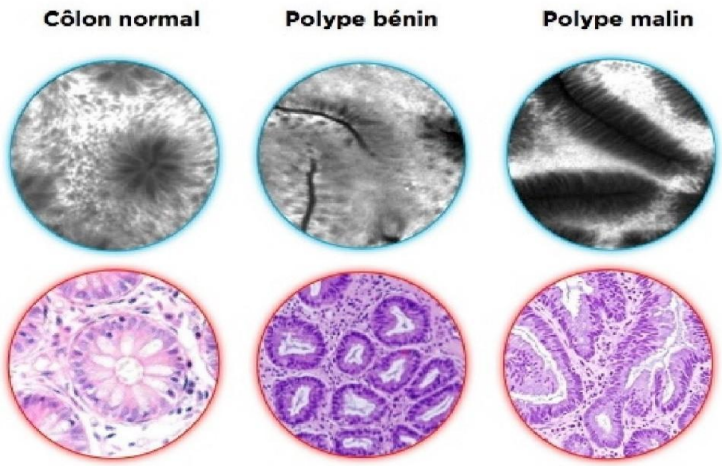
For doctors

- *In situ* and *in vivo* cellular visualization of mucous membranes at suspect sites defined by macroscopic endoscopic technologies (white light, NBI, etc.), enabling real-time visual microscopic characterization of tissues and reducing diagnostic uncertainty,
- A further element in the improvement of patient care by strengthening the role of physicians in diagnosis, in addition to their role in the choice of therapy: to be able to both avoid unnecessary therapies and anticipate those that are necessary,
- Be at the cutting edge of technology compared with their peers,
- Increase awareness of their department or care facility, and thus the number of patients treated by their department or care facility.

For care facilities

- Appear as an expert center equipped with cutting-edge technologies,
- Advanced training in digestive, pulmonary and urinary tract endoscopy, laparoscopic surgery and interventional radiology,
- Attract customers looking for the best in medical practices,
- Optimizing the efficiency of diagnostic management,
- Improved therapeutic decisions,
- Potential reduction in the number of unnecessary endoscopic and surgical procedures.

Each of these elements contributes to a significant reduction in healthcare expenditure for both public and private players.



Images obtained in vivo with the Cellvizio® during colonoscopy (top) compared with images obtained ex vivo, in the analysis laboratory. Note the similarity of the images.

Major advantage	Clinical impact
Dynamic confocal video imaging (8-12 fps)	Clinicians can monitor micro-circulation, epithelial junction permeability, leukocyte migration or, in the CellTolerance® protocol, dye leakage a few seconds after the application of a test food.
Ultra-precise biopsy targeting	Samples are no longer taken "blind", reducing the need for repeated procedures and improving diagnostic yields.
Access to difficult areas	Cellvizio® restores microscopic information even where a biopsy forceps cannot (stenoses, sub-epithelial zones, pancreatic cysts, etc.).
Immediate therapeutic decision	Depending on the visual characterization, the doctor can: treat endoscopically, refer for surgery or, on the contrary, avoid an unnecessary procedure.

Current applications

Cellvizio® is potentially aimed at all medical fields in which doctors need to assess the nature of tissues in order to make decisions in the management of their patients. These include gastroenterology, urology and pneumology, as well as surgery and interventional radiology.

As it does not have the resources to tackle all these markets head-on, in 2005 the Company selected gastroenterology as its priority market, in view of Cellvizio®'s contribution to a number of pathologies that are particularly difficult to diagnose: Endo-Brachy-Esophagus, precancerous lesions of the stomach, and later, biliary strictures, chronic inflammatory bowel disease and pancreatic cysts.

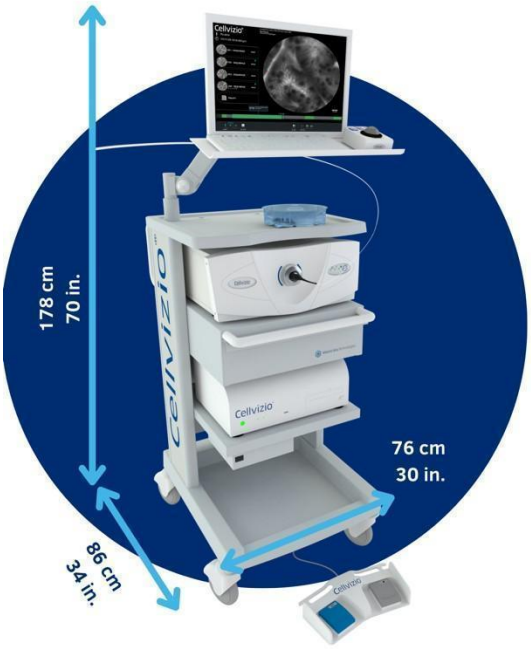
To date, endoscopically accessible digestive pathologies remain the indications in which Cellvizio® is most widely used and sold. The Company has obtained regulatory approvals and high-level clinical evidence for other applications, and is currently studying their potential. Among these, bronchial exploration and the targeting of potentially malignant peripheral lung nodules appear to be a very promising avenue. Other applications include urology and neurosurgery.

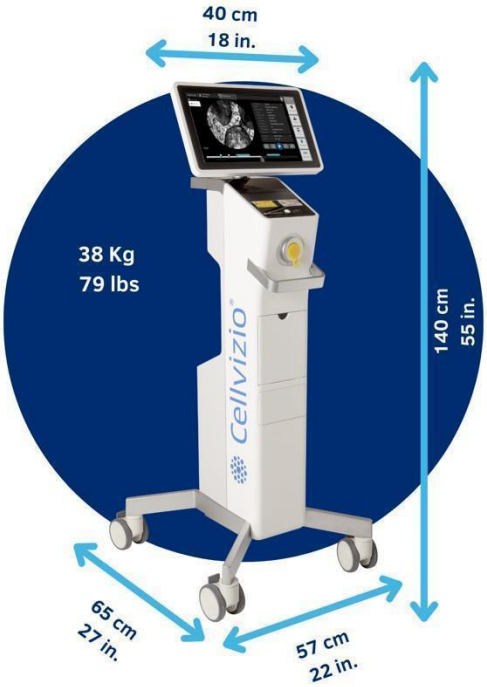
♦ The Cellvizio system®

Product description

The Group offers two ranges of Cellvizio® products:

- The Cellvizio® 100 Series,
- Cellvizio® I.V.E.





Cellvizio® 100 Series	Cellvizio® I.V.E.

Whatever its application, the Cellvizio® system consists of four main components:

- A central base comprising the display screen and the optoelectronic Laser Scanning Unit (LSU),
- The computer processor,
- Confocal Minisondes, specific to each indication, which are therefore consumable elements,
- Proprietary real-time image processing and display software. The extreme quality of the images delivered by miniprobes reflects one of the Group's key areas of expertise - image processing, without which the images captured by the tens of thousands of miniprobe fibers would simply be unreadable by the doctor.

Given technical and software developments, Cellvizio® reaches obsolescence after 6 to 7 years. The second-generation platform, called Cellvizio® 100 Series, is currently on sale in most countries, particularly in Europe and the United States. The most recent version of Cellvizio®, called Cellvizio® I.V.E., is the third generation of the platform and is currently marketed in Europe and the United States. Cellvizio® I.V.E. makes the system easier to use, thanks to its miniaturization, improved user interface and overall ergonomics, and shorter set-up times. Progress has also been made in terms of image quality.

Mini-probes can be reused between 10 and 20 times, and are reprocessed using standard equipment, in the same way as endoscopic accessories. They are a source of recurring revenue for the Group.

For each of the two platforms on the market, the tables below show the different probes designed to meet the specific needs of each medical specialty, as well as the countries in which they are authorized for sale:

- for **Cellvizio® 100 Series** and its Minisondes :

Territory	Status	Products
China	Expires in January 2026	Cellvizio 100 Series (F400) AlveoFlex GastroFlex UHD ColoFlex UHD CholangioFlex AQ-Flex 19 UroFlex B CystoFlex F
Japan	No expiration date	Cellvizio 100 Series (F400) AlveoFlex GastroFlex UHD ColoFlex UHD CholangioFlex AQ-Flex 19 UroFlex B CystoFlex F
Singapore	Permanent validity	AlveoFlex ColoFlex UHD GastroFlex UHD CholangioFlex
United States	-	Cellvizio 100 Series (F400) and (F800) All probes except AG-Flex 19 IR

- **for Cellvizio® I.V.E.** and its Minisondes :

Territory	License status	Products
Austria	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N AQ-Flex 19 IR N UroFlex N CystoFlex R N CystoFlex F N CelioFlex 5 N
Belgium	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N AQ-Flex 19 IR N UroFlex N CystoFlex R N CystoFlex F N CelioFlex 5 N
Czech Republic	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N AQ-Flex 19 N AQ-Flex 19 IR N
France	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N AQ-Flex 19 IR N UroFlex N CystoFlex R N CystoFlex F N CelioFlex 5 N
Germany	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N AQ-Flex 19 IR N UroFlex N CystoFlex R N CystoFlex F N CelioFlex 5 N
Ireland	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N

		GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N AQ-Flex 19 IR N UroFlex N CystoFlex R N CystoFlex F N
Italy	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N AQ-Flex 19 IR N
Slovakia	Extension to December 31, 2028	Cellvizio I.V.E. AlveoFlex N AQ-Flex 19 N AQ-Flex 19 IR N
Sweden	Extension to December 31, 2028	Cellvizio I.V.E. GastroFlex N ColoFlex N CholangioFlex N
United States		Cellvizio I.V.E. AlveoFlex N GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N UroFlex N CystoFlex R N CystoFlex F N
Ecuador	Expires in December 2027	Cellvizio I.V.E. AlveoFlex N GastroFlex N ColoFlex N CholangioFlex N AQ-Flex 19 N

Confocal mini-probes consist of a bundle of tens of thousands of optical fibers scanned sequentially by a laser beam emitted by the scanning unit. They carry the laser beam to the area to be observed, inside human anatomical tracts. The fluorescence (exogenous or endogenous) emitted by the tissue under laser excitation is collected by the miniprobe and analyzed to form the image of the tissue observed.

When in use, mini-probes are connected to the Laser Scanning Unit, then inserted into the endoscope's operating channel like a biopsy forceps, for example, to provide in vivo fluorescence microscopic imaging during the endoscopy procedure. They are perfectly compatible with all standard equipment already present in endoscopy rooms and, unlike conventional endoscopy, enable in-depth observation of the mucosa (down to 70 µm), the preferred layer for localizing cancerous tumors.

The major advantage of the Cellvizio® concept, in addition to its design which is particularly well-suited to easy manufacture, lies in the fact that it comprises a unique microscopy technology platform offering a guarantee of stability for several years, and that only the probes constitute the specific link between this standard platform and the application concerned (digestive tract, lung, etc.), thus enabling the platform to be shared by several hospital departments or medical users.

1.1.3. Clinical, regulatory and reimbursement validation

♦ **Clinical applications**

Clinical validation

Mauna Kea Technologies has launched an ambitious program of clinical studies, either directly or through industrial or academic partners. Although these studies are not part of the regulatory process for obtaining marketing authorization, the stakes are just as high.

Imposing a new technology within the framework of medical procedures that are perfectly well known and mastered by healthcare professionals (doctors and nurses) first requires the support of opinion leaders in the field concerned. The aim is therefore to scientifically demonstrate the benefits of confocal laser endomicroscopy compared with existing alternatives, and then to disseminate these results to opinion leaders and learned societies, so that they can take ownership of this new procedure and relay requests for reimbursement in their respective countries to national health authorities (public and private insurers).

The flagship mission of the Group's Clinical Affairs department is to initiate studies in collaboration with expert centers, in order to establish the clinical validity of Cellvizio®. With extensive experience in international multicenter and randomized studies, the clinical teams sequentially apply the following principles to each trial:

- Choice of therapeutic indication in relation to the company's development strategy ;
- Expected value proposition ;
- Once the clinical development plan has been finalized, Mauna Kea Technologies carefully selects the hospitals most likely to collaborate on the study;
- Definition and follow-up of the study protocol ;
- Patient recruitment ;
- Definition and follow-up of the study protocol ;
- Data analysis ;
- Scientific papers and medical articles.

Numerous international multi-center clinical trials to date have demonstrated that Cellvizio® enables doctors to detect or characterize early forms of pathology more precisely and more rapidly, and thus to decide on the type of treatment to prescribe in real time. This clinical validation is crucial. It is a prerequisite for the support of numerous opinion leaders around the world, as well as American and French learned societies.

It consists of over 1,000 clinical publications on confocal laser endomicroscopy in leading scientific journals, and constitutes the Group's prerequisite for the large-scale marketing of Cellvizio® in expanding indications.

The preponderance of studies carried out on indications related to digestive tract pathologies is in line with the commercial strategy initiated in 2007 of focusing primarily on the gastroenterology market. Today, confocal laser

endomicroscopy enjoys a high level of clinical evidence for digestive tract indications, demonstrating the unrivalled precision of Cellvizio® real-time tissue visualization. This level of evidence has enabled us to enter the medico-economic demonstration stage, a key element in access to reimbursement in certain countries. The results detailed below show the main clinical results published, in the most advanced indications.

A general review on the performance of confocal laser endomicroscopy focusing on major indications in gastroenterology (Fugazza, Biomed Res, 2016) takes stock of the state of the art based on 662 publications and 102 studies that highlight that the unrivalled precision of real-time tissue visualization by Cellvizio® and similar technologies is notoriously changing practitioners' diagnostic conclusions and patient management.

Confocal laser endomicroscopy significantly improves the detection of precancerous and cancerous lesions in comparison with conventional endoscopy and biopsy procedures for patients who present them, as well as confirming the absence of any suspicious lesion for healthy patients. This enables us to intervene more rapidly and in a more justified manner, thus helping patients to avoid certain cumbersome and unnecessary procedures. The specificity of CLE exceeds 90% in almost all the applications tested.

EBO (Endobrachyoesophagus)

Pathology characterized by the appearance of metaplasia in the lower esophagus following reflux. Normal esophageal tissue is progressively replaced by abnormal intestinal-type tissue in the lower esophagus, which may develop into a form of cancer if left untreated.

According to 4 studies involving 242 patients, confocal laser endomicroscopy using Cellvizio® detects 97% of patients with dysplasia characteristic of OBC, compared with traditional endoscopy techniques, which detect 10% fewer. Furthermore, the diagnostic results of this imaging technique offer the possibility of reducing the number of physical biopsies by avoiding negative samples, while enabling immediate endoscopic treatment, thanks to its ability to exclude dysplasia with a high level of confidence and a negative predictive value of 98%.

Confocal laser endomicroscopy is therefore a validated option for monitoring patients suffering from OBC, offering a diagnostic tool with reliable and immediate results, and enabling treatment to be tailored as closely as possible to their needs.

In 2015, the American Gastroenterological Association (AGA) published a "white paper" emphasizing that it was appropriate for a physician trained in the technique to replace random biopsies with targeted endomicroscopic biopsies. The College of American Pathologists (CAP) has also published a similar document. Finally, the American Society of General Surgeons (ASGS) has published a recommendation for the use of Cellvizio® for patients suffering from gastro-oesophageal reflux disease. In 2018, the results of a study, conducted by 8 non-academic centers in the USA, were published in Surgical Endoscopy, the official journal of SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) in the screening and monitoring of Barrett's esophagus. The article, entitled "Real-time diagnosis of Barrett's esophagus: a prospective, multicenter study comparing confocal laser endomicroscopy with conventional histology for the identification of intestinal metaplasia in new users," highlights the far greater sensitivity of confocal endomicroscopy with miniprobe for the detection of Barrett's esophagus than the Seattle protocol, now considered the standard protocol. Carried out on 172 patients in 8 centers, the study yielded the following key results:

- Novice users of minisonde confocal endomicroscopy identified more than twice as many patients with intestinal metaplasia (or Barrett's esophagus) as with the Seattle protocol: 99 vs. 46. This result is statistically highly significant ($p < 0.0001$);
- A blinded expert review of discordant Cellvizio® and biopsy results confirmed that Barrett's esophagus detected by Cellvizio® was present in 56 of the 61 patients with negative biopsies;
- There were no statistically significant differences between novice users of confocal miniprobe endomicroscopy and experts.

In 2020, the Technology Assessment and Efficacy Committee (TAVAC) of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) published a study on the safety and efficacy of confocal laser endomicroscopy as a diagnostic tool for the evaluation of gastrointestinal pathologies. The article, entitled "SAGES TAVAC safety and efficacy analysis confocal laser endomicroscopy", was published in the international peer-reviewed journal Surgical Endoscopy (doi.org/10.1007/s00464-020-07607-3).

SAGES TAVAC publishes technology alerts on a monthly basis and reviews on the safety and efficacy of new technologies on a longer periodic basis. This publication in Surgical Endoscopy is based on a TAVAC systematic review of published clinical studies on confocal endomicroscopy in PubMed/Medline up to May 2018 as well as key reference bibliographies for relevant studies not available in PubMed. The objective of TAVAC was to assess the safety, clinical value and efficacy of confocal endomicroscopy in the gastrointestinal tract. The results of the TAVAC analysis concluded that confocal endomicroscopy offers an excellent safety profile, with rare adverse events associated with the use of fluorescent agents. It has been shown to increase the detection of dysplasia in Barrett's esophagus, gastric intraepithelial neoplasia/early gastric cancer and dysplasia associated with inflammatory bowel and colon diseases compared with standard evaluation protocols. It also enables better differentiation and classification of colorectal polyps, indeterminate biliary strictures and pancreatic cystic lesions.

In 2022, in a recent meta-analysis entitled "High definition probe-based confocal laser endomicroscopy review and meta-analysis for neoplasia detection in Barrett's esophagus", the biomedical databases MEDLINE and EMBASE were searched for studies reporting the diagnostic results of confocal laser endomicroscopy using Cellvizio® as an adjunct to randomized 4-quadrant biopsies in the surveillance of patients with Barrett's esophagus for the early detection of dysplasia and cancer. Studies were eligible if they prospectively compared the real-time diagnostic accuracy of confocal laser endomicroscopy using Cellvizio® with the Seattle protocol, and if they used the GastroFlex™ UHD miniprobe. After applying these selection criteria, 9 studies were deemed eligible, including 688 patients and 1299 lesions. The sensitivity, specificity and negative predictive value of confocal laser endomicroscopy per patient were 96%, 93% and 98% respectively. Compared with random biopsies, the increases in absolute and relative neoplasia detection rates per patient with confocal laser endomicroscopy were significant and equal to 5% and 243%, respectively. The study demonstrates that the addition of endomicroscopy with Cellvizio® as an adjunct to guide biopsies provides a significantly higher diagnostic yield for dysplasia and cancer, and reduces sampling error compared with random four-quadrant biopsies alone, the standard method of diagnosis.

A retrospective multicenter study entitled "Health service utilization among patients with Barrett's Esophagus using Confocal Laser Endomicroscopy versus standard of care" analyzed the records of 60 patients with Barrett's Esophagus referred for endoscopic surveillance or treatment. The authors examined differences in gastroenterology health service utilization for 8 items/services among patients imaged with Cellvizio® as adjuvant versus standard diagnosis alone. The Cellvizio® cohort obtained lower scores in the order of : 1.04 fewer endoscopy and anesthesia services, 7.49 fewer biopsy vials, 1.30 fewer ablations, and 1.46 fewer cytology brush services. Thus, the researchers concluded that confocal laser endomicroscopy by Cellvizio® is associated with a lower overall burden on the healthcare system.

Biliary strictures

Biliary stenosis is a narrowing of the bile ducts, preventing bile from flowing from its source in the liver to the gallbladder and intestines. Biliary stenosis may be benign in origin, or caused by a form of cancer, cholangiocarcinoma, which has a poor prognosis and progresses rapidly if not treated early.

4 studies (including the Group-sponsored Focus study published in 2015) involving a cumulative total of 252 patients revealed that confocal miniprobe endomicroscopy detected 88% of cancerous biliary strictures, compared with 59% for traditional tissue sampling methods. This excellent result in favor of Cellvizio® points to a profound change in the management of patients suffering from this highly aggressive form of cancer, by considerably reducing the number of repeated diagnostic procedures and offering them more appropriate and earlier treatment.

Conversely, a negative Cellvizio® result reassures patients with a high level of confidence, and avoids the repetition of highly anxiety-provoking and costly procedures, thanks to a negative predictive value of 78% compared with 57% for tissue samples.

In 2022, a meta-analysis based on 18 scientific articles confirmed these excellent results, showing that confocal endomicroscopy by minisonde has a sensitivity of 88% compared with 54% for traditional tissue sampling methods. The authors of this study concluded that confocal endomicroscopy by Cellvizio® is a better approach for diagnosing biliary strictures, as it provides real-time microscopic images of the bile ducts.

Chronic Inflammatory Bowel Diseases (CIBD)

Various studies have shown that miniprobe confocal endomicroscopy can be used for IBD patients to go beyond clinical symptoms, assessing the state of the mucosa at microscopic level, and recommending a suitable treatment protocol. Confocal minisonde endomicroscopy has been evaluated in the different phases of the disease in order to :

- Identify IBD patients[3] ;
- Identify patients responding to treatment following an initial prescription[4,5] ;
- Rationalize treatment follow-up in terms of dose and duration:
    - By assessing disease progression and therapeutic response at the cellular level[6] ;
    - By identifying patients in remission via mucosal healing[7] ;
    - Anticipating relapse;
- Detect precancerous lesions and differentiate DALMs (Dysplasia Associated Lesion or Mass) from ALMs (Adenoma like Mass)[8,9] .

In 2022, Professor Timo Rath, Head of the Ludwig Demling Endoscopy Center of Excellence at Erlangen University Hospital, published the final results of the ERIca trial (Erlangen Remission in IBD, clinicaltrials.gov NCT05157750) in Gastroenterology, the flagship journal of the American Gastroenterological Association, in the article "Intestinal barrier healing is superior to endoscopic and histologic remission for predicting major adverse outcomes in IBD: the prospective ERIca trial". This long-term prospective clinical trial aimed to predict major adverse outcomes in patients

[3] Hundorfean G. et al. Confocal Laser Endomicroscopy Provides Potential Differentiation Criteria Between Crohn's Disease and Ulcerative Colitis. Inflammatory Bowel Disease, 2012.

[4] Kiesslich R. et al. Local Barrier Dysfunction Identified by Confocal Laser Endomicroscopy Predicts Relapse in Inflammatory Bowel Disease. Gut, 2012.

[5] Neumann H. et al. Assessment of Crohn's Disease Activity by Confocal Laser Endomicroscopy. Inflammatory Bowel Disease, 2012

[6] Liu J. et al. Increased Epithelial Gaps in the Small Intestines of Patients with Inflammatory Bowel Disease: Density Matters. Gastrointestinal Endoscopy, 2011.

[7] Kiesslich R. et al. Local Barrier Dysfunction Identified by Confocal Laser Endomicroscopy Predicts Relapse in Inflammatory Bowel Disease. Gut, 2012

[8] Kiesslich R. et al. Chromoscopy-Guided Endomicroscopy Increases the Diagnostic Yield of Intraepithelial Neoplasia in Ulcerative Colitis. Gastroenterology, 2007

[9] De Palma G.D. In-vivo Characterization of DALM in Ulcerative Colitis with High-Resolution Probe-based Confocal Laser Endomicroscopy. World Journal of Gastroenterology, 2011.

with chronic inflammatory bowel disease (IBD) using confocal laser endomicroscopy with Cellvizio®. Endoscopy is the key technique for monitoring IBD patients, with patients undergoing surveillance colonoscopy once a year or every two years. Endoscopic and histological remission, characterized by visual assessment of the colon and analysis of random biopsies, has become a key therapeutic goal in IBD management and is associated with favorable long-term outcomes. In this study, the authors prospectively compared the predictive value of intestinal barrier healing assessed dynamically and functionally by confocal laser endomicroscopy (Cellvizio®) with that of endoscopic and histological remission to predict long-term disease behavior in a large cohort of IBD patients in clinical remission. The study data clearly show that intestinal barrier healing, as assessed by dynamic and functional visualization using confocal laser endomicroscopy, is a prognostic parameter that far surpasses endoscopic and histological remission, or their combination, in predicting the occurrence of major clinical events in patients with ulcerative colitis and Crohn's disease. This finding has far-reaching implications for how patients with these debilitating diseases should be monitored during remission.

Cystic tumors of the pancreas: a high-potential application

Pancreatic fluid-filled cavity developing on the pancreas, usually some time after an acute attack of pancreatitis. These cysts are most often detected incidentally on CT or MRI scans, and some have the potential to degenerate into pancreatic cancer.

The results of the second phase of the CONTACT study were presented at the UEGW European Congress in October 2016 and then more fully at DDW 2017. The study, involving 209 patients in five French centers, shows that needle endomicroscopy successfully confirmed the benign nature of indeterminate pancreatic cysts with 100% specificity thanks to confirmation of the superficial vascular network present only in this type of cyst and invisible by traditional imaging, identified in the first phase of this study published in 2015 in Endoscopy and in Surgical Endoscopy. This feature, never before observed using other medical imaging techniques, represents a real breakthrough in the diagnosis of benign cysts of the pancreas (serous cystadenomas), potentially saving many patients from unnecessary operations and examinations. Other characteristic signs of equally specific malignant lesions were also presented at UEGW in 2016 and published in 2018 in the journal endoscopy (mucinous cysts and intracanal papillary mucinous tumors of the pancreas). Following these very promising results, a new analysis presented by Dr Bertrand Napoléon in October 2017 at UEGW, showed that the use of Cellvizio® :

- Modified 30% of diagnoses while significantly improving inter-observer agreement on diagnosis from 0.45 to 0.76 and increasing the number of diagnoses with a high degree of certainty from 57% to 79%,
- Modified 28% of patients' therapeutic decisions, while significantly improving inter-observer agreement on these decisions from 0.36 to 0.64.
- It enabled 42% of patients with benign cysts to avoid any form of surveillance, and transformed the choice between surveillance and surgery for 15% of patients with precancerous lesions.

This advance will counteract the limitations inherent in conventional cytological sampling, such as the absence of analyzable fluid.

These results represent an important advance in terms of patient management, avoiding unnecessary surgery in patients with benign lesions, and reducing uncertainty for the practitioner making the final diagnosis.

The study also highlights the ease with which images obtained with Cellvizio® can be interpreted, enabling even novice endoscopists to make a reliable diagnosis.

In 2019, three publications on two large prospective studies (ClinicalTrials.gov Study ID INDEX: NCT02516488 and CONTACTII: NCT01563133) were also published, demonstrating the positive impact of Cellvizio® on the diagnosis and management of pancreatic cystic lesions. The articles entitled, "Diagnostic Accuracy of EUS-guided Confocal

Laser Endomicroscopy for Differentiating Mucinous Mucinous from Non-Mucinous Pancreatic Cystic lesions", "EUS-guided confocal laser endomicroscopy: prediction of dysplasia in intraductal papillary mucinous neoplasms" and "Impact of needle-based confocal laser endomicroscopy on the therapeutic management of single pancreatic cystic lesions", were published in three scientific journals: Clinical Gastroenterology and Hepatology (2019, DOI: 10.1016/j.cgh.2019.06.010), Gastrointestinal Endoscopy (2019, DOI: 10.1016/j.gie.2019.09.014) and Surgical Endoscopy (2019, DOI: 10.1007/s00464-019-07062-9).

Currently, diagnosis of pancreatic cysts relies on carcinoembryonic antigen (CEA) analysis of intracystic fluid and/or cytology, which can be subjective or difficult to interpret with over 50% of cysts without cytological confirmation after fine-needle aspiration. Managing patients with pancreatic cysts using standard methods is also a challenge, given the lack of optimal diagnoses and divergent clinical recommendations for patient management.

In 2020, two major publications, a meta-analysis and an international Delphi consensus, were published in peer-reviewed journals, both based on systematic reviews of published clinical studies of needle endomicroscopy for the assessment of pancreatic cystic lesions.

The first publication, entitled "Needle-based Confocal Laser Endomicroscopy in Pancreatic Cysts: a Meta-Analysis", was published in the European Journal of Gastroenterology & Hepatology (2020, DOI: 10.1097/MEG.0000000000001728). Ten studies involving 536 patients were included, and the authors assessed diagnostic accuracy, sensitivity, specificity and average procedure time. The meta-analysis concluded that confocal laser endomicroscopy "clearly outperformed" fine-needle puncture guided by endoscopic ultrasound imaging in terms of diagnostic accuracy (with a ratio equal to 3.94, [1.58 - 9.82]; P = 0.003) and recommends the use of needle endomicroscopy as a safe and effective tool in the diagnostic evaluation algorithm for pancreatic cysts.

The second publication, entitled "Confocal Endomicroscopy for the Evaluation of Pancreatic Cystic Lesions: A Systematic Review and an International Delphi Consensus Report", was published in the peer-reviewed journal, Endoscopy International Open (2020, DOI: 10.1055/a-1229-4156), and is based on the consensus of an international panel of 15 experts in pancreatic diseases who reviewed the evidence for the application, performance, indications, training, and skills required to perform needle endomicroscopy in the evaluation of pancreatic cystic lesions. The consensus synthesis reflects a high level of agreement regarding the experts' claims and establishes that endoscopic ultrasound imaging-guided needle endomicroscopy is a safe, minimally invasive procedure that improves the evaluation of pancreatic cystic lesions and "should be routinely performed when fine needle aspiration is indicated for the evaluation of pancreatic cysts." The report also concluded that the use of needle endomicroscopy as an adjunct to fine-needle puncture could improve patient management and would optimize healthcare resources by reducing the number of diagnostic errors, stopping unnecessary ongoing monitoring and avoiding unnecessary surgery.

In 2021, three new clinical publications demonstrate that the use of Cellvizio® improves diagnostic accuracy, patient management, including surgical decisions, and its impact on the cost of managing these patients: the first publication evaluates the ability of nCLE to risk-stratify cystic lesions of the pancreas (CLP) using artificial intelligence (AI) models for classification of nCLE images, the second publication is a meta-analysis of needle endomicroscopy for the evaluation of PCLs, and the third demonstrates the economic advantage of Cellvizio® for the management of PCLs, with Cellvizio's proven diagnostic accuracy enabling the grade reduction of certain mucinous to non-mucinous tumors, offering significant savings in healthcare costs.

The majority of LKPs discovered incidentally in the population are papillary and mucinous intraductal tumors of the pancreas (PMITTs), a precursor to cancer (adenocarcinoma) of the pancreas. Current diagnostic methods rely on a combination of clinical history, medical imaging, ultrasound criteria and cytological analysis of cystic fluids to identify TIPMPs with advanced dysplasia. Today, around half of the TIPMPs that are surgically removed are ultimately found to have low- or medium-grade dysplasia. To avoid unnecessary resections of indolent lesions, which are correlated with high rates of postoperative morbidity (30%) and mortality (2.1%), it is essential to have more accurate methods for diagnosing TIPMPs in order to better guide the management of these patients, especially when it comes to a surgical decision.

The first study, entitled "High performance in risk stratification of intraductal papillary mucinous neoplasms by confocal laser endomicroscopy image analysis with convolutional neural networks", published in the peer-reviewed journal Gastrointestinal Endoscopy (2020, DOI: 10.1016/j.gie.2020.12.054), reported the successful development and application of artificial intelligence algorithms using nCLE images for the diagnosis and risk stratification of TIPMPs. The authors demonstrated that learning models derived from nCLE images were more accurate for diagnosing and risk stratifying advanced dysplasia in TIPMP than standard diagnostic methods and learned society recommendations.

The second publication, entitled "Needle-based Confocal Laser Endomicroscopy (nCLE) for Evaluation of Pancreatic Cystic Lesions: A Systematic Review and Meta-analysis", was published in the Journal of Clinical Gastroenterology (2020, DOI: 10.1097/MCG.0000000000001468). Seven clinical studies involving 324 patients were included, and the authors assessed diagnosis, accuracy, sensitivity, and specificity. They concluded that "nCLE appears to be an effective and safe technique for the diagnostic evaluation of PCL". Indeed, nCLE was associated with a sensitivity of 85%, a specificity of 99%, a diagnostic accuracy of 99% and a post-operative pancreatitis rate of 1%.

Conventional management of pancreatic cysts involves a diagnostic workup that can be prone to misclassification of mucinous versus non-mucinous cysts, placing patients on an incorrect therapeutic or monitoring program, and potentially leading to unnecessary surgery on a benign cyst. The third publication, entitled "Cost-Benefit Analysis and Resource Implications of Endoscopy Ultrasound-guided Confocal Endomicroscopy in Pancreas Cysts" and published in Techniques and Innovations in Gastrointestinal Endoscopy (TIGE) (DOI: https://doi.org/10.1016/j.tige.2021.10.002), assessed the impact of the proven diagnostic accuracy of ultrasonic endoscopy-guided confocal needle laser endomicroscopy (EUS-nCLE) for KPL on healthcare expenditure when added to standard management. Through a post-hoc analysis of 93 patients enrolled in the INDEX study (NCT02516488), the authors concluded that the diagnostic accuracy of EUS-nCLE enabled cysts to be reduced from mucinous to non-mucinous grade in 12% of patients, sparing them unnecessary surgery. As a result, the authors point out that "EUS-nCLE is potentially cost-effective in the management of cystic lesions of the pancreas by avoiding at least one unnecessary pancreatic surgery for every ten subjects undergoing evaluation according to current practice." In addition, EUS-nCLE also detected a mucinous cyst in one patient, enabling earlier intervention as well as a reduction in the number of repeat diagnostic procedures and subsequent follow-up examinations. Across concordant and discordant diagnoses, the addition of Cellvizio® led to a net saving of $442,438 for this cohort, or approximately $4,757 per patient. The authors also concluded that, "when combined with favorable data regarding greater diagnostic accuracy, the ability to risk-stratify the most common precancerous cystic neoplasms, papillary and mucinous intra-canal tumors of the pancreas, and the absence of a higher-than-expected risk of post-procedural adverse events, the current economic analysis favors the application of EUS-nCLE in diagnostic algorithms."

These publications demonstrate the very high diagnostic yield of confocal needle endomicroscopy (84% to 91%), while validating the accuracy of differentiation between mucinous and non-mucinous pancreatic cysts (97% in both studies). These high diagnostic performances had an impact on 28% of therapeutic decisions in patients with pancreatic cysts, enabling surveillance to be discontinued in 35% of patients with benign cysts, and reversing the choice between surveillance and surgery in 15% of precancerous lesions, thus avoiding unnecessary surgery for patients.

Irritable bowel syndrome (IBS) and food intolerance

Since 2014, confocal laser endomicroscopy (CLE) applied to the in vivo food challenge has demonstrated highly innovative results in the management of IBS :

Kiel's seminal study (Fritscher-Ravens et al., 2014): in 36 IBS patients, intraduodenal instillation of food extracts induced live fluorescein leakage and widening of intervillous spaces in 61% of cases (22 / 36). After four weeks of personalized exclusion diet, > 50% symptomatic improvement was achieved in all CLE + subjects; this benefit reached 74% one year later PubMed.

Multicenter, double-blind trial (Bojarski et al., *Gut* 2022): 147 IBS patients were blinded to wheat, milk, soy or yeast. CLE identified a reaction to one of these foods in 51% of wheat-sensitive subjects at two months (Se 51%, Sp 68%) and, importantly, predictively classified 83% of "food-sensitive" patients who remained improved at six months on Gut-targeted diet.

Prospective study Bamberg - UEGW 2024 (Langhorst): of 119 IBS patients, 62% showed immediate hyperpermeability to at least one food. Under the CellTolerance® protocol (exclusion + multimodal management), 71% showed restoration of the barrier at six months, including 46% with complete normalization, with a significant drop in the IBS-SSS severity score and an improvement in quality of life Mauna Kea Technologies.

These results suggest that one in two IBS patients has an atypical food intolerance that can be detected by Cellvizio®. By offering a real-time reading of the integrity of the intestinal barrier, the platform becomes the first endoscopic solution capable of transforming a currently empirical diagnosis into a personalized etiological approach, with high rates of lasting symptom improvement - an addressable market estimated at over 6 billion USD per year.

Respiratory

Lung nodules (rounded or oval lesions less than 3 cm in diameter surrounded by healthy lung tissue) are most often detected incidentally, and benign, but they can also correspond to forms of lung cancer, the most frequent cause of cancer death in both men and women after breast cancer, with 1.3 million deaths per year worldwide. In 2013, Mauna Kea Technologies initiated a major study in a dozen referral centers in the United States, to measure the impact of Cellvizio® on the diagnosis of lung nodules. The aim of this 2-phase study, involving 200 patients, is to demonstrate that Cellvizio® improves the accuracy of bronchoscopies, while avoiding the need for costly and invasive clinical examinations. Real-time cell visualization will offer pulmonologists a new diagnostic solution to improve the diagnostic yield of bronchoscopy, by offering the possibility of differentiating, in real time, between healthy and nodular tissue.

This study also aims to evaluate the role of confocal laser endomicroscopy in detecting rejection following lung transplantation. These fragile patients must undergo a large number of bronchoscopies with tissue sampling in the weeks following transplantation, in order to detect any signs of rejection. The risk of bleeding associated with physical biopsies subjects these patients to a non-negligible risk of morbidity. In May 2017, new data demonstrating the applicability of Cellvizio® to assess acute lung graft rejection (ALR) after transplantation were presented at the 2017 American Thoracic Society (ATS) International Conference. The study, entitled "Minisonde laser confocal endomicroscopy in the diagnosis of acute lung graft rejection: results of a prospective multicenter trial", featured an oral presentation by lead investigator Cesar A. Keller, M.D., Mayo Clinic, Jacksonville, Florida. Key points of the study are as follows:

- In a follow-up examination of 24 lung transplant patients (16 double and 8 single), Cellvizio® imaging was obtained immediately before tissue sampling (biopsy), and the images were blindly reviewed by 4 pulmonologists (1 expert Cellvizio® reviewer and 3 junior reviewers), first independently, then after a consensus meeting ;

- Reproducibility, assessed by calculating the intra-class correlation coefficient (ICC) and Fleiss' kappa (K) before and after a consensus meeting, was 0.77 and 0.39 before consensus and 0.96 and 0.77 after consensus, respectively ($p < 0.001$) ;

- The study concluded that the perivascular cellularity observed with Cellvizio® represents a reproducible criterion for assessing acute rejection *in vivo*, even if, at this stage, a learning curve is required for image interpretation.

According to Dr. Keller, "Miniprobe endomicroscopy represents a potential new tool for providing a less invasive diagnosis of acute lung graft rejection in transplant patients requiring transbronchial biopsies. The results of the study suggest that endomicroscopy could potentially spare patients from unnecessary and risky invasive biopsies. We look

forward to further investigating this application of endomicroscopy to improve the therapeutic continuum for lung transplant patients."

This study was also published in the journal Transplantation .[10]

In 2019, the team of Professor Pr. J. T. Annema, M.D. Ph.D., Head of the Department of Pulmonology at Amsterdam University Medical Centers, demonstrated, for the first time, that imaging and identifying benign and malignant cellular structures inside lung nodules and lymph nodes using confocal needle laser endomicroscopy was not only possible but also reproducible in a presentation at the ERS (European Respiratory Society) congress held in Paris in September 2018. The availability of nCLE in the lungs clearly has the potential to have a major impact on the accuracy of diagnosis of peripheral nodules, one of the most difficult challenges in the fight against lung cancer. An article "Needle-based confocal laser endomicroscopy for real-time diagnosing and staging of lung cancer" was published in the European Respiratory Journal (2019, DOI: 10.1183/13993003.01520-2018) in 2019. The use of endomicroscopic needle imaging provides precise results on the nature of lung lesions and metastatic lymph nodes, according to the team led by Prof. J. T. Annema, Professor of Pulmonary Endoscopy at Amsterdam University Medical Centers. In this well-designed pilot clinical study, nCLE was shown to detect lung tumors and metastatic lymph nodes with 89% accuracy, with significant intra- and inter-observer agreement. These promising results confirm that nCLE could be an important complement to bronchoscopic navigation for real-time targeting and identification of lung tumors. This is an important publication which further supports Mauna Kea's new market opportunities in interventional pulmonology. Indeed, it demonstrates that the use of our needle endomicroscopy platform opens up a new era in interventional pulmonology, enabling more precise guidance of the optimal sampling zone and potentially the diagnosis, evaluation and treatment of lung lesions in real time. Indeed, current navigation devices offer advanced, minimally invasive access to peripheral nodules, but have limited means of direct visualization outside the airway. Cellvizio®, with the AQ-Flex™ 19 confocal miniprobe, can now be used through the operator channel of existing navigation devices to provide direct visualization through the needle inside peripheral lesions. Cellvizio® is the first endomicroscopic device available and integrable into robot-assisted bronchoscopic navigation platforms. Validation of the needle probes for bronchial applications is therefore a critical point for further exploration of possible indications for Cellvizio® technology in a field at the cutting edge of medical research.

Other interventional pulmonology studies were also published in 2019:

- Endomicroscopy as a guidance tool for pleural biopsies in malignant pleural mesothelioma (MPM): A study published in the journal CHEST (Wijmans L. et al. Confocal laser endomicroscopy (CLE) as a guidance tool for pleural biopsies in malignant pleural mesothelioma. CHEST, 2019), shows that endomicroscopy can visualize pleural abnormalities in epithelial and sarcomatoid MPM in real time and distinguish them from pleural fibrosis. Endomicroscopy can be used as a biopsy guidance tool to significantly reduce the current rate of biopsy recurrence, by identifying in vivo areas with malignant cells.

[10] Transplantation. 2019 Feb;103(2):428-434. doi: 10.1097/TP.0000000000002306. Diagnosis of Acute Cellular Rejection Using Probe-based Confocal LaseEndomicroscopy in Lung Transplant Recipients: A Prospective, Multicenter Trial.Keller CA(1), Khoor A(2), Arenberg DA(3), Smith MA(4), Islam SU(5).

- Endomicroscopy in interstitial lung diseases: Descriptors and correlation with chest CT. A second study published in the journal Respirology (Salaün M. et al. In vivo probe-based confocal laser endomicroscopy in chronic interstitial lung diseases (ILD): Specific descriptors and correlation with chest CT: pCLE in interstitial lung diseases. Respirology, 2019), showed that endomicroscopy can image the in vivo tissue microstructure of the distal lung during bronchoscopy. Endomicroscopic criteria for cellular infiltration of the bronchiolar and alveolar zones and alteration of the acinar elastic network are reproducible between different observers.

In 2019, the Company also sponsored a pilot clinical study with the team of Professor Pr. J. T. Annema, M.D. Ph.D., Head of the Department of Pulmonology at Amsterdam University Medical Centers, to evaluate the use of endomicroscopic needle imaging in peripheral lung lesions. The study was completed in 2020 and included 26 patients.

To support these clinical efforts in the field of interventional pulmonology, Mauna Kea Technologies is conducting parallel technical trials to overcome the technological hurdles posed by compatibility with the bronchoscopes and needles on the market, and in particular the most innovative ones likely to gain market share in the coming years.

That's why feasibility trials were carried out in April 2019 with two innovative robotic interventional pulmonology platforms: Monarch (Auris, recently acquired by J&J) and ION (Intuitive Surgical).

Following the encouraging results of these feasibility tests, a more detailed study was carried out in conjunction with Auris to ensure the compatibility of the AQ-Flex 19 and AlveoFlex probes with the Monarch robotic platform. The main points of verification concerned the probes' resistance to the bending radii and bending forces imposed by the robot, the absence of any disruption to the robot's maneuverability, and the absence of any disruption to its electromagnetic field-based space localization system. These tests demonstrated the compatibility of the current probes with the navigation system and the Monarch bronchoscope.

In collaboration with Johnson & Johnson's Lung Cancer Initiative (LCI), Dr. Christopher Manley, Director of Interventional Pulmonology and Assistant Professor of Medicine at Fox Chase Cancer Center (FCCC) in Philadelphia, and Dr. Jouke T. Annema, Professor of Pulmonary Endoscopy at the University of Amsterdam Medical Center, have received approval from the FCCC to launch a pilot clinical study, combining nCLE and robotic bronchoscopic navigation, using both Cellvizio® and the Monarch™ platform from Auris Health, Inc. one of Johnson & Johnson's medical device companies, for the diagnosis of peripheral lung nodules. This study is co-funded by Johnson & Johnson's LCI and Mauna Kea Technologies (Clinicaltrials.gov: NCT04441749). The main objective of the study is to assess the feasibility and safety of nCLE during bronchoscopy with robotic navigation in the evaluation of peripheral lung lesions.

This study began in 2020 and involves 25 patients with peripheral nodules. The recruitment phase of the Fox Chase study ended in July 2021. The results of this first-in-man clinical study combining nCLE and robot-assisted bronchoscopy have been published in the international peer-reviewed journal Respirology (DOI: 10.1111/resp.14438). This study combined the dexterity of robot-assisted bronchoscopy with the information accuracy of nCLE's real-time in vivo cell imaging to precisely target small lung lesions. The data show the potential of combined robotic bronchoscopy and nCLE imaging as a safe strategy that improves the diagnosis of small, difficult-to-access lung nodules. Twenty patients with a median lung nodule size of 14.5 mm (range 8-28 mm) were enrolled. This study demonstrated that robot-assisted bronchoscopic nCLE imaging for small peripheral lung lesions is feasible and safe, and provides real-time feedback on correct needle positioning. Bronchoscopic nCLE imaging confirmed correct targeting of the needle ("tool-in-lesion") into the nodule in 19 of 20 patients (95%), whereas the corresponding rapid on-site cytological evaluation (ROSE) confirmed the presence of representative material in only 9 of 20 patients (45%).

No complications were reported during the study. Thanks to feedback from nCLE real-time in vivo cellular imaging, the needle was repositioned in 45% of patients (9/20 patients) to achieve a diagnostic yield of 80% for all nodule sizes

and locations. Of the 17 patients presenting with malignancy, 16 (94%) had the final diagnosis of lung cancer confirmed by nCLE imaging, including two patients with negative TBNA and biopsies. Blinded reviewers accurately and consistently distinguished malignant nCLE videos from airway/lung parenchyma.

In 2021, a second study was also published by AUMC and funded by Mauna Kea Technologies, to evaluate the use of needle endomicroscopy as a real-time lung cancer detection tool. This prospective study included 26 patients with peripheral lung nodules and was published in Thorax, a prestigious journal. The article entitled "Bronchoscopic needle based confocal laser endomicroscopy (nCLE) as a real-time detection tool for peripheral lung cancer" (DOI: 10.1136/thoraxjnl-2021-216885) provides further evidence that endomicroscopic imaging with Cellvizio of suspected cancerous peripheral lesions is feasible, safe, and allows real-time detection of malignancy at the needle tip with very high accuracy. This new study has confirmed that endomicroscopic needle imaging in peripheral lung cancer is feasible, safe and enables real-time detection of malignancy at the needle tip with an accuracy equal to 95%. Lead investigator Professor Annema also added that physicians can differentiate, with high reproducibility (with excellent intra- and inter-observer agreements equal to 0.82 and 0.78, respectively), malignant airway tissue from healthy lung parenchyma, demonstrating the potential of nCLE imaging as a real-time guidance tool to reduce the rate of non-contributory transbronchial biopsies of peripheral lung cancer.

In 2023, Mauna Kea Technologies also initiated a collaborative study with the Mayo Clinic. The study combines endomicroscopic imaging and robot-assisted bronchoscopy, using both Cellvizio® and Intuitive Surgical, Inc.'s Ion platform for navigation and guidance of minimally invasive peripheral lung biopsy to assess the ability of nCLE to improve the physician's ability to quickly and accurately position a biopsy tool at the center of peripheral lung nodules. The primary objective of this study is to evaluate the ability of nCLE to improve diagnostic yield and accuracy of confirmation of successful lesion targeting ("tool-in-lesion") and definitive diagnostic lesion sampling ("lesion-in-tool") during robotic-assisted bronchoscopy procedures. Secondary objectives are to assess the reproducibility of nCLE use across multiple institutions, and to evaluate the ability of nCLE to diagnose malignancy versus non-malignancy. This study includes 118 patients with peripheral lung nodules at two prestigious U.S. sites, the Mayo Clinic campus in Jacksonville, Florida, and the Mayo Clinic campus in Rochester, Minnesota.

Urology

Bladder cancer is a disease characterized by the formation of cancerous cells in bladder tissue. It is a public health problem, mainly because of the extremely high recurrence rate (75%), which means that patients have to be monitored for the rest of their lives, which is very costly for the healthcare system.

For use in the detection and treatment of bladder lesions, confocal mini-probe endomicroscopy enables dynamic visualization of the cellular organization of the bladder wall, non-invasively, by means of mini-probes introduced into the operating channel of the cystoscope.

To date, more than 10 clinical publications on the use of ECM in the bladder have been published. The technical feasibility of the ECM procedure was reported by Liao et al, starting in 2009.

In the same year, the first results of an in vivo feasibility study were published in the Journal of Urology. The study of 27 patients validated the feasibility of the in vivo technique, and its ability to obtain interpretable images of the bladder urothelium and differentiate normal mucosa from low- and high-grade lesions.

A 2011 study by the same team refined the optical specifications of the miniprobe used during rigid cystoscopy procedures.

More recently, several prospective studies have established an atlas of ECM images in the bladder and adjacent organs, and evaluated their diagnostic performance. More specifically, the atlas of ECM images obtained from a

cohort of 66 patients has enabled us to establish a preliminary classification of lesions observed in the bladder, kidney, prostate, urethra and ureters, differentiating normal tissue from inflammatory or malignant lesions.

In a study by J. Liao's team at Stanford, CA, USA published in 2012, the diagnostic accuracy of ECM was compared with that of white light on 57 patients during RTUV procedures. For low-grade lesions, the combination of white light and ECM achieved 100% diagnostic accuracy and 100% sensitivity for high-grade lesions. (Source: interobserver Agreement of Confocal Laser Endomicroscopy for Bladder Cancer, The Journal of Urology, doi: 10.1089/end.2012.0549, May 2012). Furthermore, in 2015, Prof. Traxer's team (Hôpital Tenon, Paris) published clinical results obtained in the upper urinary tract with Cellvizio® on a series of 11 patients (partially presented at the EAU congress, 2014). Tumors of the upper urinary excretory tract account for 5% of urothelial tumors. Given the difficulties of access, diagnosis of these lesions is extremely difficult with current techniques.

These preliminary data, in favor of Cellvizio® , suggest a potential role for this technique in the diagnosis and management of these lesions. ECM is also mentioned in the latest recommendations of the EAU (European Association of Urology) for its potential in the diagnosis of urothelial tumors[11] . Larger-scale studies are currently underway to validate these preliminary data.

Surgery

In the field of robotic surgery, the Company continued to develop its clinical activities as part of the BPI-funded PERSEE project. Surgery, and in particular minimally invasive surgery, is an area of medicine in which real-time microscopic imaging technology can find numerous applications. The PERSEE project, launched in 2010, is a collaborative project aimed at developing a miniature, robotized flexible endomicroscope for minimally invasive exploration of the abdominal cavity to detect possible contraindications to excision surgery. The aim is to offer cancer patients the best therapeutic strategy between surgery, chemotherapy or radiotherapy. Numerous trials have been undertaken, with doctors expressing their enthusiasm and interest in the potential of the solutions they were able to test in this first study.

The second pilot phase of the PERSEE II project began in 2017 with the aim of confirming the results of the first phases of the project with other doctors in other investigative centers. These objectives will be achieved within the framework of a multicenter trial, using specific tools developed on the basis of Cellvizio® technology.

In 2018, researchers finalized the protocols for the two multicenter pilot trials. The protocol for the urology trial involving the IMM, Hôpital des Diaconesses and Hôpital Tenon was approved, and the first patient inclusion took place in early 2019. The gastroenterology pilot trial protocol has been finalized and the investigators obtained final approval from the ANSM in January 2019.

A preliminary ex vivo study was carried out in the anatomopathology laboratory at Tenon Hospital at the end of 2018. Its aim was to establish an endomicroscopic imaging atlas of prostate tissue that would provide knowledge and facilitate location during the in vivo phase during radical prostatectomy procedures.

Anatomopathologists, on the basis of histological analysis of prostatic resection specimens, have been able to establish correlations with endomicroscopic images, namely:

- Detection of prostatic vascularization ;
- Locating periprostatic adipose tissue ;
- Characterization of normal prostate glands;

[11] Eur Urol. 2018 Jan;73(1):111-122. doi: 10.1016/j.eururo.2017.07.036. Epub 2017 Sep 1. European Association of Urology Guidelines on Upper Urinary Tract Urothelial Carcinoma: 2017 Update. Rouprêt M(1), Babjuk M(2), Compérat E(3), Zigeuner R(4), Sylvester RJ(5), Burger M(6), Cowan NC(7), Gontero P(8), Van Rhijn BWG(9), Mostafid AH(10), Palou J(11), Shariat SF(12).

- Characterization of tumoral prostate glands (a different degree of fluorescein impregnation was observed in tumoral glands compared with normal glands). In addition, it was possible to correlate tumor glands with their level of malignancy on the basis of histology, using the Gleason score to assess the tumor grade of prostate cells;

- Detection of nerve tissue with visualization of axons corresponding to the extension of a neuron's cell body;

- Visualization of striated muscle fibers of the bladder neck, playing a role in continence function.

These data were the subject of an abstract at the European Urology Congress (EAU congress) and the publication of a scientific article.

Based on this initial ex vivo analysis of prostate tissue, a multicenter prospective in vivo study has been set up to evaluate endomicroscopic imaging during robotic radical prostatectomy. The study is the fruit of collaboration between IMM, the Diaconesses Croix Saint-Simon hospital group and the Tenon hospital of the Assistance Publique - Hôpitaux de Paris. The first two centers included 31 patients between January 2019 and October 2020. Analyses of endomicroscopic images and their correlation with final histopathological diagnoses were carried out in collaboration with the anatomopathology laboratory at IMM and the anatomopathology department at Hôpital Tenon.

The surgeons performed their radical prostatectomy procedure with no change to standard practice. Dissection of the prostate was performed with the assistance of the Da Vinci surgical robot. Once the prostate had been dissected, fluorescein was used: several methods were employed. This contrast agent was either administered intravenously or applied directly to the surface of the prostate using a fluorescein-impregnated pad.

The data collected in this in vivo urology study show that :

- The use of confocal laser endomicroscopy is feasible during robot-assisted radical prostatectomy procedures,

- The CelioFlex UHD 5 Confocal Miniprobe is safe to use. There is a learning curve, but it's a very short one. So it's a good idea to support future new users of this Confocal Miniprobe model during their first procedures,

- The design of the CelioFlex UHD 5 Confocal Miniprobe is adapted to the majority of laparoscopic surgery configurations,

- The method of applying fluorescein directly to the surface of the organ is sufficient to obtain imaging with a good level of contrast for interpretation. This also helps reduce the risk of anaphylactic shock described in the scientific literature following intravenous administration of this molecule,

- The inter-center telepathology system is reliable. The viewing interface could be adapted to improve its ergonomics, for example by adding a time indicator or the image number on the video, to make it easier to find your way through an imaging sequence.

An abstract on the data analysis was written and submitted to the European Congress of Urology (EAU congress).

Development of imaging with fluorescent molecular markers

The notion of optical biopsy is becoming a reality thanks to fluorescence-guided surgery (FGS). In the space of ten years, molecular imaging has changed the game considerably. This intra-operative detection technique imagined many years ago is now being developed in operating theatres, where imaging systems are becoming more numerous and, above all, more efficient. Technical improvements will certainly continue, but several medical devices are now available in clinics (e.g., the Spectrum system and the SpyPhi intraoperative fluorescence column) thanks to very active R&D activity in recent years. The principle consists in injecting the patient with a fluorescent liquid which,

depending on the molecular markers present on certain cells, will react in a differentiated manner. While the use of non-targeted dyes can be useful in certain pathologies, specific contrast agents are indispensable in oncology.

For various reasons relating to the physical properties of incident light and induced fluorescence, and to the properties of biological tissues, the most relevant fluorochromes for FGS are in the near-infrared (NIR; 650-900 nm) range. Unfortunately, the dyes currently authorized for clinical use (fluorescein, methylene blue, ICG, IRD800CW) do not emit in these wavelengths and/or are non-targeted dyes. These molecules are very useful in ophthalmology, and are even being evaluated in surgical oncology, but they are unfortunately not the most suitable. Surgical oncologists need high-performance, tumor-targeted NIR fluorescent agents for optimal surgical guidance. Tumor-specific fluorescent contrast agents can be divided into two broad categories: permanent fluorescent agents and activatable agents. The latter category exploits (a) certain specificities of the tumor environment (acidity, presence of enzymes, etc.) or (b) certain properties of the dye (fluorescence quenching) or antibody (internalization) so that fluorescence is only inducible when the tumor target is reached. The category of permanent fluorescent contrast agents includes various targeting molecules: antibodies and their fragments, protein scaffolds (Affibody®, Nanofitin®), peptides and small molecules.

The numerous preclinical studies and a few clinical studies concerning the development of fluorescent tracers for FGS have been the subject of numerous reviews. Indeed, while extrapolation of results from preclinical models to the human situation is always tricky, this is even truer for FGS due to the impact of organism size on imaging performance. The size of a mouse means that virtually any fluorescent nodule can be detected, whereas the detection of deep nodules in humans is a real challenge. We know that fluorescent radiation cannot penetrate tissues more than around 10 to 15 mm thick.

This is one of the reasons why endomicroscopic imaging may be indispensable for assessing deeper tissues in situ with needle endomicroscopy.

Another indication for combining endomicroscopic imaging with FGS is the possibility of improving the specificity of macroscopic molecular imaging, so that the surgeon obtains in real time on his screen a set of information invisible to the naked eye or even by imaging at the time of diagnosis.

Among the most important parameters for the success of FGS with fluorescent molecular imaging markers are antigenic density, marker affinity for the target and dye fluorescence yield.

The antigenic density of the target is crucial to the effectiveness of FGS. While fluorescence enables precision imaging, clearly delineating the tumour nodules that have bound the contrast agent, it remains less sensitive than other techniques such as nuclear medicine. It is therefore essential to use an abundant target on the cell surface. Also, in the optimal configuration, marker expression should be low or non-existent in healthy tissue, at least when the target is accessible to a molecular imaging marker injected intravenously. It must also be stable on the cell surface, with little or no internalization, and stable between the primary tumor and any locoregional metastases and recurrences.

The affinity of the marker for its target must be high, and in particular, the dissociation rate must be very low to enable the conjugate to persist on the target when the serum concentration falls. This is essential to obtain the best fluorescence ratio between tumor and surrounding tissue.

The dye must have a high fluorescence yield, as the amount carried by the target remains low. This is a very different situation from that of non-targeted dyes, which are used at high doses to detect vascular leaks, for example (Fluorescein and ICG). The current consensus is to use dyes in the near infrared (650-900 nm). The two dyes evaluated clinically in target-dye conjugates, IRDye800CW and BM104, have different fluorescence excitation and emission wavelengths, 774/789 nm and 685/705 nm respectively. The debate between the advantages and disadvantages of these two wavelength pairs is still ongoing. The zone around 800 nm allows better penetration of incident light and better recovery of emitted fluorescence, but is penalized by poorer camera performance. Around 700 nm, the maximum penetration of light into living tissue is practically reached, and the use of a targeted 700 nm contrast agent makes it possible to combine it with a non-targeted 800 nm dye, enabling analysis of healthy tissue or vessels.

The Company has developed another version of its so-called F800 technology, capable of exciting fluorophores at a wavelength of 785 nanometers, which could be used to image tissues at the cellular level during surgery, enabling more precise resection and also improving the specificity of fluorescence imaging by visualizing the type and organization of fluorescent cells.

Molecular marker formats and sizes have an impact on conjugate pharmacokinetics and tumor penetration. Whatever the markers used, all the trials carried out to date have used a timeframe of 1 to 5 days, often with better results at the later times. Furthermore, the dye that absorbs and emits in the NIR is necessarily large and hydrophobic. When using larger markers, the hydrophobicity of the dye has a limited effect on the overall hydrophilicity of the conjugate. The ideal delay certainly depends on the antigenic target, the target pathology and the antibody used. Ongoing clinical studies should provide arguments as to the best delay to use. While a short turnaround time (1 day) seems easier to manage in terms of hospital organization, a longer turnaround time (3 to 5 days) will enable a better quality FGS if the antibody used is of high affinity.

- **Marketing authorizations**

Since 2006, the Company has regularly obtained regulatory approvals for its Cellvizio® platform in numerous territories.

In 2015, the Company obtained the extension of commercial authorizations for the AQ-Flex 19 Minisonde dedicated to the observation of pancreatic cysts.

In 2019, the Company obtained the extension of commercial authorizations for the Minisonde AQ-Flex 19 dedicated to the observation of pulmonary nodules (lung cancer).

In 2020, the Company received a new 510(k) clearance from the US Food and Drug Administration (FDA) to market the Cellvizio® 100 Series and all confocal miniprobes combined with a fluorescent marker, fluorescein, for the additional indication of blood flow visualization. This is the 17th 510(k) clearance received from the FDA for the Cellvizio® platform. Also in 2020, the Company obtained extended marketing approvals in Europe and the United States for the new generation of Cellvizio®, called Cellvizio® I.V.E., for indications equivalent to those of Cellvizio® 100 Series. This is the 18th 510(k) clearance from the US FDA for the Cellvizio® pCLE/nCLE platform.

In 2021, the Company renewed the license for the Cellvizio® 100 Series and confocal miniprobes for the Chinese market for a period of 5 years. In the same year, the Company received a new clearance for Cellvizio® 100 series and AQ-Flex in South Korea, and a new 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market Cellvizio® I.V.E. and all confocal miniprobes combined with a fluorescent marker, fluorescein, for the additional indication of blood flow visualization.

In 2022, the Company received new FDA approval for the combination of Cellvizio® with a specific molecular marker, Cytalux, and a contrast agent, indocyanine green. This approval is a key milestone for the molecular imaging market. The Company has also obtained marketing authorization for Cellvizio® I.V.E. in Ecuador.

In 2024, with the CE marking certificate for Cellvizio® 100S and its probes due to expire, the Company has decided not to submit them for evaluation under the regulations. As a result, Cellvizio® 100S and its probes will no longer be marketed in Europe.

Relations with healthcare professionals

The Group has adopted a code of ethics relating to these relationships since 2009, which was reviewed and extended during 2018.

In France, relations with healthcare professionals are governed by the provisions of article L. 4113-6 of the Public Health Code concerning benefits granted to healthcare professionals (the so-called "anti-gift" law). The Company has implemented ethical rules in line with these provisions.

In addition, since 2013, the Company has been declaring agreements established and benefits granted to healthcare professionals in accordance with the requirements of the Sunshine Act in France and the United States.

Environment

The Group has taken into account European regulations on the environment (e.g. REACH, ROHS, WEEE, etc.) which aim to :

- Limit waste and its hazardousnesś,
- Encourage reuse and recycling,
- Improve disposal conditions and control,
- Limit or prohibit the use of certain materials.

These regulations and their requirements are taken into account both in the design of products (eco-design and limitation of certain substances for REACH and ROHS regulations) and in their end-of-life disposal (directive 2012/19 on waste electronic and electrical equipment or WEEE).

Market access and reimbursement

Reimbursement for the medical procedure involved in using Cellvizio® is a critical factor in the widespread use of the technique. In every country, and even every region, public and/or private insurers provide reimbursement for medical procedures for their patients. Mauna Kea Technologies' ambition is to obtain reimbursement for Cellvizio® in its main clinical indications.

To this end, the Reimbursement and Market Access team works closely with Clinical and Regulatory Affairs, Marketing and Sales (and if necessary local distributors), as well as dedicated external resources in the United States, to develop and execute the reimbursement access plan in the countries most strategic from a commercial point of view for the Company, and for indications where the Company has a greater number of users.

Access to reimbursement generally involves creating a procedure (recognition of a new procedure and inclusion in the nomenclature), obtaining "coverage" for it, and pricing it; these three stages may be carried out in parallel or sequentially, depending on the country and insurer in question. It also requires the support of learned societies and experts involved in drawing up best practice recommendations.

The table below **summarizes the reimbursement codes requested/obtained** as of the date of this document:

Pays	Indication	Produit	Autorité compétente	Année de dépôt	Description	Tarification
États-Unis	Voies hautes de l'appareil digestif incluant l'accès au pancréas par aiguille fine	GastroFlex	Association Médicale Américaine (AMA) / Agence fédérale du département américain de la Santé et des Services sociaux (CMS)	2012	Code de remboursement [CPT 43206]. Œsophagoscopie avec endomicroscopie optique (œsophage). Entré en vigueur le 01 janvier 2013.	1 557 USD pour les hôpitaux, 663 USD pour les centres de chirugie ambulatoire, et 138 USD pour les médecins (tarifs applicables en 2020).
		GastroFlex / AQ-Flex		2012	Code de remboursement [CPT 43252]. Œsophago-gastroduodénoscopie avec endomicroscopie optique (voies hautes de l'appareil digestif). Entré en vigueur le 01 janvier 2013.	2 998 USD pour les hôpitaux, 1 306 USD pour les centres de chirugie ambulatoire et 176 USD pour les médecins (tarifs applicables en 2020).
		-		2012	Code de remboursement [CPT 88375] pour l'interprétation des images obtenues avec l'endomicroscopie optique (anatomopathologie). Entré en vigueur le 01 janvier 2013.	51 USD pour les médecins en 2020.
	Voies biliaires	CholangioFlex		2014	Code de remboursement [CPT 0397T]. Cholangio-pancréatographie rétrograde endoscopique (CPRE) avec endomicroscopie optique (voies biliaires). Entré en vigueur le 01 janvier 2016. Renouvelé pour une période de 5 ans.	Selon tarifs publiés.
France	Cartographie d'un endobrachyœsophage	GastroFlex	Haute Autorité de Santé (HAS) / Union Nationale des Caisses d'Assurance Maladie (UNCAM)	2010	Avis favorable de la HAS à l'inscription de l'endomicroscopie optique réalisée lors de la cartographie d'un endobrachyœsophage sur la Liste des actes et prestations (17 septembre 2014).	Par décision de l'UNCAM (18 avril 2019), l'acte d'endoscopie œsophagienne avec biopsie guidée par endomicroscopie confocale par laser [HEQE263] est créé à la CCAM et tarifé à 150 euros pour l'examen et 69 euros pour l'anesthésie.
	Caractérisation des sténoses bilaires	CholangioFlex	Haute Autorité de Santé (HAS)	2010	Avis défavorable de la HAS à l'inscription de l'endomicroscopie sur la Liste des actes et prestations (22 juillet 2015). Des données complémentaires sont nécessaires pour apporter la preuve de l'utilité clinique de l'endomicroscopie dans cette indication.	N/A
	Suivi des cicatrices de résection de polypes du côlon	ColoFlex		2010	Aucun avis ne sera publié. Le dossier a été retiré du programme de travail de la HAS (T1-2017).	N/A
Allemagne	Endomicroscopie confocale de l'appareil digestif	GastroFlex / CholangioFlex / ColoFlex	Institut allemand pour la documentation et l'information médicale (DIMDI)	2013	Code [OPS 3-301] ajouté dans la nomenclature médicale pour une procédure d'endomicroscopie dans l'appareil digestif, inclus les voies biliaires et pancréatiques. Entré en vigueur le 01 janvier 2014.	Prise en charge locale en hospitalisation privée pour les allergies alimentaires atypiques associées au syndrome de l'intestin irritable. NB : La tarification à l'activité (G-DRG) est alors appliquée.
Royaume-Uni	Endomicroscopie par aiguille fine pour la caractérisation des lésions du pancréas	AQ-Flex	Institut national pour la santé et l'excellence des soins (NICE)	2015	Avis défavorable du NICE-MTEP (30 novembre 2015). Des données complémentaires sont nécessaires pour apporter la preuve de l'utilité clinique de l'endomicroscopie dans cette indication. Publication d'un rapport d'évaluation technologique (MIB) le 26 juin 2016.	N/A
Chine	Endomicroscopie confocale	GastroFlex / CholangioFlex / ColoFlex / AQ-Flex	Ministère de santé Chinois	2016	Une tarification a été obtenue dans plusieurs régions permettant aux hôpitaux de facturer les patients, selon la méthodologie chinoise.	Varie selon les régions.
Croatie	Endomicroscopie confocale	GastroFlex / CholangioFlex / ColoFlex / AlveoFlex / UroFlex / CystoFlex	Fonds croate d'assurance maladie (HZZO)	2017	Les procédures réalisées avec le Cellvizio® sont couvertes pour les patients atteints de pathologies gastrointestinales, bilio-pancréatiques, respiratoires et urinaires.	Remboursements associés aux procédures compris entre 250 et 800 euros, selon l'indication.
Corée du Sud	Endomicroscopie confocale de l'œsophage, estomac et des voies biliares	GastroFlex / CholangioFlex	Agence nationale de collaboration des soins de santé fondée sur des preuves (NECA) / Service d'examen et d'évaluation de l'assurance santé coréenne (HIRA)	2015	Le NECA a reconnu l'ECM comme "une technologie sûre et efficace pour les applications dans l'œsophage, l'estomac et les voies biliaires" (2018). Évaluation par l'HIRA pour obtention du remboursement (2019). Ratification ministérielle de la décision pour les codes [E7612] et [J28100000]. NB : Des critères de couverture pour l'application du remboursement concernant l'allocation de soins médicaux ont été définis (2020).	Applicable à compter du 1er février 2020, le tarif de l'acte à été fixé à environ 83 096 KRW pour les hôpitaux généraux et 92 526 KRW pour les cliniques. La Minisonde Confocale™ sera remboursée à 338 290 KRW par utilisation dans l'œsophage et l'estomac.

In the United States

As of the date of this document, the Company mainly has 4 reimbursement codes (43206, 43252, 0397T, 88375) in the United States, three of which are Category I with no expiry date. For the Category III code, the CPT advisors of the AGA, ACG and ASGE issue a recommendation every five years.

At the same time, Mauna Kea Technologies has taken action to defend this existing coverage and to extend it to private insurers, using specialist consultants. The results have been convincing, with several insurers announcing that they will pay for Cellvizio® procedures. Increasing coverage by private insurers, and ensuring that the latest clinical data are taken into account when determining coverage, is the Company's long-term challenge in the United States. Demonstrating the value of Cellvizio®, based on data from the available scientific literature, has therefore become a major concern.

Understanding the following points is essential to assessing the importance of reimbursement in the United States:

- CPT codes are used for procedures that can be performed on an outpatient basis, and therefore do not apply to surgical procedures requiring overnight hospitalization;
- Obtaining a CPT code is one of the 3 steps in obtaining reimbursement for a procedure. It is also necessary to obtain a fee and payment from government insurers (including Medicare and Medicaid) and private insurers ;
- Obtaining a CPT code is very difficult, but getting it paid for by insurers, especially private ones, is even harder.

Mauna Kea Technologies succeeded in passing the essentials of these 3 stages: obtaining several reimbursement codes, obtaining a tariff and obtaining near-complete national coverage by Medicare / Medicaid and partial coverage by private insurers. The Company changed its angle of attack for private insurers and achieved very good results as early as the last months of 2015. Today, it is continuing this approach in order to obtain not only local coverage but also national coverage by one of the major private insurers. The success of these initiatives is a key success factor

for the expansion of gastroenterology applications. The use of Cellvizio® in the treatment of Barrett's Esophagus and in the management of patients suffering from gastro-oesophageal reflux disease has been recommended by several recognized learned societies in this field, respectively the American Gastroenterology Association (AGA), the American Society of General Surgeons (ASGS) and the American Esophageal Society (AFS). The College of American Pathologists (CAP) has also created a division dedicated to in vivo microscopy (IVM).

In 2024, hospital reimbursement for CPT 43252 was downgraded from APC 5303 "Upper-GI Level 3" to APC 5302 "Upper-GI Level 2" in Medicare's OPPS rule, causing the technical rate to fall by around -40%. CMS relied on median costs reported by hospitals; however, the learned societies (AGA, ACG, ASGE) believe that these reports underestimate the true cost of the Cellvizio® procedure, explaining the drop. Mauna Kea Technologies is working with these societies and specialized consultants to have the cost data corrected, document the clinical savings (fewer biopsies and repeat procedures) and request, in the next OPPS cycle, that the code be reclassified - while securing reimbursement from private insurers.

In France

A request for the creation of a procedure relating to the main digestive indications was submitted to the Haute Autorité de Santé (HAS) in September 2010. Admissibility of the application was notified in January 2011. The procedure evaluation program finally got underway at the end of 2013, and concluded for the first indication evaluated - endobrachyoesophageal surveillance - with the HAS issuing a favorable opinion at the end of 2014 for the inclusion of a new procedure on the list of reimbursable procedures. Subsequently, the Syndicat des Médecins de l'Appareil Digestif referred the matter to the Union Nationale des Caisses d'Assurance Maladie (UNCAM), the body responsible for reviewing the scope of services eligible for reimbursement and the rate at which care is covered. In 2016, representatives of the Conseil National d'Hépato-Gastroentérologie and the Société Française d'Endoscopie Digestive were also able to discuss with the Direction Générale de l'Offre de Soins the conditions under which this new procedure could be applied in public and private healthcare establishments. In June 2019, UNCAM published its decision to create a new procedure reimbursed under the nomenclature, worded as follows "Esophageal endoscopy with laser confocal endomicroscopy-guided biopsy - Pre-therapeutic esophageal mapping with laser confocal endomicroscopy-guided biopsy". The reimbursement rates are as follows: 150 euros for the endoscopist (Activity 1) and 69 euros for the anesthetist (Activity 4).

In September 2015, the HAS issued an unfavorable opinion on the use of Cellvizio® for the characterization of biliary tract stenoses. Then, the dossier on the use of Cellvizio® in the colon (awaiting assessment since 2011) was withdrawn from the work program by HAS in the first quarter of 2017.

In 2020, the HAS planned to evaluate confocal endomicroscopy using a puncture needle to characterize cystic tumors of the pancreas, with a view to its inclusion in the Common Classification of Medical Acts (CCAM). A multidisciplinary working group was set up to assess the technique's contribution to French healthcare.

In Germany

An OPS (Operationen- und Prozedurenschlüssel) code was created in 2013 to document endomicroscopy procedures in the digestive tract, and confocal endomicroscopy with Cellvizio® has been included on the definitive list of 2014 OPS codes for reimbursement of associated medical and surgical procedures by the German Institute for Medical Documentation and Information (DIMDI). The allocation and implementation of an OPS code allows the German authorities to measure not only the volumes of procedures but also the costs of associated treatments, and then to define a reimbursement tariff.

Some private clinics (part of the HELIOS hospital group) are experimenting with confocal laser endomicroscopy using minisondes to help diagnose atypical food allergies in patients suffering from irritable bowel syndrome. The "tarification à l'activité" (G-DRG) system was then applied to ensure local coverage by health insurance organizations.

In Croatia

Since June 2017, the Croatian Health Insurance Fund (HZZO), which manages the universal medical protection system in Croatia, has provided reimbursement for endomicroscopy procedures using Cellvizio® for patients with gastrointestinal, bilio-pancreatic, respiratory and urinary pathologies, with associated reimbursement rates ranging from 250 to 800 euros. This new "coverage" demonstrates that healthcare systems around the world are beginning to appreciate the benefits of this technology.

In other countries where Mauna Kea Technologies markets the Cellvizio®, steps are underway to prepare and/or follow up claims for reimbursement, notably in the UK and South Korea. It is interesting to note that in China, there are regional codes enabling hospitals to bill for the use of Cellvizio.

In the United Kingdom

In June 2016, the National Institute for Health and Clinical Excellence (NICE) published a technology appraisal report on the use of Cellvizio® in the pancreas. It will not be issuing recommendations in the immediate future.

In South Korea

In March 2018, Cellvizio® received a positive evaluation from the Korean Health Authority (NECA). Confocal laser endomicroscopy is thus recognized as a safe and effective method that can help identify cancerous lesions and target biopsies for patients with suspected dysplasia in the esophagus, stomach, or with bile duct stenosis. Files have therefore been submitted to request reimbursement with specific codes. In 2019, the Korean Health Insurance Review and Assessment Service (HIRA) assessed the clinical and medico-economic data provided. In February 2020, selective reimbursement guidelines for the GastroFlex™UHD probe and confocal endomicroscopy procedure in the esophagus and stomach were ratified by the Ministry of Health and Welfare (MoHW).

1.1.4. Marketing and markets

Marketing strategy and actions

Since early 2017, the Company has dedicated a significant part of its sales resources to developing the gastroenterology market in the United States, which it now addresses directly with a dedicated but reduced sales team since December 2021.

The other market targeted today is China, a market for which the Company had dedicated resources and a regional distribution partner, Youhe Shanghai Medical Technology Co. Ltd. since 2017 and until the joint venture agreement with Tasly Pharmaceuticals in July 2022.

The sales teams are supported by the marketing department, whose organization following the implementation of the cost-cutting plan is described below.

Marketing and product department

With a staff of 6, including 4 based in the United States, the marketing department develops and implements the Group's marketing strategy.

The marketing department is structured around several divisions:

- The product (upstream marketing);
- Sales lead generation (LeadGen);
- Downstream marketing;
- Communication and digital marketing;
- Key account management, dedicated to partner support and development.

Lead generation

It's essential to constantly provide sales reps with new, upstream qualified sales opportunities. This is the objective of this group within the marketing team, which uses several means to achieve this: purchase of relevant data for account targeting, inbound marketing, presence at events, etc...

Application and product marketing

The marketing department is responsible for marketing Cellvizio® for specific indications, mainly in gastroenterology and interventional pneumology, but also in other areas currently under study.

This department acts as a relay between the Clinical Affairs department and the direct and indirect sales forces deployed in the field. In particular, the marketing teams provide ongoing training for their sales force, roll out new products or new offers, carry out local communications actions, and participate in local events.

New product development or improvement projects are mainly initiated by the Marketing Department's product managers.

This department is responsible for monitoring the market and customers in order, firstly, to select the best projects in terms of return on investment and, secondly, to write the corresponding functional specifications and then follow up the technical development efforts.

Once products have been developed, the Product Management team is responsible for their worldwide launch and for providing the corresponding sales support. It is also responsible for the educational and application aspects of each indication.

This includes educating new and potential users through educational activities and doctors among themselves. The product marketing department monitors users' progress to ensure they learn quickly.

The Group's business model is based on the sale and use of medical equipment, the Cellvizio® and the various types of limited-life mini-probes required to use the Cellvizio®. The market for Cellvizio® sales is therefore based on the number of healthcare facilities that can use the technology, and the market for mini-probes is based on the number of procedures in which Cellvizio® will be used.

Cellvizio® is used via the operating channel of most flexible endoscopes on the market. However, Cellvizio® is not in direct competition with existing product ranges on the flexible endoscopy market. Rather than competing with the flexible endoscope market, Cellvizio® is used as a complement.

Event communications and digital marketing

The aim of the communications/digital marketing team is to increase the visibility of the Group's products and brands, and to generate commitment that complements other sales activities. More specifically, the communications team is responsible for disseminating marketing messages developed by the clinical and product teams, and implementing them in the form of marketing and communications media. It organizes events for prospects and customers, and participates in international congresses. Its remit also extends to the digital communications platform (in particular websites) and public relations.

The media are divided into five categories:

- websites and social networks,
- production of printed documents,
- events,
- public relations and corporate communications,
- local communication campaigns for hospitals and clinics.

The hospital and clinic market

The Cellvizio® in its current configuration is intended for use only by hospitals and private clinics that have an endoscopy room and doctors trained in endoscopy.

The Cellvizio® market needs to be defined by geography and by product, depending on the application.

The Group's current focus is on the United States and China, but sales initiatives remain active in Europe. In terms of applications, business development is focused on gastroenterology, and in particular on upper digestive endoscopy. Other applications, such as pneumology, are currently being evaluated and could represent future growth levers.

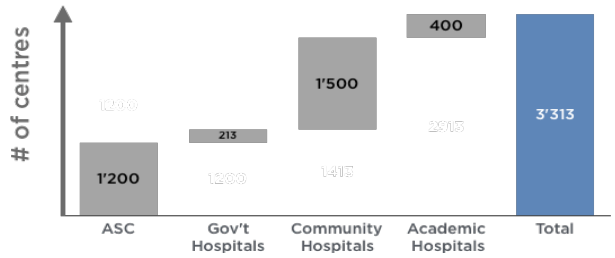
United States

Mauna Kea Technologies' priority target markets in the United States over the next few years are mainly Community Hospitals and Ambulatory Surgical Centers.

The American Hospital Association counted 6,093 hospitals, 5,139 of which were designated "Community Hospitals". Community Hospitals" are non-governmental hospitals that care for patients on a short-term basis. In addition, there is a list of 207 government hospitals (Source: American Hospital Association - Fast facts on US hospitals 2020, https://www.aha.org/statistics/fast-facts-us-hospitals).

The Academic Medical Centers segment numbers 400 establishments according to the AAMC (Association of American Medical Colleges - https://www.aamc.org/members/coth), which remains a secondary target.

Limiting these numerous prospects to facilities involved in digestive endoscopy, Mauna Kea estimates the total number of target centers in the United States at just over 3,000.



Of this number, the Group is targeting 1,100 hospitals (1,500 doctors) specializing in digestive endoscopy, whether they be community hospitals with a high level of activity around gastro-oesophageal reflux, or Ambulatory Surgical Centers (ASCs) which treat a very large number of these patients. This represents an equipment market of the order of $200 million, to which must be added a recurrent market linked to probe sales, which depends on the number of procedures performed, and which the Company estimates at around $200 million a year.

Europe

In 2009, there were more than 15,000 hospitals in the European Union, providing advanced care (medicine, surgery, obstetrics) or another activity (psychiatry, medium or long stay) (Source: Dexia "Hospitals" study in partnership with Hope, the European Hospital and Healthcare Federation - July 2008). In terms of population, Germany and France are the two European countries with the highest number of hospitals, at nearly 3,500 and 3,000 respectively.

Country	Number of hospitals
Germany	3 460
France	2 890
United Kingdom	1 300
Italy	1 295
Spain	740
Russia[12]	9 000
Other	4 615
Total	**23 300**

In France, the Group is targeting a market of around 300 hospitals and clinics that perform interventional digestive endoscopy. This ratio applies to the rest of the target countries, bringing the number of centers potentially equipped with Cellvizio® to around 2,000, for gastroenterology alone.

Asia

Japan and China are the most important markets for Cellvizio® in Asia. The number of hospitals per country breaks down as follows:

Country	Number of hospitals
Japan	7 474

12 *source http://dcc2.bumc.bu.edu/RussianLegalHealthReform/ProjectDocuments/n970.IIIE1.Analysis.pdf*

China	23 170
Total	**30 644**

In China, out of a total of over 23,000 facilities, there are more than 1,000 first-class hospitals, which are the Group's prime target today.

In Japan, the Group is specifically seeking to penetrate the academic hospital market, which numbers between 200 and 300 hospitals.

- **The potential market for probes: the number of targeted biopsy procedures**

This section will focus primarily on indications in digestive endoscopy, where Cellvizio® is most widely used, bearing in mind that many other medical fields could make use of Cellvizio® technology (see paragraph 1.1.4 below).

Endomicroscopy is a medical procedure distinct from the endoscopic procedure during which it is performed. Thanks to Cellvizio® 's compatibility with endoscopes and endoscopic tools on the market, miniprobe endomicroscopy (with Cellvizio®) can be performed during an endoscopic procedure, to improve diagnostic reliability, for example. It is therefore possible to estimate the endomicroscopy market in terms of the number of procedures, taking into account, for example, the indications on which the greatest number of validation studies have been carried out.

Barrett's disease and gastroesophageal reflux disease

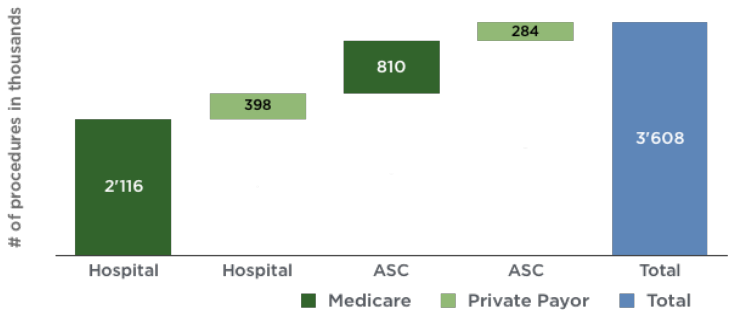
In the United States, an estimated 1.6% of the adult population (3.6 million people) suffer from Barrett's Esophagus, and 20% of the adult population suffers from gastroesophageal reflux disease.

The ability to monitor these patients endoscopically is directly linked to the detection of precancerous areas and their potential treatment.

In 2016, the American Society of General Surgeons, published a major recommendation, echoing these strong arguments, for surgeons to evaluate their Barrett's or reflux patients with Cellvizio® prior to surgical treatment.

The total number of upper GI endoscopy procedures is close to 9 million per year in the United States. The Group's assessment shows that over 3 million procedures per year could benefit from Cellvizio® and be reimbursed. This represents a potential annual recurring revenue of over $2 billion, considering that a probe can be reused around 10 times, and that its average price is around $7,000.

These procedures can be broken down by type of plant as follows.



Sources : Burden of Gastrointestinal Disease in the United States: 2012 Update; Peery et al, Gastroenterology. 2012 November ; 143(5): 1179-1187.e3. doi:10.1053/j.gastro.2012.08.002. Repeated Upper Endoscopy in the Medicare Population, Pohl et al, Ann Intern Med. 2014;160:154-160. U.S. census; Medicare website.

Pancreatic cysts

Between 3% and 10% of the American population has a pancreatic cyst, which represents several million patients. It is estimated that around 120,000 new cysts are identified each year. If we make the conservative estimate that 40% of patients with these cysts could benefit from an endoscopic diagnostic procedure in which Cellvizio® could be used (since some cysts can be characterized as benign or malignant on the basis of endoscopic ultrasound imaging), we reach the figure of 50,000 procedures per year in which Cellvizio® could be indicated to characterize a pancreatic cyst.

Indeterminate biliary stenosis

In the field of bile ducts, it is estimated that 500,000 ERCP procedures are performed each year in the United States, and that 10% of these are performed on patients with stenosis for whom endomicroscopy could be indicated, i.e. 50,000 procedures per year.

Competition

Optiscan

Australian company Optiscan has developed a technical solution for confocal endomicroscopy that does not rely on the same technological choices as Cellvizio®.

Optiscan markets a system called FIVE II, an evolution of the first generation FIVE 1, which is a rigid endomicroscope 6 mm in diameter (source: Optiscan), designed for tissue visualization in the context of examinations of numerous organs such as the breast, brain, gastrointestinal organs, among others. All these applications are still the subject of clinical studies, and are only marketed in research centers.

Relying on similar technology (same diameter and image cadence) but this time in collaboration with the Zeiss company, Optiscan has developed a semi-rigid endomicroscope dedicated to neurosurgery called ConVivo. Zeiss obtained marketing authorization for this product from the US authorities in 2018.

Olympus

Olympus, the Japanese company that leads the world in flexible endoscopy with a 71% market share (source: Endoscopy Devices Market to 2016, GBI Research, December 2010), has no commercial solution for endomicroscopy in any form whatsoever. A so-called "endocytoscope" prototype has been shown at a few congresses and conferences, with very preliminary and mixed clinical results (source: American Gastroenterology Association http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/endocytoscopy.pdf. Quote: "the diagnostic performance of EC for the differentiation of Barrett's epithelia has been suboptimal. In a recent study, the application of EC in Barrett's esophagus resulted in a high proportion of unusable images because of suboptimal image quality, fair interobserver agreement, and poor diagnostic specificity").

This prototype, which appears to be in use at just one center worldwide (in Japan), requires the use of several dyes (ibidem) and does not appear to be suitable for routine clinical practice. What's more, the few publications on this experimental device point to major difficulties in mastering image reading by doctors and making it reproducible (ibidem).

Fujifilm

Fujifilm is a major player in flexible endoscopy, under the Fujinon brand. Fujifilm offers advanced imaging systems on the high-end part of its flexible endoscopes under the names FICE (Fuji Intelligent Color Enhancement) and LASEREO, which was launched at the end of 2015. These are systems with electronic filters or a Laser source that enhance certain colors in the image. Developed to aid tissue characterization, the FICE system was proven inferior to Cellvizio® by an independent study conducted by the Mayo Clinic (reference: Comparison of Probe-Based Confocal Laser Endomicroscopy With Virtual Chromoendoscopy for Classification of Colon Polyps, Buchner et al, Gastroenterology, January 2010).

In addition, the Company entered into a distribution partnership with Fujifilm at the end of 2012 for the Chinese market, which was renewed in 2016.

Although the Group and Fujifilm operate in the same market, Fujifilm endoscopes are not in direct competition with Cellvizio®.

SpectraScience

American company SpectraScience has developed a spectroscopic interrogation system for colorectal polyps called Wavstat. This device does not produce images, but analyzes the light backscattered by the tissues making up the polyps, and uses a proprietary algorithm to provide biochemical data. The device was distributed by Pentax in certain regions, but this effort was halted fairly quickly. SpectraScience is listed on the stock exchange, but is currently worth less than $1 million, with a share price of $0.0005.

Oncoscope

The American company Oncoscope has developed a tissue interrogation system called SCOBE-E, designed to detect precancerous lesions in the esophagus. This system does not provide any images, but a mathematical analysis of the tissue. It has only been clinically tested on 34 patients, and is currently neither FDA-approved nor CE-marked for marketing (source: Document Oncoscope).

In 2015 the company filed for bankruptcy (Source: bizjournals.com) and its assets were taken over by SpectraScience.

Chinese competitors

Two Chinese companies have developed and are preparing to market endomicroscopy systems based on technologies very similar to those of Cellvizio®.

The Company has undertaken an in-depth study of these products to determine whether any action needs to be taken to protect its intellectual and industrial property rights.

- **Growth drivers for the platform, on its own and through partnerships**

While the Group started its sales in the gastroenterology and then pneumology sectors, it also obtained marketing agreements for a range of mini-probes dedicated to urological applications in 2013, then laparoscopic in 2015. Mauna Kea Technologies intends to extend its commercial offering to other areas of endoscopy and surgery. Microscopic vision is key for a large number of cancers as well as many other diseases, and the Cellvizio® could provide a minimally invasive answer to a great many diagnostic problems.

The irritable bowel syndrome and food intolerance market

Irritable Bowel Syndrome (IBS) is a chronic gastrointestinal disorder affecting 9-15% of the population, characterized by a range of symptoms including abdominal pain, bloating and bowel transit disorders (diarrhea, constipation or both), with no underlying lesion visible through standard diagnostics. IBS has a considerable impact on the quality of life of sufferers, who often face a long and arduous medical consultation process lasting 2-3 years on average, with no guarantee of identifying the underlying cause of their symptoms. Its management often requires a multidisciplinary approach, including dietary changes, medication and psychological support, reflecting the complex interaction between the gut and the brain.

Significant advances have been made in the study of IBS using confocal laser endomicroscopy. Extensive research has revealed that 50-60% of affected patients may actually suffer from atypical food intolerances, undetectable via traditional diagnostic methods such as blood IgE tests, skin tests or respiratory tests. The use of Cellvizio® has enabled these intolerances to be accurately identified by observing the immediate reactions of the intestinal mucosa to certain food stimuli, offering a detailed insight into intestinal barrier dysfunctions such as cell erosion. The implementation of a targeted eviction diet led to symptomatic improvement in 96% of patients[13] , demonstrating the effectiveness of this advanced diagnostic method.

The market potential for diagnosing food intolerances associated with IBS is considerable. Although not all patients suffering from IBS are concerned, notably due to the presence of symptoms that can be attributed to other causes such as celiac disease, it is estimated that the target market could reach nearly 8 million patients, representing an addressable market of approximately $6 billion.

The interventional pulmonology market

Lung cancer is still the leading cancer in men, although its incidence has stabilized (*source: American Cancer Society 2008 - stats)*. In women, incidence is still rising slightly. Lung cancer is the most frequent cause of death in the Western world, for both men and women. The prognosis of lung cancer depends on a number of factors, one of the most important of which is the stage of development of the cancer at the time of diagnosis. Patients with peripheral lesions less than 3 centimetres in diameter (T1) are better candidates for surgical resection and have the best chances of survival, with a 5-year survival rate of 60-80%. Less than 1% of patients with extended-stage cancer are still alive 5 years after diagnosis. (*Source: World Health Organization*)

When the patient is symptomatic, the disease is generally very advanced at the time of diagnosis, and the prognosis is highly critical. But more often than not, a peripheral nodule (a small mass, benign or malignant) is discovered in the lung during a routine examination, such as a CT scan. The challenge is to characterize this nodule in order to make the most appropriate therapeutic choice. With the improvement of wide-field imaging techniques such as CT scans, and the introduction of lung cancer screening programs, the number of nodules detected during these imaging examinations is multiplying, as is the need for characterization. American scientific societies have been recommending organized lung cancer screening since 2013, as it has been shown to improve patient prognosis while reducing the cost of care (source: Powell et al., Ann Surg. 2004 september; 240(3): 481-489, and CHEST / 142 / 2 /385-393 AUGUST 2012). By 2021, new recommendations from the U.S. Preventive Services Task Force (USPSTF) have almost doubled the number of people eligible for lung cancer screening in the U.S., and should increase the number of lung cancer cases detected at an early stage by screening by 27%.

Several techniques are used to characterize a lung mass. The most effective, when achieved, is to physically remove a tissue sample from the nodule, either by taking a biopsy through a bronchoscope and/or transbronchial needle, sometimes equipped with an electromagnetic navigation device in the lung tree, or by taking a biopsy transpleurally, with external access. In the former case, the risk is low, but the current diagnostic yield of these procedures is low

[13] Kiesslich R, Adib-Tezer H, Teubner D et al. Endomicroscopic detection of atypical food allergy in patients with irritable bowel syndrome - a new diagnostic era? DDW 2020, Su1344 (Ref 5)

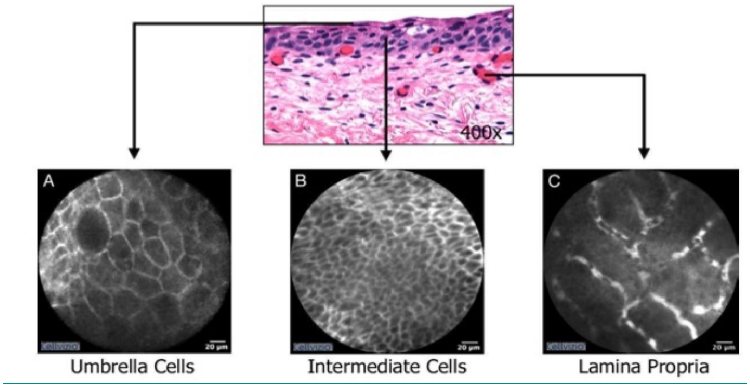
due to sampling errors. In the second case (transthoracic access), the procedure is burdensome for the patient, as it is highly invasive, and is not widely practised.

Despite the development of new technologies, the yield and accuracy of transbronchial biopsy diagnosis remain low (between 30 and 65%), and it is impossible to confirm with a high level of certainty that the biopsy needle is taking a sample from the targeted lesion. It is becoming increasingly clear that Cellvizio® imaging has the potential to significantly increase the diagnostic yield and accuracy of transbronchial biopsies.

An AlveoFlex confocal miniprobe being inserted into a bronchoscope

The bronchoscopy market is very similar to the digestive endoscopy market in terms of medical equipment: all healthcare institutions with an endoscopy unit have at least one bronchoscopy room, which could be equipped with Cellvizio®. This represents over 60,000 hospitals and clinics in Europe, the USA and Asia. The number of bronchoscopy procedures is estimated at around 500,000 per year in the United States, with over 240,000 biopsies taken per year. These figures are constantly rising. This volume, although lower than that of digestive endoscopy, translates into a potential of several hundred thousand procedures for Cellvizio® in the field of pneumology, and an associated renewal of several tens of thousands of confocal miniprobes per year. *Source: Center for Disease Control and Prevention, ww.cdc.gov*

The endo-urology market



Example of Cellvizio® images obtained in the bladder and correlated with standard histology.

Endo-urology is a part of urology that involves endoscopic examination of the urinary tract, in order to search for obstructions or cancer, and if necessary to perform endoscopic treatment procedures. The most commonly performed exploration in endo-urology is cystoscopy, which involves examining the bladder. In 2010, there were around 71,000 new cases of bladder cancer in the United States, and 15,000 deaths from the disease. One man in 27 will develop this pathology in his lifetime, compared with one woman in 85. Nearly 90% of bladder cancer patients are over 55 (*Source: American Cancer Society,* https://www.cancer.org/).

The management of bladder cancer requires several cystoscopy procedures.

The first is usually carried out in the office with a flexible cystoscope, to identify a lesion.

The second, performed in the operating room with a rigid cystoscope, enables biopsies of the lesion to be obtained.

Thirdly, when possible, the tumor can be resected endoscopically, which is not always the case since too many cancers are diagnosed at an advanced stage.

A quarter of patients present with cancer that has invaded the muscle barrier and/or metastasized, while over 20% have less advanced but already high-grade cancer. The recurrence rate of bladder cancer is very high, ranging from 50 to 90%, which means that patients who have survived bladder cancer require ongoing, lifelong surveillance. This is achieved by repeating cystoscopy procedures at regular intervals. The multiplicity of endoscopic diagnostic and follow-up procedures makes the management of bladder cancer the most costly of all cancers, accounting for some $3.7 billion in the USA in 2001. (Source: Jemal A, et al. CA Cancer J Clin, 2010. 60(5):277-300.)

The cystoscopy market is estimated as follows:

- In France (*source: ATIH, 2008)*, the number of diagnostic cystoscopy procedures is estimated at 37,000 per year, while the number of therapeutic cystoscopy procedures is estimated at 52,000 per year. On this basis, we can estimate that there are around 470,000 diagnostic cystoscopy procedures per year in Europe, and 670,000 therapeutic cystoscopy procedures;

- In the United States (source: *NHSR, Number 11, 2009 "Number of ambulatory surgery procedures, US, 2006),* the number of diagnostic cystoscopy procedures is 750,000 per year, while the number of therapeutic cystoscopy procedures is around one million per year.

As with bronchoscopy, all care facilities with an endoscopy unit have at least one cystoscopy room, which could be equipped with Cellvizio®.

Cellvizio® can be used during diagnostic and therapeutic cystoscopy procedures, as shown by several studies by Prof. Liao of the VA Hospital in Palo Alto (*source: interobserver Agreement of Confocal Laser Endomicroscopy for Bladder Cancer, The Journal of Urology, doi : 10.1089/end.2012.0549, May 2012*). Clinical work is underway to confirm these American data with European results. The use of Cellvizio in endo-urology appears to bring critical benefit in optimizing the transurethral booking gesture of precancerous and cancerous lesions, in identifying additional lesions not spotted during the primo-diagnostic examination (flexible cystoscopy), as well as in post-resection follow-up, which could ultimately make it possible to envisage a reduction in recurrences.

The volume of procedures represented by endo-urological applications is considerable. Finally, as urology is a speciality at the frontier between endoscopy and surgery, urological indications can provide Mauna Kea Technologies with a gateway to surgical applications, which are a major challenge for the company.

In December 2015 Mauna Kea Technologies signed a commercial partnership agreement with Cook Medical covering urological indications. The agreement calls for Mauna Kea Technologies to develop a customized version of the Cellvizio® based on Cook Medical's graphic charter over the course of 2016. Thanks to its international sales expertise, marketing and medical know-how, as well as its comprehensive portfolio of complementary urology products, Cook Medical could rapidly optimize commercial opportunities for Cellvizio. Prototypes of the Cellvizio Cook have already been successfully introduced at the European Annual Urology Congress EAU, the American Congress AUA and the World Congress WCE in 2016.

The surgery market

With their keen interest in innovation, and naturally taking over from endoscopists in the management of certain types of cancer (digestive, pulmonary and urological), it was only natural that surgeons should be interested in Cellvizio®,

seeing it as a tool that could enable them to refine their procedures, to better preserve the functions of resected organs while ensuring complete eradication of cancer cells.

In 2010, Mauna Kea Technologies and its partners in the PERSEE project (a collaborative project supported by the OSEO/ISI program, see 6.6.1.2) initiated the development of a robotized, minimally invasive endomicroscopic abdominal cavity exploration solution designed to improve the management of cancer patients, with the aim of reducing the number of unnecessary and/or incomplete surgeries (up to 25% of pancreatectomies, for example). The prototype was tested in a feasibility clinical trial on patients, completed during 2015. In 2016, at the American SAGES congress, two Posters were presented and very favorably received. The PERSEE project is structured in four successive phases, the last of which was due to end in May 2016. In practice, the third of these phases ended in July 2015, and the end-of-stage 3 report was submitted to BPI France in May 2016. In 2018, the fourth phase was initiated; in 2019, the Company obtained BPI France's agreement to extend the duration of phase 4 until October 31, 2020, the end of which will consecrate the end of the project.

Mauna Kea Technologies is also devoting increasing efforts to developing endomicroscopy solutions for surgical specialties, through :

- the identification of this development as a central company project,
- recruitment of dedicated resources,
- the integration of operating room constraints into the design of its next generation of Cellvizio® systems,
- the launch of clinical trials specifically for surgical applications, whether initiated by the Group or directly by surgeons who have been exposed to Cellvizio®.

Such clinical trials are currently underway or planned in the fields of laparoscopic abdominal surgery, neurosurgery, robotic surgery for urological and gynecological cancers, and colorectal surgery.

1.1.5. A dual marketing strategy also based on partnerships

Since the beginning of 2017, the Company has dedicated a significant part of its sales resources to developing the gastroenterology market in the United States, which is its priority market, as well as in Europe (mainly France and Germany), focusing on direct marketing through with a dedicated sales team. Over the years, Mauna Kea Technologies has also built up a network of distributors in other countries where it has marketing authorizations.

Faced with the various commercial obstacles slowing down the deployment of the technology, while at the same time consuming a lot of cash, a strategic shift was announced at the end of 2021, as described in paragraph 1.2.3. From now on, the commercial roll-out strategy will be based primarily on partnerships, the first of which will take shape in 2022 with the creation of a joint venture in China with Tasly Pharmaceuticals. The direct approach will be maintained, notably in the United States, in order to capitalize on the Group's installed base and continue to target high-potential customers, while limiting dedicated sales budgets.

A direct approach in the United States, Germany and France

A direct approach to the United States, Germany, France and the Benelux countries

In these countries, where the direct approach has been favored, the Group has a sales force made up of 2 teams with different skills and responsibilities. The first team is made up of equipment sales staff (Area Sales Manager - ASM), and the second of Clinical Support and consumables sales staff (Account Manager - AM), responsible for procedures and therefore for Cellvizio® adoption and staff training in the establishment, as well as for the correct use of equipment and probes during procedures.

Each equipment sale is accompanied by a clinical training course designed to teach users how to use Cellvizio® and, in particular, how to read the images obtained. The training covers every step, from connecting the equipment to the probe and disinfecting it after the procedure.

The medical teams in charge of the procedures are supported over the long term to ensure that Cellvizio® is used in the best possible conditions. To this end, in the early months of the acquisition, the AMs meet regularly with hospital schedulers to identify patients whose pathology is particularly suited to Cellvizio®. The AMs are also present in the endoscopy rooms at the time of the procedure to train the medical teams.

This commercial presence in the field is the decisive factor in getting professionals to adopt this new tool and make it part of their clinical routine.

At the end of 2024, the Group's commercial sales force will comprise 8 people, compared with 18 at the end of 2021 before the implementation of the cost-cutting plan undertaken in 2022 (see paragraph 1.2.3):

- The United States zone has a sales team of 5, compared with 8 at the beginning of the year, due to the departure of several sales representatives during the year. As of the date of this document, the team comprises 7 people, with the recruitment of 2 sales representatives at the beginning of 2025;
- The EMEA region benefits from a sales team of 3 employees based in France, Germany and Italy;
- The rest of Europe is managed directly by the International Sales Director;
- China is managed by the joint venture with Tasly Pharmaceuticals (see section 1.2.3).

▯ A network of exclusive distributors for other countries

Apart from France, Germany and the United States, the Group's sales strategy is based on a network of distributors covering numerous regions. The Group has chosen to be particularly active in the main countries of the European Union. Distributors have been selected according to the following criteria:

- In-depth, mastered knowledge of the sector and specialty entrusted to them,
- A "product" synergy enabling Cellvizio® to be integrated into a complementary ecosystem,
- A real ability to quickly relay sometimes complex sales pitches,
- The ability to maintain a presence in the field is essential for effective technology promotion.

This network comprises some 10 distributors, who enjoy sector exclusivity in their sales area. The activity of these distributors varies considerably from region to region and from year to year. The distribution network is under the responsibility of the International Sales Director.

He is responsible for the operational support of the direct sales force: he assists in their training, and sets them both strategic and operational objectives. He communicates constantly with the distributor network and ensures that objectives are met. In China, the Group has set up a local distributor support system.

To date, the Group is present through its distributors in the following geographical areas:

- Europe (UK, Italy, Croatia, ¨Poland, Romania, Czech Republic, etc.),
- In Japan,
- Latin America.

In addition to supporting distributors, the International Sales Director works with the marketing department in each region to ensure that the Group and its products are properly "visible":

- Participation in professional conventions and industrial and trade shows,
- Organization of workshops to train prospects and customers,
- In situ demonstrations at "target" medical centers,
- Regular training of distributors in the technical aspects of the product, as well as in the purely clinical aspects - always evolving - of the system's applications,
- Definition and validation of "communications", which must be coherent and consistent, but also adapted to the "cultural" specificities and commercial expectations of different markets.

A list of the Group's commercial partners is available at www.maunakeatech.com.

An operational installed base of around 250 units

Since its creation, the Group has installed over 700 systems, including both those sold and those made available. However, the Group estimates the actual installed base to be around 250 systems.

Historically, this installed base came mainly from the direct sale of systems, generating immediate income, supplemented by recurring income from the sale of probes and services, notably maintenance. Recently, due to budgetary constraints on hospitals and care centers, a growing proportion of installations are carried out via "pay per use" programs - exclusively in the USA - or via leasing contracts in Europe.

Thus, only the operational base enables the Group to capitalize on sales of minisondes, fee-for-service invoicing and the marketing of annual maintenance contracts.

1.1.6. Operations

Internalizing high value-added stages

The Company outsources part of its production chain, retaining only the high value-added stages that represent the core of its know-how.

In this context, in addition to identifying and selecting suppliers of raw materials (lasers, moving mirrors, mechanical elements of the housing, electronic components, etc.), the Company has developed a network of subcontractors to carry out certain stages in the manufacture of the laser scanning unit (pre-assembly of the mechanical elements of the housing's optical base, integration and wiring of the electronic and power supply boards). With regard to the manufacture of mini-probes, the Company has chosen to subcontract the manufacture of certain mini-probe models, or part of their assembly, in order to optimize its production capacity and cost, while retaining in-house expertise and higher value-added know-how.

Thanks to the quality of the design defined and validated at the product design stage, whether for custom-made parts (e.g. optical lenses) or off-the-shelf parts, manufacturing procedures are optimized. The result is a production cost that is largely made up of material costs.

Lean Manufacturing

As part of its quality assurance and continuous improvement approach, the company has also been working since 2008 on "Lean Manufacturing" projects that bring together R&D, quality, production and supply chain teams.

Lean Manufacturing is a production management system based on three fundamental elements:

- reducing costs by eliminating waste,
- just-in-time production,
- quality.

Making these three elements work together in an interdependent and optimal way produces sustainable and efficient results, and enables the Company to be more competitive and adaptable to any changes in the market.

This production organization enables the Group to maintain a high level of responsiveness in the face of uncertainty over the speed of equipment deployment, so as to be able to meet customer expectations as quickly as possible.

The implementation of a "lean" approach to production has also enabled us to more than double production capacity since 2008, with constant resources, and to reduce cycle times by a factor of three.

Since 2013, the Company has also subcontracted the assembly of several confocal mini-probe models to a supplier with expertise in fiber optics and precision optical assembly. The full validation of this subcontracting has already enabled the Group to offload part of its mini-probe production to this partner, thus ensuring productivity growth without additional investment.

After all the productivity-enhancing work carried out under Lean Manufacturing, and given the structure of the current production team and the subcontracting carried out, the Company is now in a position to ensure the production of Cellvizio® systems and miniprobes, and to anticipate the increase in its production capacity through outsourcing.

The company adapts its internal processes to efficiently implement a growing range of products, based on identical technological building blocks, then adapted to different product or market requirements.

Quality assurance

Quality has been an integral part of the company's management system since its creation in 2000, and the first ISO 9001 certification was obtained in 2002. This was extended to ISO 13485 for medical devices in 2005.

The Company has updated its quality management system to comply with the new editions of the quality system management standards (ISO 9001:2015 and ISO 13485:2016 for medical systems), and obtained certification on these new editions during its renewal audit at the end of 2017.

It also constantly monitors the standards and regulations applicable to its products, to ensure that they remain compliant in the various countries in which they are marketed. In this regard, the Company has set up a Unique Device Identifier (UDI) system for its medical products to meet the requirements made applicable in September 2016 in the United States.

This process was extended in 2018 to affix direct UDI marking to reusable consumables (confocal miniprobes) in line with FDA requirements. This work also anticipates compliance with the unique identification requirements of European regulation DM 2017/745.

The production chain is certified during certification renewal audits (every three years) or follow-up audits (annually), with certification covering activities related to product procurement, manufacturing and packaging.

Within this framework, all major changes in the production chain (subcontracting, relocation, etc.) must be reported to the third-party organization, and may be audited to ensure that certification is maintained.

Quality controls are carried out on raw materials entering the production line, during the various stages of manufacturing and on the final product before shipment.

Finally, in early 2020, the Company obtained certification as an Authorized Economic Operator in accordance with the provisions of Article 22 of European Regulation no. 962/2013 establishing the Union Customs Code. As of the date of this Document, renewal is suspended pending an improvement in the Company's shareholders' equity.

Selection and monitoring of suppliers and subcontractors

The Company is careful to identify and select suppliers with the industrial capabilities needed to support its commercial ambitions. The choice of partners is based on product and regulatory constraints, production capacities in line with the Group's ambitions, and economic and profitability considerations.

With raw materials accounting for the lion's share of production costs, purchasing is one of the company's key processes:

- The selection of partners for the production chain is carried out jointly by the R&D and Purchasing departments. Once the selection has been made, the R&D department works upstream with subcontractors to manufacture the first prototypes, and with suppliers to validate critical or sensitive components and assemblies (i.e. those meeting critical technical specifications or having a strong impact on product quality and safety). Once the partner has been validated, the service is contracted by the Purchasing department on the basis of the specifications validated during industrialization. Critical suppliers and subcontractors are required to notify and submit to the Company for approval any modification to their own manufacturing chain (raw materials, manufacturing methods and processes, relocation or subcontracting, etc.),

- Suppliers and subcontractors are monitored and evaluated by the Purchasing department on the basis of multiple criteria covering, for example, compliance with deadlines, delivery non-conformities, organization, financial exposure, etc,

- Supplier audits are carried out periodically by the Company on sensitive suppliers, on the basis of an annual schedule drawn up by the Purchasing and Quality Assurance teams and depending on the results of the assessment carried out.

Choice of main partner subcontractors

Among the Company's current industrial partners, the optical fiber supplier Fujikura is of particular importance, as the Cellvizio® was entirely designed with this component in mind (imaging system, image processing). Based in Japan, Fujikura is one of the world's leading manufacturers of optical fibers, and has entered into a genuine long-term partnership with the Company.

The Company has implemented an outsourcing strategy with Fujikura, transferring part of the assembly stages for some of its confocal mini-probe models to benefit from this supplier's industrial know-how.

The Company's other subcontractors carry out specific assembly stages (mechanical or electronic integration of components to specifications) or translation work, enabling the company to concentrate its workforce on high value-added production stages.

In 2015, the Company also validated a new subcontractor for the production of electronic boards and electromechanical integration of its laser enclosures for the medical field. This was the result of a joint project between the R&D, purchasing, production, regulatory and quality teams, and led to a simplification of the supply chain and a reduction in manufacturing costs.

In 2018, the Company initiated the validation of a new subcontractor for the manufacture and wiring of the mechanical cart integrating the Cellvizio® 100 Series components.

Finally, as part of the Cellvizio® I.V.E development program, the Company has renewed a large part of its panel of suppliers, all of whom have been qualified in 2019. This work ensures a diversification of supply sources, particularly in the fields of precision mechanics and electronics.

In the logistics department, the Company uses different service providers depending on local constraints (country, delivery times, need for local storage, etc.). The selection of logistics subcontractors offering local storage of finished products (e.g. in the United States) ensures delivery times to end customers that are comparable to market standards and adapted to their needs, particularly in the case of confocal miniprobes.

1.2 Innovation, patents, licenses, trademarks and domain names

1.2.1. Innovation policy

Innovation is the company's raison d'être. Its products and applications reflect this positioning in the medical device field.

These products aim to bring to medicine and research a real-time, minimally invasive diagnostic imaging capability that not only improves service to patients and physicians, but also opens the way to new medical or scientific practices, such as *in situ & in vivo* optical biopsy of tissues previously inaccessible to histopathological examination.

As for the Group itself, its innovative character is reflected not only in its ability to develop such products, but also in a corporate approach that encourages a fresh approach to the problems associated with its business. This ability can be seen across the board in management, communication, product development, research and development, customer relations, production, quality control and regulatory affairs, human resources management and administration.

The Group's innovation policy is underpinned by a series of measures taken to ensure this approach, which guide recruitment, staff training, internal and external communication, working methods and coordination.

This policy fosters the emergence and collection of ideas, notably by setting up collective work sessions such as Strategic Days, clinical meetings (MED), LAB meetings, "Brain Storming Brevets", innovation competitions such as "Hackfests", for example, supported by a continuous cross-functional (medical, scientific and technological) watch activity. The multidisciplinary nature of the representation of Group skills in these activities is an essential key to their success.

1.2.2. Patents and patent applications

- **Intellectual property protection policy**

The Group's commercial success depends to a large extent on its ability to protect its products, notably by obtaining and maintaining patents in France and the rest of the world. This is why the Group has implemented and maintains an ongoing patent filing policy.

At the end of December 2024, the Group had 266 patents granted in 41 families, and 5 under review. The Group also has a share in a joint venture with Tasly Pharmaceuticals in China, to which it has transferred 19 patents (see paragraph 5.2.1, note 1.17).

The Group considers that its technology has not been misused or copied in whole or in part by third parties or competitors, and is not aware of any third party disputing either the use of its intellectual property or the rights to use it.

- **Nature and coverage of patents**

The nature of these patents and patent applications, and the rate at which they are filed, reflect the Group's research and development work. They do not, of course, only concern products currently marketed by the Company, but also cover complementary technologies that could form an integral part of future products, in the clinical or research fields.

Of these patent families or patent applications, 7 are the result of partnerships or collaborations with academic partners such as CNRS, Observatoire de Paris, the Universities of Rouen and Limoges, or Pierre & Marie Curie University, and are co-owned with these institutions.

The Company is also the exclusive licensee of two patents, the first (INSERM-APHP patent, or Endoscope, in the following table) relating to a particular endomicroscopy modality of the Cellvizio®, and the second (Université Denis Diderot (or Paris 7) patent, or P7 in the same table) relating to high-resolution *in vivo* tomography solutions for the human retina, not yet exploited. In both cases, the Company has filed (and obtained), in agreement with its co-contractors, several patents to improve these technologies.

Patent portfolio					
Description	**N°**	**Priority date**	**Acronym**	**Family ref. no.**	**Description**
Afocal correctors	1	28/12/01	AFO	WO03/056378	Confocal imaging equipment, especially for endoscopes
Endoscopic head	2	28/12/01	TEM	WO03/056379	Miniaturized optical focusing head, especially for endoscopes
Fluorescence spectroscopy	3	28/12/01	TMS	WO03/060493	Subsurface autofluorescence spectroscopy equipment
CVZ Fluo	4	18/07/02	FVC	WO2004/008952	Fibered confocal fluorescence imaging method and apparatus
CVZ Fluo Divisional (EU only)	4	18/07/02	FVC	EP 1986031	Method and apparatus for high-resolution confocal fiber fluorescence imaging
Image processing	5	18/07/02	IMA	WO2004/010377	Method of processing an image acquired by means of a guide composed of a plurality of optical fibres
VCSEL	6	20/12/02	SCV	WO2004/066015	Parallel confocal laser microscopy system based on VCSEL technology
MEMS	7	20/12/02	TBL	WO2004/066016	Confocal optical head, in particular a miniature one, with integrated scanning, and confocal imaging system using said head
S probes (FR only)	8	11/03/03	CV2	FR 2 852 394	High-resolution fibered fluorescence imaging method and equipment
Super Reso	9	31/12/03	ON	WO2005/073912	Method and system for super-resolving confocal images acquired through an image guide, and device for carrying out such a method
Slow. Ball	10	31/12/03	LEB	WO2005/072597	Miniature integrated scanning optical head for homogeneous confocal imaging, and confocal imaging system using said head
OCT-OA	11	22/01/04	DAT	WO2005/080911	System and method for high-resolution in vivo lateral and axial tomography of the human retina

Wollaston	12	22/01/04	MY	WO2005/080912	Device and method for measuring fringe contrast in a michelson interferometer, and eye examination system including such a device
Active sight	13	22/01/04	TOM	WO2005/079655	Sighting device and method for eye examination, in vivo tomographic eye system equipped with this device
Active sight (CIP)	13	22/01/04	TOM	US 7,658,495	Sighting device and method for eye examination, in vivo tomographic eye system equipped with this device (*Continuation in Part*)
Velocimetry	14	02/04/04	VIT	WO2005/098474	Method and system for measuring blood flow velocity
Multimarking	15	14/06/04	MTM	WO2006/000704	Method and system for multi-marker fibered fluorescence microscopic imaging
2Photons	16	22/10/04	2PH	WO2006/045936	System and method for fibered multiphoton microscopic imaging of a sample
Methylene Blue	17	31/03/06	BDM	WO2007/118954	Methylene blue-based fiber fluorescence microscopy
UHD probe	18	05/05/06	UHD	WO2007/128909	Miniaturized optical head with high spatial resolution and sensitivity, especially for confocal fiber fluorescence imaging
Alveolar Imaging	20	17/08/06	ALV	WO2008/020130	Use of an in vivo in situ fibered confocal fluorescence imaging system, system and method for in vivo in situ fibered confocal fluorescence imaging
Mosaicing	21	02/08/07	MOS	FR 2 904 927	Image mosaicing method, in particular including compensation of motion distortions and tissue deformations, for fiber confocal microscopy.
CVZ 2	22	11/10/07	VZ2	WO2009/053632	Modular imaging device, module for this device and method implemented by this device
ERCP	23	12/03/08	CPR	US2009-0240143	Method and optical probe for in vivo imaging of the mucosa of the biliary or pancreatic ducts, and method for

					selectively treating a tissue sample of the mucosa of the biliary or pancreatic ducts
Automatic calibration	24	29/12/08	CAL	WO2010/076662	Image processing method and apparatus
OBF	25	31/12/08	OBF	US 8,267,869	Multi-purpose biopsy forceps
Freeze algorithms	26	30/01/09	FRZ	WO2010/086751	Method and system for processing images acquired in real time by a medical device
Polished connector and probes	27	12/03/09	CON	WO2010/103406	Connector for a fiber-optic probe and fiber-optic probe adapted to this connector
Jerry (provisional)	28	29/07/09	JRY	NA	Apparatus and method for fiber-beam microscopic imaging of the brain
Microscopy in solid organs (provisional)	29	17/09/09	MSO	NA	A method, an optical probe and a confocal microscopy system for inspecting a solid organ
Microscopy in Solid Organs 2 (prov. MSO + new matter PCT)	31	17/09/10	MS2	WO2011/033390	A method, an optical probe and a confocal microscopy system for inspecting a solid organ
Cellvizio with Photoactivation (CIP of CVZ2)	32	10/01/11	CVP	US 8,644,663	Modular imaging system, modules for this system and process implemented using this system
Continuous Calibration (RICE)	33	16/05/11	RIC	WO2012156826	Continuous, real-time calibration of fiber-based microscopy images
Stabilized micropositioner	34	29/06/11	MPS	WO2013/000873	Endoscopic instrument with support foot
Mosaicing (Cont of MOS)	35	08/07/11	MOS_C	US 8,218,901	Continuation of Mosaicing
Spiraler	36	13/04/12	SPI	WO2013/153448	Miniaturized scanning system
Fluorescent markers	37	18/05/12	RED	WO2013/171583	Red and far-red fluorescent dyes for characterizing biological tissues at the cellular level
Smart Review (provisional)	38	11/10/13	EVA	NA	Method for characterizing images acquired by a medical video device

Smart Review 2 (prov. Smart Review + new matter PCT)	39	23/05/14	EV2	WO2015052351	Method for characterizing images acquired by a medical video device
Smart Review (continuation)	39	23/05/14	EV3	US 15/997,802	Method for characterizing images acquired by a medical video device
Smart Review (continuation)	39	23/05/14	EV4	US 15/997,915	Method for characterizing images acquired by a medical video device
Smart Review (continuation)	39	23/05/14	EV5	US 15/997,936	Method for characterizing images acquired by a medical video device
AURA (IA Gen3)	41	09/07/21	AUR	US29/798747	Graphical user interface for medical imaging equipment

List of inventions covered by the 19 patents transferred to the joint venture in Q1th2023 :

Patent portfolio					
Description	**N°**	**Priority date**	**Acronym**	**Family ref. no.**	**Description**
Multiple probes	19	12/05/06	EMS	WO2007/132085	Endoscopic device and method for simultaneous observation of several areas of interest
Jerry 2 (prov. JRY + new matter PCT)	30	29/07/10	JR2	WO2011/013011	Apparatus and method for fiber-beam microscopic imaging of the brain
Jerry 3 (Div US)	40	05/06/15	JR3	US2015-0265153	Apparatus and method for fiber-beam microscopic imaging of the brain

Multiple probes	19	12/05/06	EMS	WO2007/132085	Endoscopic device and method for simultaneous observation of several areas of interest

Generally speaking, the coverage of the Company's patents or patent applications fairly accurately reflects the main aspects of the architecture of the technical solutions developed by the Company, i.e. :

- the system itself (light excitation, detection, scanning means, etc.);
- endomicroscopic probes (optical probes + distal optics) ;
- image processing and analysis algorithms.

The Company has also filed and continues to file patent applications to protect certain applications related to its products, such as :

- alveolar imaging,
- biliary tract imaging,
- imaging of solid organs,
- deep intracerebral imaging in animals.

Protected areas

With rare exceptions, all the Company's patent applications are systematically extended abroad, via the PCT procedure. As a minimum, the territories selected are always :

- The United States,
- Europe,
- Japan,
- Canada,
- Australia.

The most important patent applications are also extended to China, India and Israel. In Europe, the countries selected for validation after the European title has been granted are Germany, the United Kingdom, Spain and Italy.

Dispute

The Company is not currently the subject of any third-party infringement action. Nor has the Company yet brought any such action against a third party. However, the Company does its utmost to keep a close watch on the commercial activity of players in the field and on developments in the patent landscape, so as to fully guarantee the freedom to exploit its products and respect its rights.

1.2.3. Collaboration, research, service and licensing agreements granted by or to the Company

Research collaborations with industrial partners

To date, three main scientific partnerships have continued or been set up with industrial, pharmaceutical and/or medtech partners.

Partnership with Johnson & Johnson and the Lung Cancer Initiative ("LCI")

The first partnership with Johnson & Johnson and more specifically its entity called the Lung Cancer Initiative ("LCI") was established in 2019 and continued. In 2020, Mauna Kea Technologies and LCI co-founded an initial pilot clinical study with the team of Dr. Christopher Manley, Director of Interventional Pulmonology and Assistant Professor of Medicine at Fox Chase Cancer Center (FCCC) in Philadelphia, and Prof. Jouke T. Annema, Professor of Pulmonary Endoscopy at the University of Amsterdam Medical Center. This pilot clinical study combined nCLE and robotic bronchoscopic navigation, using both Cellvizio® and the Monarch™ platform from Auris Health, Inc. one of Johnson & Johnson's medical device companies, for the diagnosis of peripheral lung nodules. The primary objective of this study was to evaluate the feasibility and safety of nCLE during bronchoscopy with robotic navigation in the evaluation of peripheral lung lesions.

Following the highly promising results of this pilot study, a new research and development collaboration agreement was signed with LCI at the end of 2021. This collaboration will enable the validation of Cellvizio® as a real-time biopsy guidance tool during robotic bronchoscopic navigation, to potentially reduce the substantial failure rate of transbronchial biopsies of peripheral lung cancers. The study will combine nCLE and robotic bronchoscopic navigation, using both Cellvizio® and the Monarch® platform, to assess nCLE's ability to accurately confirm needle position for the diagnosis of peripheral lung nodules. In 2021, Mauna Kea Technologies began setting up the CLEAR clinical trial. This ongoing multicenter study of 75 patients enrolled at 3 investigating centers aims to explore the potential of real-time nCLE to help position the biopsy needle "in the lesion" during robotic bronchoscopic navigation (the Monarch™ platform from Auris Health, Inc) for peripheral lung nodules, compared with positioning using CBCT as the standard of care. In addition to its potential role in improving the diagnostic yield of robotic bronchoscopy, this technology could enable the precise application of intra-lesional therapy such as transbronchial intratumoral chemotherapy or gene-mediated cytotoxic immunotherapy in the treatment of malignant lung tumors.

Partnership with On Target Laboratories

The second partnership involves the pharmaceutical company, On Target Laboratories (https://ontargetlabs.com/). On Target Laboratories discovers and develops targeted fluorescent imaging agents to illuminate cancer during surgery to identify and remove cancerous tissue. Their fluorescent imaging technology, based on the pioneering work of Philip S. Low, PhD, Purdue University drug discovery researcher and Ralph C. Corley Professor Emeritus of Chemistry, aims to reduce the uncertainty associated with finding and removing cancerous tissue during surgical procedures, helping surgeons perform more accurate and complete surgical resection. CYTALUX, also known as OTL38 and pafolacianin, the company's first product, was studied as part of the ELUCIDATE Phase 3 experimental trial for lung cancer in the USA. This collaboration has been set up to develop the combined clinical and technological knowledge of both companies, focusing initially on interventional pulmonology and lung cancer, with the possibility of extending this collaboration to other indications. Molecular imaging is a fast-growing field in interventional and surgical procedures. It enables cancer cells to be detected for easier and more accurate visualization. On Target's imaging agents target and bind to cancer cells, providing physicians with a tool for detecting cancer and eliminating it. Mauna Kea's Cellvizio® platform enables tissue imaging at the cellular level, including cancer cell identification, through a minimally invasive bronchoscopy procedure. The combination of these two technologies could create a new category of medical procedures - Molecular Image Guided Procedures (MIP) - that enable real-time visualization of cancer at

the cellular level. The use of MIP during bronchoscopic lung biopsy could improve the diagnostic accuracy of biopsies while reducing the number of procedures, time and complications associated with obtaining a diagnosis.

Partnership with Telix Pharmaceuticals Limited

The third partnership concerns the pharmaceutical company, Telix Pharmaceuticals Limited (https://telixpharma.com/). Telix Pharmaceuticals is a company focused on the development of diagnostic and therapeutic products based on "Targeted Molecular Radiation" (TMR) technology. The scientific research collaboration between Telix and Mauna Kea called the "Alliance for Imaging and Robotics in Surgery (IRiS)", or "IRiS Alliance", was created at the end of 2020, to develop and validate the potential of the two companies' combined technologies. The IRiS Alliance is founded on the conviction that the use of molecular imaging agents for cancer-specific positron emission tomography (PET), combined with fluorescent dyes, in conjunction with laser confocal endomicroscopy, can significantly improve surgical techniques and clinical outcomes in patients with urological cancers. The IRiS Alliance intends to demonstrate that preoperative planning, intraoperative guidance, assessment of resection margins and other surgical parameters can be improved by combining these modalities. The first objective of the IRiS Alliance is to develop and evaluate the use of Telix's dual-modality molecular marker, PET and fluorescence imaging, with the near-infrared version of the Cellvizio® endomicroscopy platform, to improve surgical interventions for prostate and kidney cancers.

Joint venture with Tasly Pharmaceuticals

In July 2022, Mauna Kea Technologies signed a framework agreement with Tasly Pharmaceuticals to create a joint venture dedicated to manufacturing and marketing Cellvizio in China, opening up a new global field of application in neurosurgery. The agreement gives the joint venture the exclusive right to manufacture and market in China the digestive and pulmonary indications already approved, while transferring to it the mission of developing and distributing, on an international scale, a version of Cellvizio dedicated to neuroscience. In exchange for licensing and intellectual property assets, Mauna Kea receives a 44% equity stake, milestone payments and multi-year commitments to purchase systems and probes.

The structure, named Tasly Mauna Kea Medical Engineering Technology Co. Ltd. was legally registered in November 2022 in Zhejiang province, with a registered capital of 250 million RMB. Its role is twofold: to serve as a unique commercial platform for the Chinese market - the world's largest for endoscopy - and to steer, jointly with Mauna Kea, the development of a Cellvizio range tailored to the requirements of neurosurgery.

Following the legal phase, in June 2024 the joint venture obtained a Class II medical device distribution license from the NMPA, giving it the regulatory green light to start selling systems and probes throughout China. This authorization marks Cellvizio's effective entry into the local marketing circuit and paves the way for the first clinical installations.

For Mauna Kea, this alliance represents a strategic lever: it combines Tasly's industrial power and sales network with Cellvizio's technological expertise, while pooling R&D costs for future neurosurgical applications. It offers the Group accelerated access to a huge domestic market, the prospect of recurring royalty revenues, and a vector for worldwide distribution of the portfolio of indications beyond gastroenterology.

1.2.4. Other intellectual property

The Company owns the "Cellvizio" trademark in a number of countries, including France, Europe, Australia, Japan, the United States, China, India, Israel and Canada.

It is also the French owner of the "MKT", "Mauna Kea Technologies", "Proflex" and "Confocal Miniprobe" trademarks.

The Company owns more than 70 domain names including: "cellvizio.fr", "diagnosingbarretts.com", "maunakeatech.fr", "cellvizio.com", "maunakeatech.com", etc.

CHAPTER 2: RISK AND INTERNAL CONTROL

2.1 Risk factors

Investors are invited to consider all the information contained in this Document, including the risk factors described in this chapter, before deciding to subscribe for or acquire shares in the Company.

As of the filing date of this Document, the risks described below are those identified by the Company as likely to have a material impact on its business, image, financial position, results, ability to achieve its objectives and shareholders.

All identified risks and threats are regularly analyzed as part of the Company's risk management process.

The table below summarizes the main risks, organized into four categories: risks relating to the markets in which the Company operates, risks associated with the Company's business/organization, financial risks, and legal risks.

In each of the 4 categories, the risks remaining after the implementation of management measures are classified according to their level of criticality (combination of probability of occurrence and estimated impact). Only risks assessed as "significant" are detailed in this chapter.

Risk criticality legend :

Probability of occurrence	
***	Probable
**	Possible
*	Unlikely

Estimated impact	
***	High
**	Medium
*	Low

Criticality level	
***	High
**	Medium
*	Low

Trend
⇘ On the rise
⇨ Stable
⇘ Decreasing

Risk factors	Probability	Impact	Criticality	Trend
Risks relating to the markets in which the Group operates				
Risk of non-adherence to the new technology	**	***	***	⇘
Regulatory risks	**	***	***	⇨
Risk of technological competition	**	**	***	⇘
Risk associated with the need to deploy in new indications	**	**	**	⇘
Risk of maintaining and obtaining repayment	**	**	**	⇘
Risks relating to the Group's activities/organization				
Distributor network risk	**	***	***	⇨

Supplier dependency risk	**	***	***	⇨
Sales force loyalty risks	*	**	**	↘
Risk of dependence on key men	*	*	*	↘
Risks related to strategic partnerships	*	*	*	
Financial risks				
Liquidity risk	***	***	***	⇨
Financial debt risk	***	**	***	⇨
Dilution risk	**	**	**	⇨
Research tax credit risks	*	*	*	↘
Risks related to access to public advances	*	*	*	⇨
Foreign exchange risk	*	*	*	⇨
Legal risks				
Product liability risks	**	*	**	⇨
Risks related to the warranty on products sold by the Company	**	*	**	⇨
Intellectual property risks	*	*	*	⇨
Cybersecurity risk	*	*	*	↖
Foreign investment control risk in France	*	*	*	↖

2.1.1. Risks relating to the markets in which the Group operates

♦ Risk of non-adherence to the new technology

The products developed by the Company are positioned in markets where, in some cases, alternative solutions already exist (e.g. traditional biopsy), and which are sometimes widely used by doctors and other medical staff.

The Group's development will depend in part on the pace at which healthcare professionals adopt its breakthrough technology.

The Group anticipates that healthcare professionals will not make widespread use of its products until they are convinced, on the basis of clinical data or scientific publications, that its products offer advantages or constitute an attractive alternative to equipment already on the market, the use of which they have already mastered, and when its products are better covered (in full or in part) by public or private health insurance systems, depending on the geographical area.

Despite the convincing results of clinical trials already carried out, the support of numerous learned societies around the world, the numerous scientific publications reporting on the benefits of the solution proposed by the Company compared with existing technologies, and the installed base of the Company's products, these same professionals may be reluctant to change their medical treatment practices in favor of Cellvizio®, for the following reasons in particular:

- their lack of experience in using Cellvizio® ;
- an insufficiently significant number of favourable published clinical data;
- the fear of liability arising from the use of new products, new interventional procedures and the interpretation and integration of the resulting new information (mainly in vivo microscopic images); and
- limitations on reimbursements by public or private health insurance schemes or complementary organizations.

Without the support of healthcare professionals, the large-scale commercial deployment of Cellvizio® could be more or less compromised, which could have a material adverse effect on the Group, its business, financial situation, results, development and future prospects.

- **Regulatory risks**

The Group's products fall into the category of medical devices whose control, manufacture and sale are subject to obtaining and maintaining regulatory authorizations and certifications. All marketing authorizations are presented in section 3.3.2 of this document. In fact, the Company's products are subject to strict and constantly evolving regulations, notably following the process of European harmonization, and in particular the replacement of European Directive 93/42/EC (on the conditions for the marketing and free movement of medical devices within the European Economic Area) by a new European regulation on medical devices or "MDR[14] ", which was approved by the European Parliament and published in May 2017, with a deadline for compliance of May 2021 (but which has since been partly postponed) and which results in stricter requirements that are more difficult to apply.

Compliance with this regulatory process can be lengthy and costly, and no guarantee can be given that authorizations will be obtained, or that they will be obtained, or maintained. Should certification or marketing authorization for the Company's products be refused, their marketing could be delayed or prohibited in the countries concerned.

Similarly, even if the Company takes into account potential changes in legislation, standards or regulations applicable in the States in which it markets and plans to market its products, notably in the United States where the Company has obtained some fifteen marketing authorizations for its products, new regulatory constraints could prevent the marketing of the Company's products in the event of withdrawal or suspension of marketing authorizations, or slow them down by making their production more costly.

- **Risk of technological competition**

[14] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The Company cannot guarantee that other alternative or competing technologies with similar or even superior characteristics to those of Cellvizio® will not develop, even if it believes that the other solutions available are less effective than Cellvizio® and its confocal mini-probes, particularly insofar as they are more invasive and do not allow microscopic visualization in vivo.

These technologies could take significant market share and restrict the Group's ability to market its products successfully. They could therefore prevent the technology integrated by the Company in the Cellvizio® (laser scanning optical fibers) from establishing itself as the benchmark in optical biopsy.

In particular, the leaders in the endoscopy market are very large players compared with the Company, and have substantial financial resources that could enable them to develop new technologies that are more effective, safer and/or less costly than those developed by the Group, which could lead to a drop in demand for the Group's existing products.

In addition, companies developing diagnostic solutions such as liquid biopsies, which would make it easier to analyze tumor cells and detect possible genetic mutations, could offer effective alternatives to tissue biopsy.

The Group's long-term success depends in part on its ability to constantly improve and broaden its product offering, in order to meet ever-changing market demands and withstand strong competitive and technological pressure.

With this in mind, and in addition to its policy of protecting intellectual property (see section 1.2.2 of this document), the Group maintains an ongoing technology watch, patent watch and product watch activity, enabling it to understand and anticipate developments in its technological and commercial ecosystem. The Group thus devotes significant and constant efforts to improving its existing products and developing new ones, in order to provide solutions adapted to new fields of medicine and new pathologies, while maintaining its technological lead.

However, in its current configuration, the Group may not be able to meet these requirements. It may therefore have to resort to selective acquisitions of new or complementary technologies in the not-too-distant future. The implementation of this strategy depends, in part, on the Group's ability to identify attractive targets, to carry out these acquisitions on satisfactory terms, and to integrate them successfully into its operations or technology.

- **Risk associated with the need to deploy in new indications**

The Group's development also depends on its ability to market its products for new medical and research indications.

As of the filing date of this document, the Group markets Cellvizio® and its mini-probes to healthcare establishments (hospitals and clinics), where Cellvizio® is marketed in the fields of gastroenterology, pneumology and urology. Confocal miniprobes used in clinics have a limited number of uses, and thus generate recurring revenue.

The Company intends to pursue its research and development efforts in order to perfect its existing products and develop new products and services to broaden the range of medical applications benefiting from the information obtained from Cellvizio® examinations.

From 2005 to the present day, the clinical contribution of Cellvizio® has been the subject of numerous publications. More than 1,000 clinical publications worldwide concern endomicroscopy, including several randomized multicenter clinical trials, some funded by the Group, on key applications in gastroenterology.

The quality and interest of these multi-center clinical trials depend on the Group's ability to select partner care facilities and recruit the necessary number of patients within a relatively short timeframe, so as to be able to publish results rapidly. The remoteness or geographical distribution of clinical study centers, although rationalized, may also give rise to operational and logistical difficulties likely to result in additional costs and delays.

If the Group were unable to recruit the planned number of patients, or encountered logistical difficulties, leading to delays in clinical trials and the publication of results, this would result in a delay in acceptance by both learned societies and professionals in the medical fields concerned, and the Group's ability to market its equipment would be affected.

The Group is also seeking to clinically validate the benefits of Cellvizio® in new medical fields (urology, pneumology, surgery, interventional radiology, neurosurgery and biomarkers, etc.). These studies are not systematically carried out by the Company as sponsor, and some are initiated by investigators. Should the results of these studies, whether randomized or not, fail to prove the medical benefit of the equipment offered by the Group, the medical community's recognition of Cellvizio® would be compromised.

If these risks were to materialize, the Group's ability to win market share would be durably affected, which would be likely to have a material adverse effect on the Group, its business, financial condition, results of operations, development and prospects.

- **Risk of maintaining and obtaining repayment**

As of the date of this document, the United States remains the main country where the Group has obtained reimbursement rates. The Group's commercial development depends on its ability to maintain the level of reimbursements already granted by certain paying organizations (public and private health insurance funds), and to extend reimbursements to other indications and geographical areas.

Governments and public or private health insurance schemes are striving to control healthcare spending by limiting both the level of reimbursement and the coverage of certain products, in particular innovative products such as Cellvizio® and confocal miniprobes.

Despite the clinical validation obtained, the Group cannot guarantee that it will be in a position to obtain, for all the countries in which it wishes to market its products, on the one hand, the eligibility of these products for reimbursement and, on the other hand, the levels of coverage and reimbursement that will encourage healthcare professionals to integrate the endomicroscopic procedure into their practices, nor is it or will it be in a position to anticipate possible changes over time in the conditions of coverage and reimbursement that it may have obtained.

The absence or inadequacy of reimbursement or coverage for the Group's products, or the adoption of more restrictive measures in terms of reimbursement or coverage, could have a material adverse effect on the Group, its business, financial condition, results of operations, development or prospects.

2.1.2. Risks relating to the Group's business and organization

- **Risks linked to dependence on a network of distributors**

Successful international deployment of the Group's products in countries where it has no direct sales force, i.e. outside France, Germany, the UK, Benelux and the USA, depends largely on partners and distributors to whom it has granted sectoral and territorial exclusivity, and who market the technology under the Cellvizio® brand. To date, the Group has signed a number of exclusive distribution contracts in countries where it has marketing authorization. However, it cannot guarantee that it will be able to retain its existing distributors or enter into new distribution or partnership agreements to cover all countries with sales potential. Moreover, given that these distributors generally carry several products, sometimes even products of their own manufacture, the Group cannot guarantee that they will devote the necessary resources to the commercial success of its products. In order to limit this risk, the Group has assigned part of its direct sales force to assist its distributors with face-to-face sales actions, notably at trade fairs and demonstration sessions in care facilities.

The risk of dependence is greater in certain regions or countries where the Group uses a limited number of distributors. In China, since the creation of the joint venture with Tasly Pharmaceuticals in 2022, the latter has become the exclusive distributor of the Group's products in the country. Nevertheless, the Group considers that this joint venture is a major factor in securing sales outlets in this high-potential region.

Supplier dependency risk

The Group depends on a single partner for the supply of a major component.

The Group relies on a single partner for the supply of optical fibers, an important component of its products, namely the Fujikura Group (and its subsidiary Fibertech), a Japanese conglomerate active in a wide range of sectors. This situation results from the Group's choice to develop its product from a certain type of optical fiber with very specific characteristics. For this reason, the Group has been building a long-term partnership with Fujikura for several years.

In addition, Fujikura carries out certain manufacturing stages and the assembly of a confocal mini-probe model on behalf of the Group, enabling the latter to anticipate an increase in its production and further strengthen its relationship with this critical supplier.

The framework agreement with Fujikura has been renewed several times. It includes a financial commitment by the Group to make minimum purchases over a 3-year period, in return for maintaining, barring exceptional conditions, the maximum price levels for products and services supplied to the Group. The contract also includes a commitment to build up a safety stock and to allow the transfer of optical fiber manufacturing technology to a third party, so as to ensure the continuity of the Group's business.

For all these reasons, the Group considers that the supply risk with its partner is well managed, even if the risk of contractual breach cannot be ruled out. The Group has carried out technical assessments of other sources to satisfy new developments or offset a possible breakdown in relations with Fujikura. However, these alternatives would require time to adapt our product and supply chain, which could have a significant adverse effect on the Group, its business, financial situation, results, development and prospects.

The Group depends on third parties to manufacture its products.

As the Group depends on third parties for the manufacture of all its products, its commercial success depends in part on its ability to obtain from its subcontractors products manufactured to specifications, on time and on acceptable financial terms. Problems may arise during the manufacturing and distribution of these products, which could lead to delays in delivery, resulting in higher costs, lower sales, poorer customer relations and, in some cases, product recalls, with consequent damage to the Group's image and liability.

This dependence is heightened by the regulatory status of the Group's products. Indeed, a change of critical suppliers or subcontractors (optical fibers, optical lenses, opto-electronic components) for its equipment and consumables could require the revalidation of product manufacturing processes and procedures in compliance with current standards. In this eventuality, additional tests and validations could be required to maintain CE marking and other regulatory registrations, notably in the United States. This procedure could be costly and time-consuming. If these new authorizations were to be refused, the Group could be forced to look for another supplier or subcontractor, or to retain its current suppliers and subcontractors, which could delay the production, development and marketing of its products and increase their manufacturing costs. Furthermore, if relations with one of its suppliers or subcontractors were to be terminated, the Group might be unable to find a subcontractor with the same skills within a sufficient timeframe or on satisfactory commercial terms.

In addition, although the Group has set up a process for the selection and periodic assessment of its critical suppliers and subcontractors, and carries out compliance checks, it has less control over the compliance of products manufactured by these third parties with regulatory standards and over the quality control of its products, as well as over the continuity of its activities in the event of the termination or non-renewal of these agreements than if it produced its products itself.

Although the Group is looking for new suppliers or subcontractors for its entire production and distribution chain, it cannot guarantee that it will be able to conclude new contracts on acceptable commercial terms, given the limited number of specialized companies with the infrastructure, experience and approvals and/or certifications to produce

this type of medical device. Should relations with subcontractors break down or deteriorate, or should the Group's requirements increase, it could find itself unable to establish relations with other suppliers or subcontractors, which could adversely affect its ability to produce, develop and market its products successfully.

** The use of Cellvizio® depends on the supply of contrast agent (fluorescein).**

Cellvizio® and confocal miniprobes are used in combination with a fluorescent contrast agent, Fluorescein. However, there are a limited number of FDA-approved fluoresceins, particularly since the bankruptcy in 2022 of Akorn Pharmaceuticals, which produced the AK-Fluor agent, creating dependence on a limited number of suppliers.

This dependence can have a direct impact on Group sales, since any fluorescein supply problem could limit the use of Cellvizio® and the ability of centers to carry out procedures.

To avert any risk of fluorescein supply difficulties, particularly in ASCs ambulatory centers in the USA, which can perform a large number of procedures per month with the Cellvizio®, the Group has set up a communication plan with its customers. It aims to help them resolve any fluorescein supply problems by seeking alternative distribution channels, and to establish direct contact with key suppliers to find out stock levels in real time.

- **Sales force loyalty risks**

The Group's commercial deployment depends largely on its sales force, and it may not be able to recruit and retain them within the timeframe or on terms compatible with its expansion.

In particular, in France, Germany, the UK, Benelux and the USA, the Group relies on a direct sales force for gastroenterology and pneumology applications, and its success in these territories depends in particular on its ability to recruit, train and retain this internal sales force.

- **Risk of dependence on key men**

Given its size and competitive environment, the Group could lose key employees and be unable to attract new skilled personnel on acceptable economic terms, while its success, particularly in developing its activities, depends largely on the commitment and expertise of its managers and skilled personnel, as well as on additional recruitment.

The Group's inability to attract and retain these key people could prevent it from achieving its overall objectives, and thus have a material adverse effect on its business, results, financial situation, development and prospects.

Thus, even if the Group has taken out "key man" insurance, the departure of one or more people could result in :

- loss of know-how and the weakening of certain activities, all the more so in the event of transfer to competitors, where
- shortages of technical skills, which can slow down business and ultimately affect the Group's ability to achieve its objectives.

To address this risk, the Group has put in place contractual provisions specific to its business, such as non poaching, intellectual property transfer and confidentiality clauses. It has also set up systems for motivating and retaining staff, in the form of performance-based variable remuneration and the allocation of financial instruments giving access to the Company's capital.

- **Risks related to strategic partnerships**

The new commercial strategy based on strategic partnerships to exploit Cellvizio® in new indications and territories could expose the Group to new types of risk in the future, including dependence on third parties.

Thus, following the conclusion of the 1st partnership with Tasly Pharmaceuticals, the joint venture created in 2022 exposes the Group to certain risks likely to concern in particular:

- Significantly longer than anticipated start-up time (recruitment, assembly unit construction, etc.);
- operational management, covering a wide range of issues such as JV governance, Mauna Kea's ability to supply components to the future assembly site, etc.
- Regulatory changes likely to affect trade relations between France and China, with possible difficulties relating to financial flows;
- The Group's dependence on the joint venture for future commercial deployment in China, which remains one of the Group's two priority markets:

The Group will keep a close eye on these points, although at present, given the recent creation of the JV, these risks are considered to be of little significance, but are likely to become increasingly important in the future.

2.1.3. Financial risks

Liquidity risk

Historically, the Group has financed its development mainly through equity capital increases and, to a lesser extent, by obtaining public aid for innovation and repayment of Research Tax Credit receivables. The Group has also taken on debt, mainly with the European Investment Bank and also via the government-guaranteed loan mechanism. More recently, the Group signed an exclusive licensing agreement in China with Tasly Pharmaceuticals, enabling it to obtain non-dilutive financing of which $9 million has already been received in 2023.

Despite reducing its operating loss over the last few years, the Group has not yet managed to generate an operating cash surplus. It may take a few more years to achieve operating profitability, and the Group therefore considers that it will need to obtain new financing to fund its business in the meantime.

At December 31, 2024, the Group's cash position stood at 2 million euros, providing financial visibility until July 2025, but not sufficient to cover operating requirements for at least the next 12 months, which the Group estimates at around 5 million euros. As a result, there are significant uncertainties hanging over the Group's ability to continue as a going concern.

The Group intends to continue to seek additional financing to ensure that it is able to fund its business until it reaches profitability. It could finance its future cash requirements through a combination of capital increases via public offerings or private placements, bank or bond financing, collaboration, licensing and development agreements, or other non-dilutive forms of financing. In addition, given the turmoil on the world's financial markets as a result of the conflict in Ukraine and macro-economic uncertainties, the Group cannot guarantee that it will be able to obtain financing in line with its needs or on attractive terms. As the Group's market capitalization is affected, a sharp and prolonged fall in its share price could limit its ability to raise capital on the market. If it is unable to meet its financing targets, the Group could be forced to scale back its activities, notably by delaying or reducing the scope of its research and development efforts, or to obtain financing through collaboration or other agreements, which could require it to relinquish rights to its technologies.

Risks relating to the Group's financial debt

At December 31, 2024, consolidated gross financial debt amounted to €31,932,000. Most of this debt relates to a loan agreement with the European Investment Bank (EIB).

This debt is subject to guarantees and financial covenants:

- *Guarantees given :* The guarantees given by the EIB relate to the Company's trade receivables and inventories. In addition, in accordance with the financing agreement as amended by a rider dated June 19, 2020, the Company has pledged the intellectual property rights relating to three patents it holds.

- *Financial covenants*: The following covenants are attached to this EIB debt:

  - a cash position in excess of 4 million euros

  - from January 1(st), 2023, a debt coverage ratio greater than 2.0:1.0

  - from January 1, 2023, a debt-to-equity ratio of 1.

  - from December 31, 2024, a minimum level of income and EBITDA, a condition added during the renegotiation agreement reached in April 2024.

The guarantees given by the EIB on inventories and trade receivables, and on the pledge of certain patents, have been extended to cover the new maturities.

As of the date of this document, and in view of the opening of a safeguard procedure in favor of the Company on March 31, 2025, which has the effect of freezing liabilities, all these commitments have been suspended and are being renegotiated with the EIB.

Dilution risk

The Company's shareholders are exposed to a significant risk of dilution in view of the financing requirements described above, and also in the event of a share issue in connection with a potential acquisition by the Company.

Dilution may also result from the issue or allocation of shares or new financial instruments giving access to the Company's capital as part of its policy of motivating its managers and employees.

Since its creation, the Company has regularly issued or allocated stock options, share subscription warrants ("**BSA**") and business creator share subscription warrants ("**BSPCE**"), preference shares and bonus shares. At December 31, 2024, the full exercise of all outstanding instruments giving access to the share capital would result in the subscription of 19,717,773 new shares, generating dilution equal to 22.5% on the basis of the existing share capital.

As part of this policy of motivating its managers and employees, the Company may in the future issue or grant new financial instruments giving access to the Company's capital. Any additional issue of shares or financial instruments giving access to the Company's capital would result in potentially significant additional dilution for the Company's shareholders.

Research tax credit risks

To finance its activities, the Company is reimbursed the Research Tax Credit ("**CIR"**) by the French tax authorities for certain of its research and development expenditure. The Company has been subject to two tax audits covering all taxes for 2009-2010 and 2014-2015, including the research tax credit. No adjustments have been made.

In the future, it cannot be ruled out that the tax authorities may question the methods used by the Company to calculate research and development expenditure, or that the CIR may be called into question by a change in regulations, even though the Company complies with documentation and expenditure eligibility requirements. If such a situation were to arise, it could adversely affect the Group's results, financial position and prospects.

Risks related to access to public advances

At December 31, 2023, the Company had received innovation grants totalling €3,407,000.

Should the Group fail to comply with the contractual conditions set out in the repayable advance agreement with BPIFrance for the PERSEE project, the Company may be required to repay the sums advanced early. In addition, the Beneficiary Agreement governing the PERSEE project provides that early repayment may be required by OSEO in the event of a contribution / merger / demerger / transfer of control or assets of the Company. Such situations could deprive the Company of some of the financial resources required to complete its research and development projects.

- **Foreign exchange risk**

The Group's main foreign exchange risk relates to changes in the EUR/USD exchange rate. The Group markets its products and services in the United States via its subsidiary Mauna Kea Technologies Inc. where all revenues and expenses - including the purchase of Cellvizio® and probes from Mauna Kea Technologies SA - are denominated in US dollars, the subsidiary's functional currency. The Group is therefore exposed to fluctuations in the EUR/USD exchange rate through this subsidiary.

The Group regularly assesses its exposure to currency risks and may decide to set up hedges to limit this risk.

2.1.4. Legal risks

- **Product liability risks**

The Company's products are classified as medical devices and, as such, are subject to specific regulations and standards in all countries where they are manufactured, tested or marketed. These regulations and standards impose obligations concerning, in particular:

- design ;
- pre-clinical testing and clinical trials of products ;
- manufacturing, control and product quality assurance ;
- product labelling, including instructions for use ;
- product storage ;
- product identification and traceability ;
- data retention procedures; and
- post-market surveillance and reporting of incidents related to product use.

These regulations and standards apply to the Company as the manufacturer of these products.

The principle of full traceability of all critical product components, as well as the implementation and maintenance by the Company of a Quality Management System (QMS) certified to the international standard ISO 13485 and an optimized production system (Lean Manufacturing), aim to guarantee the full compliance of each product with applicable regulations, as well as its quality.

Although the Company has set up a process for selecting and monitoring its suppliers, it cannot guarantee that its suppliers or subcontractors comply or will comply with applicable regulations at all times. The notified body, during a certification or monitoring audit, or the regulatory authorities, during an inspection or any other regulatory process, may identify failures to comply with applicable regulations or standards, and request that they be remedied by taking corrective action that could interrupt the manufacture and supply of the Company's products. The suspension, total shutdown or total or partial prohibition of the activities of the Company's suppliers could significantly affect the Group's business, financial situation, results and reputation.

The Group may be exposed to liability risks in connection with the clinical development or commercial use of its products, in particular product liability. Users (patients, practitioners, researchers and other healthcare or research professionals), regulatory authorities, distributors and any other third parties using or marketing the Group's products could file or take legal action against the Group.

To date, the Group has not been the subject of any claims or lawsuits in this area, and has taken out product liability insurance providing coverage up to a maximum of 4 million euros per policy year, plus 5 million dollars per policy year for the United States.

The Company cannot guarantee that its current insurance coverage is sufficient to respond to any liability claims that may be brought against it. If it were to be held liable in this way, and if it were unable to obtain and maintain appropriate insurance cover at an acceptable cost, or to protect itself in any way against product liability claims, this would seriously affect the marketing of its products and, more generally, harm the Group's business, results, financial situation, development and prospects.

- **Risks related to the warranty on products sold by the Company**

In parallel with the implementation and maintenance of a Quality Management System (QMS) certified to the international standard ISO 13485 version 2016, aimed at ensuring that its products meet strict quality criteria, the Company generally grants its customers a product warranty for one year from the date of delivery of the products. This warranty covers material defects as well as the conformity of delivered products to technical descriptions and specifications; it is limited to the initial purchasers of the Company's products and is non-transferable.

The Company has put in place a policy of covering the main insurable risks with guarantee amounts that it considers compatible with the nature of its business. Although the financial consequences of the risk of implementing this contractual guarantee have been anticipated, the Company cannot guarantee that these current estimates will be sufficient to cover the implementation of the contractual guarantee by all its customers. If the Company's liability were thus called into question, and if it were unable to obtain and maintain an appropriate provision, or to protect itself in any way whatsoever against the implementation of this contractual warranty, this would have the effect of seriously affecting the marketing of products and, more generally, of harming the Company's business, results, financial situation, development and prospects.

- **Intellectual property risks**

The Company relies to a large extent on the proprietary nature of its intellectual property and know-how. However, the Company may not be able to maintain or obtain adequate protection, and thereby retain its technological and competitive edge.

To protect its products and technology, the Company relies on intellectual property rights, such as patents covering both the hardware and software aspects of its current products, but also a number of alternative technologies or processes currently under development, trademarks, as well as its trade secrets and know-how covering, in particular, manufacturing methods and the choice of certain critical components protected by confidentiality agreements or other contracts. However, these means offer only limited protection and may not prevent illicit use of the Group's products or technology.

The Company may encounter difficulties in obtaining some of its patent applications currently under examination. Furthermore, the granting of a patent does not guarantee its validity or enforceability, both of which may be contested by third parties. In addition, the Company has not, to date, filed patent applications in all the countries in which it operates, even though its patents or patent applications are most often filed in the United States, certain European countries, Canada, Japan, Australia, and for the most important patents in China, India and Israel.

The Company cannot guarantee with certainty that :

- the Company's patent applications currently under examination will effectively lead to the granting of patents, and consequently to protection of the inventions covered by the patent applications in question in all the countries

in which these patent applications have been filed (please refer to section 1.1.2 "Patents and patent applications" of this document, presenting the patents obtained and patent applications pending);

- patents issued to the Company will not be challenged, invalidated or circumvented;
- the scope of protection conferred by the patents is sufficient to protect it against competition and third-party patents covering similar products or devices;
- the Group's competitors have not already developed technology or products similar to those of the Group; and
- the Group's products do not infringe third-party patents.

The Group's competitors could thus successfully challenge the validity of its patents before a court or in other proceedings, which, depending on the outcome of such challenges, could reduce their scope, result in their invalidity or allow them to be circumvented by competitors. As a result, the Company's patent rights may not provide the expected protection against competition.

Nor can the Company guarantee that its products and technology, which are closely linked to its know-how and trade secrets, are adequately protected from competitors and cannot be usurped or circumvented by them. In fact, in collaboration and research and development contracts entered into by the Company, the latter is frequently required to provide its co-contractors, in various forms, with certain elements of its know-how, whether or not protected by patents, and in particular with information, data or intelligence concerning the research, development, manufacture and marketing of its products.

The Company seeks to limit the communication of key elements of its know-how to third parties to that which is strictly necessary for its collaboration with them, and contractually ensures that such third parties undertake not to misappropriate, use or communicate such information, notably by means of confidentiality clauses. However, the Company cannot guarantee that these third parties will respect these agreements, that the Company will be informed of any breach of these clauses, or that any compensation it may obtain will be sufficient to cover the loss suffered.

In addition, these collaboration and R&D contracts expose the Company to the risk of its co-contractors claiming intellectual property rights over the Group's inventions, knowledge or results. Lastly, these agreements could give rise to co-ownership of intellectual property rights, or to exclusive operating concessions under conditions unfavorable to the Group.

The Company's trademarks are important elements of its identity and its products. Even though the Cellvizio® trademark has been registered in France, Europe, the United States and many other countries, third parties could use or attempt to use this trademark or other trademarks of the Company, which would be likely to generate commercial and image damage for the Group.

The Company's protection of its intellectual property rights represents a significant cost, linked in particular to the filing and maintenance of patents and the management of its other intellectual property rights, a cost which could increase, particularly if legal action were to be taken by the Company to enforce its rights. In addition to these costs, should legal action prove necessary to enforce the Company's intellectual property rights, to protect its trade secrets or know-how, or to determine the validity and scope of its intellectual property rights, it could adversely affect the Group's earnings and financial position, and fail to provide the protection sought.

Similarly, monitoring unauthorized use of products and technology is difficult, and the Company cannot be certain that it will be able to avoid misappropriation or unauthorized use of its products and technology, particularly in foreign countries where its rights would be less well protected.

The occurrence of one or more of these risks could have a material adverse effect on the Group's business, financial condition, results of operations, development and prospects.

Part of the Company's business could in future depend on technologies belonging to third parties.

The Company benefits from two exclusive licenses on third-party technologies, namely INSERM-APHP and Université Denis Diderot (Paris 7).

To date, the technology covered by this licensing agreement has not been exploited by the Company, but it could be incorporated into future products, depending on the outcome of research and development work currently underway.

Any breach by the Company of the terms of these licenses could result in the loss of the right to use the technologies in question.

In addition, it is important for the success of its business that the Company is able to exploit its products and technology freely in relation to third-party patents or intellectual property rights.

Given the intense competition in its field, the Company cannot guarantee that there are no patents or other intellectual property rights held by third parties which might cover certain of the Company's activities, products or technologies, enabling such third parties to bring infringement actions, or similar claims, against the Group with a view to obtaining damages or the cessation of use of the offending product or process.

If these actions were brought to a successful conclusion and found to be founded in whole or in part, the Group could be forced to halt or delay the research, development, manufacture or sale of the products or processes targeted by these actions, which would significantly affect its business.

In particular, the Group could be required, in addition to the payment of financial indemnities, to :

- cease to manufacture, sell or use the products or technology in question in a given geographical area, which could reduce its revenues;
- obtain, under conditions unfavorable to the Group, a license to third-party intellectual property rights; and
- find alternative solutions so as not to encroach on the intellectual property rights of third parties, which could, in some cases, prove impossible or costly in terms of time and financial resources, and could therefore hinder its marketing efforts.

Any proceedings brought against the Group, regardless of their outcome, could result in substantial costs, disrupt its operations and compromise all or part of its business, image and reputation.

- **Cybersecurity risk**

The Group's digital transformation over the last few years has resulted in greater exposure to risks associated with cyber-attacks, as well as those associated with IT and communications system failures. These risks are becoming increasingly important in the day-to-day processing, storage and transmission of data.

In addition, certain tools and applications required for the Group's business are hosted by service providers on which the Group depends. IT outsourcing generates uncontrollable risks and requires close monitoring of our IT subcontractors to guard against various cyber-attacks:

- viruses and malware ;
- fraudulent emails;
- PIRACY;
- industrial espionage;
- embezzlement;
- loss of confidential information; and

- handling error.

In addition, the tightening of personal data protection regulations (RGDP) increases the risks associated with regulatory non-compliance.

The Group has taken a number of measures to meet its legal obligations with regard to :

- data cybersecurity (RGPD). These measures must be both material (securing premises), administrative (procedures for restricting access to information) and technical (use of passwords and encryption) ;
- protection of intangible and informational heritage; and
- protection mechanisms against cyber-attacks on individuals.

However, the Group cannot guarantee that cybersecurity risks, in an increasingly digitalized environment, are totally secure.

- **Foreign investment control risk in France**

The completion of any investment (i) by (a) an individual of foreign nationality, (b) any individual of French nationality not domiciled in France within the meaning of article 4B of the French General Tax Code, (c) any entity governed by foreign law and (d) any entity governed by French law controlled by one or more entities mentioned in (a) to (c), (ii) which would result in (a) the acquisition of control - within the meaning of article L. 233-3 of the French Commercial Code - of a French company, (b) acquire all or part of a branch of activity of a French company, or (c) for individuals who are not nationals of a member state of the European Union or of a state party to the Agreement on the European Economic Area which has concluded an administrative assistance agreement with France and/or which is not a national of a member state of the European Union or of a state party to the Agreement on the European Economic Area which has concluded an administrative assistance agreement with France administrative assistance agreement with France and/or are not domiciled in one of these countries, or for legal entities in which at least one of the members of the control chain is not governed by the law of one of these countries or is not a national and/or domiciled there, to cross the threshold of 25% of the voting rights of a French company, and (iii) whose activities concern, even on an occasional basis, the research and development of so-called critical technologies, such as biotechnologies, and considered essential to the protection of public health, is subject to prior authorization by the Minister of the Economy.

Decree no. 2023-1923 of December 28, 2023 perpetuated the temporary regime introduced by Decree no. 2022-1622 of December 23, 2022, which expired on December 31, 2023. The crossing of the 10% voting rights threshold in French companies whose shares are admitted to trading on a regulated market is subject to a rapid review procedure (filing of a simplified form, deadline for the Minister's response limited to 10 days, transaction deemed authorized in the absence of a response at the end of the deadline).

If an investment in the Company requiring the prior authorization of the Minister of the Economy is made without such authorization having been granted, the Minister of the Economy may cancel the transaction or order (possibly under penalty) the investor concerned (i) to submit an application for authorization, (ii) to have the previous situation restored at its own expense, or (iii) to modify the investment. In addition, the Minister may impose undertakings and conditions on the investor (including a commitment to regular reporting). The investor concerned could also be declared criminally liable and punished, in particular by exclusion from all public contracts, or by a fine not exceeding the highest of the three following amounts: (i) twice the amount of the investment concerned, (ii) 10% of the Company's annual pre-tax sales, and (iii) 5 million euros (for a company) or 1 million euros (for an individual). The application of these regulations is likely to act as a potential brake on investments made by investors located outside the European Economic Area, and could therefore limit the Company's access to sources of financing.

Although the Company considers that its business does not fall within the scope of the foreign investment control regulations described above, the application of these regulations could potentially act as a brake on investments made by investors located outside the European Economic Area and could therefore limit the Company's access to sources of financing.

2.2. Risk management

2.2.1. General risk management principles

Mauna Kea Technologies continues to formalize its risk management approach.

The aim of this approach is to identify all the risks and risk factors that may affect the company's activities and processes, and to define the means of managing these risks and maintaining or reducing them to a level acceptable to the Company. It is intended to encompass all types of risk, and to apply to all activities of the Company and the Group.

Mauna Kea Technologies adopts the definition of risk management proposed by the Autorité des Marchés Financiers[15] , according to which risk management is a management lever for the Company that contributes to :

- create and preserve the Company's value, assets and reputation;
- secure the Company's decision-making and processes to help it achieve its objectives;
- ensure that actions are consistent with the Company's values;
- mobilize employees around a shared vision of the Company's main risks.

2.2.2. Relationship between risk management and internal control

The aim of risk management is to identify and analyze the main risks and risk factors that could affect the company's activities, processes and objectives, and to define the means of maintaining these risks at an acceptable level, notably by implementing preventive measures and controls that fall within the scope of the internal control system.

At the same time, the internal control system relies in particular on risk management to identify the main risks to be controlled. Historically, the Company has developed an internal control system since its creation, while the formalization of the risk management approach is more recent. The Company has now embarked on a process of linking the two systems, with the aim of identifying the control procedures to be applied to key company processes likely to be affected by risks analyzed as "major".

2.2.3. General principles of internal control

Mauna Kea Technologies adopts the definition of internal control proposed by the Autorité des Marchés Financiers[16] , according to which internal control is a system implemented by the Company to ensure :

- compliance with laws and regulations ;
- the application of instructions and guidelines set by General Management;
- the proper functioning of the Company's internal processes;
- the reliability of financial information,
- and generally contributes to the control of its activities, the effectiveness of its operations and the efficient use of its resources.

15 Guide to implementing the internal control reference framework for small and mid caps updated July 22, 2010

16 Guide to implementing the internal control reference framework for small and mid caps updated July 22, 2010

During the year, Mauna Kea Technologies continued to implement an internal control process designed to "guarantee internally the relevance and reliability of the information used and disseminated in the Company's activities".

Organization of the validation system

The internal control system is based on a clear organization of responsibilities, guidelines, resources and procedures. From the outset, the company has implemented a Quality Assurance system. Processes in all areas of activity are described in procedures, operating modes, manuals and forms. These written documents trace the progress of activities, define the resources and responsibilities of those involved, specify the Company's know-how and give precise instructions for carrying out a given operation.

In 2013, in order to strengthen its quality system and internal control, the Company chose to implement an ERP (Integrated Management Software Package) through the publisher SAP with a pre-configured offer designed for Small and Medium-sized Enterprises. The functions concerned by this software package are Purchasing/Suppliers, Sales/Customers, Accounting and Management Control.

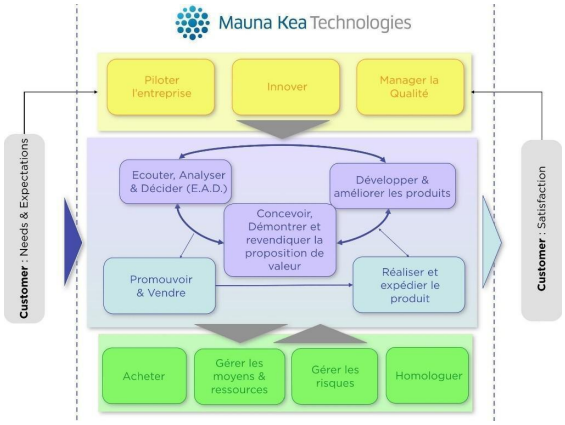
All Company personnel are involved in the internal control system.

Procedures for operational processes

All documentation relating to the Quality Management System (QMS) is stored on a dedicated intranet, which optimizes access to documents and their ongoing adaptation to changes in the business (document lifecycle management). The aim is to continuously improve the quality of the Company's and the Group's operational, management and support processes.

Each of these processes is placed under the responsibility of a pilot who, together with the quality manager, manages all the quality procedures and forms describing the activities covered by the process, as well as the performance indicators linked to the process. The various processes are reviewed at regular intervals by the company's management during the management review.

The quality assurance system covers the following areas:



The quality management system is audited once a year by the notified body GMED as part of the CE marking of its medical devices. Since 2017, the results of the annual follow-up audits have demonstrated, through the absence of non-conformities, that the quality system has reached solid maturity. CE marking has been assured and maintained since the origin of its certification. Furthermore, in 2018, the Company's quality system was inspected by the FDA in accordance with the requirements of 21 CFR part 820. The outcome was positive, and while only one non-conformity was identified, the corrective action was quickly defined, and this outcome did not call into question the US marketing authorizations. On a day-to-day basis, the Company provides the level of efficiency required to maintain compliance with the requirements to which we are subject, through the involvement of all its employees.

Financial reporting procedures

The Company has set up the following organization to limit financial management risks:

- The Company's General Management, and in particular the Finance Department staff, are committed to improving internal control, and integrate the recommendations of the external auditors and the Audit Committee,
- The Company maintains an in-house separation between the production and supervision of financial statements, and calls in independent experts to assess complex accounting items such as the Research Tax Credit and the valuation of stock options and warrants,
- A chartered accountant prepares the consolidated financial statements in accordance with IFRS,
- The financial and accounting management of the US subsidiary, Mauna Kea Technologies Inc. is subject to regular internal review by the head office accounting team,
- Payroll management in France and the United States is outsourced to specialized independent service providers.

Generally speaking, all the Company's accounting options are defined by the Finance Department, discussed with General Management and the Statutory Auditors, then presented to and debated by the Audit Committee. This ensures that the Company's practices comply fully with French and international accounting standards (IFRS), and that the presentation of its financial statements is consistent.

At the end of the year, a detailed budget for the following year is prepared by the Finance Department and approved by General Management. This budget is presented to the Board of Directors. At the end of each half-year, the accounting teams close the Group's consolidated accounts.

Periodic budget reviews with all operational managers ensure analytical validation of entries and a review of all expenses. At each Board meeting, a report is prepared by the Finance department for the attention of General Management and the Board members. This report is presented and discussed periodically at Board meetings.

2.2.4. Risk management and internal control players

Since the company was founded, General Management has played a leading role in defining and driving forward the internal control system, followed by risk management.

2.2.5. Limitations of risk management and internal control and areas for improvement

The Company is committed to adapting its risk management system to its information system (ERP) and to improving the follow-up of identified action plans.

In the medium term, the Company could extend the functional coverage of its ERP system with additional functions such as production and after-sales service.

2.3. Insurance and coverage

The Company has put in place a policy of covering the main insurable risks with amounts of cover that it considers compatible with the nature of its business. The following policies are currently in force:

Insurance policy / Risks covered	Insurer	Warranty amount
Corporate multi-risk	AXA	
Fire and related risks		Ceiling €12.3 M
Glass breakage		20 000 €

Operating losses		9 607 878 €
Machinery breakdown	AXA	
Cellvizio loaned or leased to a care facility		350 000 €
Operating liability	CHUBB	
All bodily injury, property damage and consequential loss combined, up to a maximum for the following losses:		8 500 000 €
- Inexcusable fault		3 000 000 €
- Material and immaterial damage		3 000 000 €
- Immaterial and non-consecutive damage		300 000 €
- Damage resulting from accidental damage to the environment (excluding sites subject to authorization)		750 000 €
Criminal defense - Recourse		50 000 €
Product liability		
All damage resulting from product liability		10 000 000 €
- Of which non-consecutive consequential loss (not covered in the USA and Canada)		1 000 000 €
- Withdrawal costs incurred by third parties or the Insured outside the USA and/or Canada		500 000 €
- Including withdrawal costs incurred by third parties or the Insured in the USA and/or Canada		500 000 €
Assistance for people on the move	AXA	
All travelers (Company and Subsidiaries)		
Personal accident insurance		50 000 €
Liability insurance guarantee		4 500 000 €
Key man accident	CHUBB	
Risks covered :		
- Accidental death		150,000 € / person
- Total and irreversible loss of autonomy		450,000 € / event
Three people involved: General Manager, VP Finance and Scientific Director		
Employer liability	AIG	500,000 per year
Liability for social violation		
Defense Legal advice		
Directors' liability	AIG	3 000 000 €

All de jure and de facto managers (Company and Subsidiaries)

Transport of goods	GATS	Maximum selling price: €1.5 M / claim
Cyber security	AIG	3 000 000 €

CHAPTER 3: CORPORATE GOVERNANCE REPORT

3.1. Composition of the Board of Directors, Committees and Executive Board

3.1.1. Composition of the Board of Directors and General Management

The Board comprises at least three members, two of whom must be, as far as possible, independent within the meaning of the MiddleNext Code (as defined below). Directors are appointed for a two-year term.

As of the date of this document, the Company's Board of Directors comprises five members. No non-voting director has yet been appointed.

Company name	Function	Date of appointment	End of term of office	Committee
Alexandre LOISEAU	Chairman and Chief Executive Officer	Appointed Director by the AGM of 05/25/2011, reappointed at the AGMs of 07/02/2020, 06/02/2022 and 06/06/2024. Appointed Chairman of the Board of Directors on 10/10/2018 with effect from 10/22/2018 Appointed Chief Executive Officer on 03/10/2022, with concurrent appointment as Chairman of the Board of Directors.	At the close of the Annual General Meeting called to approve the financial statements for the year ending 12/31/2025	
Chris MCFADDEN	Independent Director	Board meeting of 09/04/2014, ratified at the AGM of 11/06/2014 Renewed at the AGMs of 07/02/2020, 06/02/2022 and 06/06/2024	At the close of the Annual General Meeting called to approve the financial statements for the year ending 12/31/2025	Chairman of the Compensation Committee
Molly O'NEIL	Independent Director	Board meeting of 01/25/2018, ratified at the AGM of 05/30/2018 Renewed at the AGMs of 07/02/2020, 06/02/2022 and 06/06/2024	At the close of the Annual General Meeting called to approve the financial statements for the year ending 12/31/2025	Member of the Audit Committee
Claire BIOT	Independent Director	AGM of 02/07/2020, Renewed at the AGMs of 06/02/2022 and 06/06/2024	At the close of the Annual General Meeting called to approve the financial	Member of the Compensation Committee

			statements for the year ending 12/31/2025	
Jacquelien TEN DAM	Independent Director	Board meeting of 02/12/2020, ratified at AGM of 03/06/2021 Renewed at the AGMs of 06/02/2022 and 06/06/2024	At the close of the Annual General Meeting called to approve the financial statements for the year ending 12/31/2025	Chairman of the Audit Committee

Term of office as director

In accordance with the thirty-fourth resolution adopted by the Combined General Meeting of July 2, 2020, the term of office of Directors has been reduced to two years, compared with three years previously. This term is adapted to the specific characteristics of the Company.

By way of exception, and for the sole purpose of implementing or maintaining the staggered terms of office for directors, the Annual General Meeting may appoint one or more directors for a term of one or three years.

Criteria qualifying the independence of directors

Four out of five members of the Board of Directors are considered to be independent within the meaning of the Middlenext Reference Code. Five criteria are used to justify the independence of Board members, which is characterized by the absence of any significant financial, contractual or family relationship likely to affect the independence of judgment:

- not to be an employee or executive officer of the Company or a Group company, and not to have been so during the previous five years;
- not to have a significant business relationship (customer, supplier, competitor, service provider, banker, etc.) with the Company or its Group, and not to have had such a relationship within the last two years;
- not be a reference shareholder of the Company or hold a significant percentage of voting rights;
- have no close family ties with a corporate officer or a reference shareholder;
- not to have been the Company's statutory auditor for the last six years.

The Board of Directors examines the situation of each of its members on a case-by-case basis, with regard to the criteria set out above, in order to ensure that directors are independent.

At its meeting on April 19, 2022, the Board of Directors considered that four of its members - Christopher McFadden, Molly O'Neill, Claire Biot and Jacquelien Ten Dam - met the independence criteria set out in the MiddleNext Code.

Following the appointment of Alexandre Loiseau as CEO on October 3, 2022, he can no longer be a member of the Remuneration Committee. The Board of Directors appointed Claire Biot, an independent director, as a member of the Remuneration Committee on April 5, 2023.

Rules of professional conduct

The internal regulations and code of ethics have been approved by the Board of Directors. These documents set out the rules to be followed by Board members, in accordance with recommendation no. 1 of the MiddleNext Code.

Choice of directors

At the time of each director's appointment or reappointment, information on his or her experience, skills and list of offices held is provided in the Universal Registration Document and at the Annual General Meeting. This information is also posted on the Company's website, in accordance with recommendation 10 of the MiddleNext Code. The appointment or reappointment of each director is the subject of a separate resolution put to the vote of shareholders. The rules applicable in this respect are set out in the Articles of Association and comply with the law.

- **Other current directorships and positions**

Other directorships in progress at December 31, 2024

Corporate officers	Companies	Nature of duties and appointments
Alexandre LOISEAU	Therapixel SA	Chairman of the Board of Directors
	Mdoloris	Member of the Strategic Committee
	Lifen	Member of the Board of Directors
	SeqOne	Member of the Strategic Committee
	Azalea Vision	Member of the Strategic Committee
Chris MCFADDEN	Kohlberg Kravis Roberts	Director
	Reliant Rehabilitation	Director
	Clinical Care Medical Centers	Director
	Gracent	Director
	One Call	Director
Molly O'NEIL	Aegis Ventures	Chief Strategic Partnerships Officer
	Fidari	Director
	Curative Strategy Group	President
Claire BIOT	Dassault Systèmes	VP Healthcare Industry
Jacquelien TEN DAM	Mimetas	Chief Financial Officer

Other offices held outside the Group during the last five years but now closed

Corporate officers	Companies	Nature of duties and appointments
Alexandre LOISEAU	Aqmedia	Director
	InHeart	Observer on the Board of Directors
	i-Virtual	Observer on the Board of Directors
	Gleamer	Director

Christopher MDFADDEN	InnovaTel Telepsychiatry	Director
	ValueCentric	Director
Molly O'NEIL	WorldCare	Director
Claire BIOT	-	-
Jacquelien TEN DAM	-	-

Directors' biographies

ALEXANDRE (SACHA) LOISEAU, PH D.

CHAIRMAN AND CHIEF EXECUTIVE OFFICER

Co-inventor of the Cellvizio® laser confocal endomicroscopy platform, Sacha Loiseau oversaw its development and has raised over 120 million euros to finance Mauna Kea's development since its creation, taking the company public on Euronext in July 2011.

In 2013, he was appointed co-leader of the Plan Industriel sur les Dispositifs Médicaux et Nouveaux Equipements de Santé, then a member of the "Medicine of the Future" steering committee. He helped found the French association of innovative medical technology entrepreneurs, MedTech in France, of which he has been Vice-Chairman since June 2016.

Sacha Loiseau began his career at the Centre National d'Etudes Spatiales (CNES) in Toulouse, the Paris Observatory and NASA's Jet Propulsion Laboratory (JPL) in Pasadena. He is a graduate of the Ecole Polytechnique and holds a PhD in Astrophysics and Space Instrumentation from the Université Paris-Diderot. He is the author of numerous scientific articles, is listed as inventor on seven patents and was the winner of the 2018 Marius Lavet Prize.

CHRISTOPHER D. MCFADDEN

INDEPENDENT DIRECTOR

Prior to joining KKR, Mr. McFadden founded Canyon Healthcare Partners, a private equity firm specializing in healthcare, and was a senior advisor at Athyrium Capital Management.

Previously, he was a partner at Health Evolution Partners and held the position of Senior Financial Analyst at Goldman, Sachs & Co. in New York before heading the healthcare investment activities for Goldman Sachs' Americas Special Situations Group (AmSSG). Mr. McFadden is President of InnovaTel Telepsychiatry and a member of ValueCentric's Board of Directors.

MOLLY O'NEILL

INDEPENDENT DIRECTOR

Over the past thirty years, Molly O'Neill has held various operational and strategic positions at Tenet Healthcare, Ascension, Duke Medicine and Partners Healthcare in Boston. From 2015 to 2017, she was Chief Commercial Officer of Proteus Digital Health.

Molly O'Neill held the position of Vice President Disease Management & Business Development at Gambro Healthcare. Throughout her career, she has demonstrated an exceptional ability to bring clinical value to patients and the healthcare community.

She studied at Virginia Commonwealth University, where she obtained a Bachelor of Science in Journalism and a Master of HealthCare Administration.

CLAIRE BIOT

INDEPENDENT DIRECTOR

Claire Biot is Vice-President of the Healthcare Industry at Dassault Systèmes, where she is responsible for long-term growth strategy in the healthcare and life sciences sector, as well as commercial strategy for the current portfolio of solutions. She has been selected as a "Young Leader" in 2022 by the French-American Foundation.

Before joining Dassault Systèmes, she headed the Agence Générale des Equipements et Produits de Santé (AGEPS), an agency of the Assistance Publique - Hôpitaux de Paris (AP-HP), and was head of the Health Products Office at the French Ministry of Health.

Claire Biot is a graduate of the Ecole Polytechnique and the Corps des Mines. She holds a master's degree in life sciences from Cold Spring Harbor Laboratory, NY, USA, and a doctorate in immunology from the Institut Pasteur.

JACQUELIEN TEN DAM

INDEPENDENT DIRECTOR

Jacquelien Ten Dam is CFO of Mimetas, where she is responsible for the company's development and financing activities. Mimetas develops and markets 3D predictive models.

Before joining Mimetas, she worked at Picnic, one of the Netherlands' most disruptive start-ups, playing a key role in accelerating the company's B2B activities. She led the team providing data and e-commerce consulting to FMCG companies such as PepsiCo, Unilever and AB InBev.

Jacquelien Ten Dam began her career at Kempen & Co, a European investment bank, where she advised companies in the life sciences sector on strategy, mergers and acquisitions.

Jacquelien Ten Dam holds a Master's degree in Biomedical Sciences from Leiden University. She has lived and worked in the USA (UCLA), India (Dr. Reddy's Laboratories) and the Netherlands.

3.1.2. Conflicts of interest in administrative and management bodies

The Chairman and Chief Executive Officer and certain directors who make up the management team are shareholders, directly or indirectly, of the Company and/or holders of financial instruments giving access to the Company's capital. As of the date of this document, there are no agreements with related parties.

To the best of the Company's knowledge, there are no current or potential conflicts of interest between the duties to the Company and the private interests and/or other duties of the members of the administrative, management and executive bodies referred to above.

3.2. Functioning of the Board of Directors, Committees and Executive Management

3.2.1. Company management

The Company is a société anonyme with a Board of Directors.

On October 3, 2022, the Board of Directors decided to combine the functions of Chairman and Chief Executive Officer. Since that date, Alexandre Loiseau has chaired the Board of Directors and represented the Company in its dealings with third parties as Chief Executive Officer.

The Chairman of the Board of Directors is appointed for a term which may not exceed the duration of his directorship.

The terms of office of all directors were renewed at the Annual General Meeting 2024. They will expire at the Annual General Meeting 2026.

During the year ended December 31, 2024, the Board of Directors met 11 times. The average attendance rate was 91%.

3.2.2. Specialized committees

In accordance with recommendation no. 7 of the Middlenext Code, the Board of Directors has decided to set up two specialized committees: the Audit Committee and the Remuneration Committee.

- **Audit Committee**

At its meeting on May 25, 2011, the Board of Directors set up an Audit Committee, whose members adopted the internal rules described below.

Composition and appointment

The Audit Committee comprises, if possible, a minimum of three members appointed by the Board of Directors from among its members. As far as possible, two-thirds of its members should be independent, one of whom should have specific financial or accounting skills, it being understood that all members have minimum financial and accounting skills.

The term of office of Audit Committee members may not exceed the term of their directorship.

At the date of preparation of this Document, the members of the Audit Committee are :

- Jacqueline Ten Dam, Chairman of the Audit Committee and independent director;
- Mrs Molly O'Neill, independent director.

This number of two was deemed sufficient in view of the total number of directors of the Company.

How it works

The Audit Committee's internal rules, adopted on May 25, 2011 after approval by the Board of Directors, set out the Audit Committee's legal missions and organizational procedures, in particular the minimum number of meetings the Committee must hold each year.

It also specifies that the Committee may interview any member of the Company's Board of Directors, and carry out any internal or external audit on any subject it deems relevant to its mission. The Chairman of the Audit Committee

informs the Board of Directors in advance. In particular, the Audit Committee has the right to interview persons involved in the preparation or control of the accounts (Vice-President Finance, Chief Financial Officer). It also has the right to consult the statutory auditors directly, independently and confidentially.

The Audit Committee met twice in fiscal 2024.

Allocations

The Audit Committee is responsible for :

- monitor the financial reporting process;
- monitor the effectiveness of internal control and risk management systems;
- monitoring the statutory audit of the annual and consolidated financial statements by the statutory auditors;
- issue a recommendation on the Statutory Auditors whose appointment is proposed to the Annual General Meeting, and review the terms and conditions of their remuneration;
- monitor the independence of the Statutory Auditors;
- examine the conditions under which derivatives may be used;
- periodically review the status of major disputes; and
- in general, to provide advice and make recommendations in the above-mentioned areas.

Compensation Committee

Composition and appointment

The Remuneration Committee is, if possible, composed of at least two members appointed by the Board of Directors, it being specified that no member of the Board of Directors exercising management functions within the Company may be a member of the Remuneration Committee.

The term of office of members of the Remuneration Committee coincides with their term of office as members of the Board of Directors.

At the date this document was drawn up, the members of the Remuneration Committee were :

- Chris McFadden, Chairman of the Compensation Committee and independent director;
- Claire Biot, independent director.

The Remuneration Committee met twice in fiscal 2024.

Allocations

The Remuneration Committee is responsible for :

- examine the main compensation targets proposed by Executive Management for the Group's non-corporate officers, including bonus share and stock option plans;

- examine the remuneration of non-executive directors, including bonus share and stock option plans, pension and welfare schemes, and benefits in kind;
- make recommendations and proposals to the Board of Directors concerning :
    - the remuneration, pension and welfare schemes, benefits in kind and other pecuniary entitlements, including in the event of retirement, of members of the Board of Directors. The Committee proposes remuneration amounts and structures and, in particular, rules for determining the variable portion, taking into account the Company's strategy, objectives and results, as well as market practices, and
    - bonus share plans, stock option plans and any other similar incentive schemes and, in particular, grants of registered shares to members of the Board of Directors,
- examine the total amount of remuneration paid to Board members (i.e. directors' fees) and the system for allocating them among Board members, as well as the conditions for reimbursing any expenses incurred by Board members;
- prepare and present reports as required by the Board of Directors' internal rules, and ;
- to prepare any other recommendations concerning compensation that may be requested by the Board of Directors.

In general, the Committee provides advice and makes recommendations in the above areas.

3.3. Allocation of free shares and stock options to corporate officers

Stock options granted during the year to each executive director by the issuer and by any Group company						
Name of corporate officer	Plan no. and date	Type of options (purchase or subscription)	Valuation of options in accordance with the method used for the consolidated financial statements	Number of options granted during the year	Exercise price	Exercise period

None

Stock options exercised during the year by each executive director				
Name of corporate officer	Plan no. and date	Number of options exercised during the year	Exercise price	Year of award
None				

Shares granted free of charge during the year to each executive director by the issuer and by any Group company						
Name of corporate officer	Plan no. and date	Number of shares granted during the year	Valuation of shares using the method adopted for the consolidated financial statements	Acquisition date	Availability date	Performance conditions
Alexandre Loiseau, Chairman and CEO	AGM 06/24/2024	1 600 000	335 872	24/06/2025/ 2026/2027	24/06/2027	None

Shares allocated free of charge and made available during the year to each executive director				
Name of corporate officer	Plan no. and date	Number of shares made available during the year	Acquisition conditions	Year of award
Alexandre Loiseau, Chairman and CEO	AGM 05/18/2021	45 000	The definitive vesting period for the AGA plans allocated begins on the date of the Board of Directors' decision to allocate the said shares and ends three (3) years after that date.	2021

3.4. Declaration on corporate governance

The Company refers to the Corporate Governance Code published in September 2016 by Middlenext (MiddleNext Code) and updated in September 2021 insofar as the principles it contains are compatible with the Company's organization, size, resources and shareholder structure.

As of the date of this document, the Company's practices comply with the recommendations of the MiddleNext Code, namely :

Recommendations of the MiddleNext Code	Already adopted	Will be adopted	Will not be adopted	Under consideration
Supervisory power				
R1 Board member ethics	x			
R2 Conflicts of interest	x			
R3 Composition of the Board - Presence of independent members	x			
R4 Information for Board members	x			
R5 Training of Board members (Note1)				x
R6 Organization of Board and Committee meetings	x			
R7 Setting up committees	x			
R8 Setting up a CSR Committee (Note 2)				x
R9 Establishment of Board rules of procedure	x			

R10 Choice of each Board member	x	
R11 Terms of office of Board members	x	
R12 Compensation of Board members	x	
R13 Evaluation of the Board's work	x	
R14 Shareholder relations	x	
Executive power		
R15 Diversity and equity policy (Note 3)		x
R16 Definition and transparency of executive compensation	x	
R17 Preparing management succession	x	
R18 Combination of employment contract and corporate office	x	
R19 Severance pay	x	
R20 Supplementary pension plans	x	
R21 Stock options and free share grants (Note 4)	x	
R22 Review of vigilance points	x	

Note 1: Directors must discuss the most appropriate training plan for the Company's size and resources.

Note 2: Consideration is currently being given to setting up a CSR to complement the existing CSE.

Note 3: Proposals are currently being studied to strengthen the Group's existing diversity and equity policies.

Note 4: The majority of the various financial instruments giving access to capital do not include performance conditions. They are implemented by the Company with a view to building loyalty among beneficiaries, in the absence of any other incentive scheme.

3.5. Related party transactions

3.5.1. Agreements between a corporate officer or a shareholder holding more than 10% of the voting rights and a controlled company

None

3.5.2. Related-party agreements entered into by the Company

Since the previous Statutory Auditors' Special Report, no new regulated agreements have been entered into during the year.

3.5.3. Statutory Auditors' special report on regulated agreements

Mauna Kea Technologies

Annual General Meeting to approve the financial statements for the year ending December 31, 2024

Statutory auditors' special report on regulated agreements

To the Annual General Meeting of Mauna Kea Technologies,

In our capacity as Statutory Auditors of your Company, we hereby report on certain contractual agreements with certain related parties.

Our responsibility is to report to shareholders, based on the information provided, about the main terms and conditions of agreements that have been disclosed to us and the reasons why they are of interest to the Company. We are not required to comment as to whether they are beneficial or appropriate, nor to identify any undisclosed agreements. It is your responsibility, under the terms of article R. 225-31 of the Commercial Code, to evaluate the benefits resulting from these agreements prior to their approval.

In addition, we are required to provide you with the information specified in Article R. 225-31 of the French Commercial Code relating to the performance during the year of agreements already approved by the Shareholders' Meeting.

We performed those procedures which we considered necessary to comply with professional guidance issued by the national auditing body (Compagnie Nationale des Commissaires aux Comptes) relating to this engagement.

Agreements submitted for approval at the Annual General Meeting

We hereby inform you that we have not been advised of any agreements authorized and entered into during the year ended December 31, 2009 that would require the approval of the Annual General Meeting pursuant to Article L. 225-38 of the French Commercial Code.

Agreements already approved by the Annual General Meeting

We hereby inform you that we have not been advised of any agreements previously approved by the Annual General Meeting which remained in force during the year.

Paris-La Défense, April 30, 2025

The Statutory Auditor

ERNST & YOUNG et Autres

Franck Sebag

CHAPTER 4: INFORMATION ON THE COMPANY AND ITS CAPITAL

4.1. Corporate elements

4.1.1. Company name

The Company's name is Mauna Kea Technologies SA.

4.1.2. Company registration number and location

Mauna Kea Technologies was registered with the Registre du Commerce et des Sociétés de Paris on May 3, 2000 under the unique identification number 431 268 028.

4.1.3. Date of incorporation and duration

The Company has been incorporated for a period of 99 years, expiring on May 3, 2099, except in the event of early dissolution or extension.

4.1.4. Company headquarters, legal form, legislation governing its activities

Initially incorporated as a société par actions simplifiée (simplified joint-stock company), the Company was transformed into a société anonyme (joint-stock company) by decision of the General Meeting of Shareholders held on May 25, 2011.

The Company is governed by French law, and its operations are governed primarily by articles L. 225-1 et seq. of the French Commercial Code.

The Company's registered office is located at: 9 rue d'Enghien 75010 Paris. The Company's contact details are as follows:

Telephone: 01 48 24 03 45

Fax: 01 48 24 12 18

Email address : investor@maunakeatech.com

Website: www.maunakeatech.com

4.2. Description of the main statutory provisions

4.2.1. Corporate purpose

The Company's purpose, both in France and abroad, is to:

- the design, development and marketing of scientific instruments, in particular optical instruments for medical imaging, by all existing or future technological means;
- all research activities with a view to developing, registering and exploiting all patents, processes or industrial or intellectual property rights, as well as all operations relating to these patents and rights;
- all directly or indirectly on its own behalf or on behalf of third parties, either alone or with third parties, through the creation of new companies, the contribution of limited partnerships, mergers, alliances, joint ventures or the lease or management of any assets or rights, or otherwise;

- and generally, any financial, commercial, industrial, securities, real estate and financial transactions that may be directly or indirectly related to one of the specified purposes or to any other similar purpose or that may promote the development of the Company's assets.

4.2.2. Devices to delay, defer or prevent a change of control

The Company's bylaws do not contain any provisions for delaying, deferring or preventing a change of control.

4.3. Share capital

4.3.1. Amount of share capital

At December 31, 2024, the Company's share capital stood at €2,709,285.08 divided into 67,732,127 fully paid-up shares with a par value of €0.04 each, including 12,130 preferred shares.

The preference shares, which are not listed on a stock market, break down into 4,915 2016 preference shares (hereinafter "AP2016") and 7,215 2018 preference shares (hereinafter "AP2018").

Main features common to PA 2016 and PA 2018

These shares are issued in connection with the allocation of bonus shares to the Company's officers and/or employees and/or to companies or groupings that are directly or indirectly related to the Company.

They are not listed for trading on the Euronext regulated market in Paris.

They do not carry voting rights at Shareholders' Meetings, although it is specified that the beneficiaries of preference shares will be convened to a special meeting under the conditions set out in Article L. 225-99 of the French Commercial Code to approve any changes to the rights attached to preference shares;

They will not be entitled to dividends or reserves.

In the event of liquidation of the Company, preference shares benefit from the same right to the liquidation bonus as ordinary shares, i.e. a right proportional to the share that their nominal amount represents in the share capital;

They do not have pre-emptive subscription rights for any capital increase or transaction with pre-emptive subscription rights, although their conversion ratio into ordinary shares (see below) will be adjusted to preserve the rights of their beneficiaries.

The specific characteristics of each of the two categories of preference shares relate to the vesting period, the holding period and the conditions for conversion into ordinary shares.

4.3.2. Securities not representing capital

None

4.3.3. Changes in the Company's capital

The table below shows changes in the Company's share capital since January 1, 2022:

Nature of operations	Number of shares issued	Number of shares outstanding	Nominal amount in €	Total share capital in € (in ')	Share premium
At December 31, 2021		**44 595 075**		**1 783 803**	
AGAP conversion	6 400	44 601 475	0,04	1 784 059	536
Capital increase	1 875 000	46 476 475	0,04	1 859 059	774 469
At December 31, 2022		**46 476 475**		**1 859 059**	
AGAP conversion	1 920	46 478 395	0,04	1 859 136	-
Exercise of warrants - Kepler	1 790 000	48 268 395	0,04	1 930 736	640 930
Exercise of warrants - Vester	1 430 000	49 698 395	0,04	1 987 936	679 998
Capital increase	11 911 852	61 610 247	0,04	2 464 410	5 514 376
Transaction costs	-	61 610 247	-	2 464 410	(70 241)
At December 31, 2023		**61 610 247**		**2 464 410**	
AGAP conversion	121 880	61 732 127	0,04	4 875	(4 875)
Exercise of warrants - Vester	6 000 000	67 732 127	0,04	240 000	1 758 068
BSA subscription	-	67 732 127	-	-	24 100
Transaction costs	-	67 732 127	-	-	(62 227)
At December 31, 2024		**67 732 127**		**2 709 285**	

4.3.4. Acquisition by the Company of its own shares

On November 20, 2024, the Company terminated its liquidity contract with Gilbert Dupont, and no longer held any treasury shares at December 31, 2024.

None of the Company's shares are held by a third party on its behalf.

4.3.5. Securities entitling holders to a share of the capital

At December 31, 2024, the securities giving access to the capital are as follows:

Stock option plans

Date of Shareholders' Meeting that granted (or delegated its authority to grant) the stock options	**27-May-15**	**03-May-17**				**05-Oct-18**				**02-Jul-20**			**03-June-21**		**02-June-23**			**06-Jun-24**
Date of allocation decision by the Board of Directors	26-Jul-16	19-Jul-17	28-Feb-18	24-Jul-18	19-Sep-18	12-Nov-18	28-Nov-18	07-Feb-19	19-May-19	22-Jul-20	24-Sep-20	18-May-21	19-Apr-22	Feb-02-23	06-Jul-23	31-Jan-24	05-Apr-24	24-June-24
Maximum number of stock options authorized	400 000	400 000				750 000				500 000			500 000		728 526			
Number of stock options issued	80 000	154 000	300 000	80 000	40 000	600 000	35 000	40 000	75 000	242 500	25 000	232 500	296 000	37 500	309 000	20 000	50 000	1 580 000

Total number of shares that may be subscribed by exercising stock options at the grant date	80 000	154 000	300 000	80 000	40 000	600 000	35 000	40 000	75 000	242 500	25 000	232 500	296 000	37 500	309 000	20 000	50 000	1 580 000
the number of which may be subscribed by corporate officers	-	-	-	-	-	*600 000*	-	-	-	*100 000*	-	*82 000*	-	-	-	-	-	-
Directors concerned (at grant date)	-	-	-	-	-	*600 000*	-	-	-	*100 000*	-	*82 000*	-	-	-	-	-	-
Including Robert Gershon - Chief Executive Officer	-	-	-	-	-	*600 000*	-	-	-	*100 000*	-	*82 000*	-	-	-	-	-	-
Number of non-executive beneficiaries at grant date	2	12	14	2	4	0	4	1	3	8	1	1	11	1	12	1	1	11
Starting date for exercising stock options	26-Jul-17	19-Jul-18	28-Feb-19	24-Jul-19	19-Sept-19	12-Nov-19	28-Nov-19	Feb.7-20	18-May-20	21-July-21	24-Sept-21	18-May-22	19-Apr-23	Feb.2-24	6-Jul-24	31-Jan-24	5-Apr-23	24-June-24
Stock option expiry date	26-July-26	19-Jul-27	28-Feb-28	24-Jul-28	19-Sept-28	12-Nov-28	28-Nov-28	Feb. 7-29	19-May-29	22-Jul-30	24-Sept-30	18-May-31	19-Apr-32	Feb. 2, 33	6-July-33	31-Jan-34	6-Apr-34	June 25-34
Stock option exercise price	1,60 €	2,34 €	3,12 €	2,54 €	2,86 €	2,59 €	2,52 €	2,13 €	1,63 €	1,22 €	1,13 €	1,34 €	0,57 €	0,72 €	0,64 €	0,46 €	0,41 €	0,39 €
Terms and conditions	(1)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)
Number of stock options exercised at balance sheet date (3)	10 000	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cumulative number of stock options forfeited or cancelled at balance sheet date	-	154 000	300 000	80 000	20 000	600 000	30 000	-	75 000	177 500	25 000	184 500	173 000	-	104 000	-	-	280 000
Number of stock options outstanding at the balance sheet date	70 000	-	-	-	20 000	-	5 000	40 000	-	65 000	-	48 000	123 000	37 500	205 000	20 000	50 000	1 300 000
Maximum total number of shares that may be subscribed to by exercising stock options at the balance sheet date, taking into account the exercise conditions.	70 000	-	-	-	20 000	-	5 000	40 000	-	65 000	-	38 400	73 800	7 500	45 400	-	-	-
Number of shares likely to result from the exercise in full of stock options existing at the date of filing of this Document	70 000	-	-	-	20 000	-	5 000	40 000	-	65 000	-	48 000	123 000	37 500	205 000	20 000	50 000	1 300 000

(1) Stock options may be exercised as follows:

- 25% of the S.O. may be exercised from the 1st anniversary date of their allocation;
- A further 25% may be exercised as from the second anniversary date of the grant;
- An additional 25% may be exercised as from the 3rd anniversary date of their allocation;
- The remaining balance, i.e. 25% of the S.O., may be exercised as from the 4th anniversary date of their allocation.

(2) Stock options may be exercised as follows:

- 20% of the S.O. may be exercised from the 1st anniversary date of their allocation;
- A further 40% may be exercised as from the second anniversary date of the grant;
- A further 20% may be exercised as from the 3rd anniversary date of their allocation;

The remaining balance, i.e. 20% of the S.O., may be exercised as from the 4th anniversary date of their allocation.

Stock warrant plans (BSA)

	BSA 2016	BSA 2018	BSA 2018	BSA 2018	BSA 2019	BSA 2019 "BEI" (1)	BSA 2020 "BEI" (2)	BSA 2020	BSA 2021 "Kepler" (3)	BSA 2021	BSA 2021	BSA 2021 "JJDC" (4)	BSA 2021 "Armistice" (5)	BSA 2022	BSA 2023 "Vester	BSA 2023	BSA 2024	BSA 2024	BSA 2024 "Vester
Date of shareholders' meeting that granted (or delegated its authority to grant) the warrants	**04-May-16**	**03-May-17**	**03-May-17**	**05-Oct-18**	**05-Oct-18**	**05-Jul-18**	**02-Jul-20**	**02-Jul-20**	**02-Jul-20**	**02-Jul-20**	**03-June-21**	**03-June-21**	**03-June-21**	**03-June-21**	**02-Jun-22**	**02-June-23**	**02-June-23**	**02-June-23**	**06-Jun-24**
Date of Board of Directors' decision	**26-Jul-16**	**28-Feb-18**	**22-March-18**	**12-Nov-18**	**19-May-19**	**02-Jul-19**	**07-Jul-20**	**22-Jul-20**	**24-March-21**	**18-May-21**	**June 10-21**	**23-Sep-21**	**23-Sep-21**	**19-Apr-22**	**May 24-23**	**06-Jul-23**	**31-Jan-24**	**31-Jan-24**	**23-Jul-24**
Maximum number of warrants authorized	**400 000**	**400 000**	**400 000**	**400 000**	**400 000**	**-**	**-**	**400 000**	**-**	**400 000**	**400 000**	**2 181 818**	**2 363 600**	**400 000**	**-**	**-**	**-**	**-**	**-**
Number of warrants issued	**115 000**	**55 000**	**50 000**	**40 000**	**170 000**	**1 450 000**	**500 000**	**135 000**	**6 000 000**	**244 000**	**61 000**	**2 181 818**	**2 363 600**	**400 000**	**5 500 000**	**320 000**	**50 000**	**720 000**	**5 500 000**
Total number of shares that may initially be subscribed by exercising the warrants	**115 000**	**55 000**	**50 000**	**40 000**	**170 000**	**1 450 000**	**500 000**	**135 000**	**6 000 000**	**244 000**	**61 000**	**-**	**2 363 600**	**400 000**	**5 500 000**	**320 000**	**50 000**	**720 000**	**5 500 000**
the number of which may be subscribed by corporate officers	***115 000***	***55 000***	**-**	***40 000***	***170 000***	**-**	**-**	**135 000**	**-**	***244 000***	***61 000***	**-**	**-**	***400 000***	**-**	***320 000***	**-**	***240 000***	**-**
Including André Michel Ballester	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Including Christopher Mc Fadden	***40 000***	**-**	**-**	***40 000***	***50 000***	**-**	**-**	**45 000**	**-**	***61 000***	**-**	**-**	**-**	***100 000***	**-**	***80 000***	**-**	***240 000***	**-**
Including Jean-Luc Boulnois	***25 000***	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Including Joseph Devivo	***25 000***	**-**	**-**	**-**	***40 000***	**-**	**-**	**-**	**-**	***61 000***	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Including Marie Meynadier	***25 000***	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Including Jennifer Tseng	**-**	***30 000***	**-**	**-**	***40 000***	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Including Molly O'Neill	**-**	***25 000***	**-**	**-**	***40 000***	**-**	**-**	**45 000**	**-**	***61 000 (8)***	**-**	**-**	**-**	***100 000***	**-**	***80 000***	**-**	**-**	**-**
Including Claire Biot	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**45 000**	**-**	***61 000***	**-**	**-**	**-**	***100 000 (8)***	**-**	***80 000***	**-**	**-**	**-**
Including Jacquelien ten Dam	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	***61 000 (8)***	**-**	**-**	***100 000 (8)***	**-**	***80 000***	**-**	**-**	**-**
Number of beneficiaries who are not corporate officers	**-**	**-**	**1**	**-**	**-**	**1**	**1**	**-**	**1**	**-**	**-**	**1**	**1**	**-**	**-**	**-**	**-**	**-**	**1**
Starting date for exercising the warrants	**26-Jul-17**	**Feb-28-19**	**22-March-19**	**12-Nov-19**	**19-May-20**	**03-Jul-28**	**03-Jul-29**	**22-Jul-20**	**24-March-21**	**18-May-21**	**June 10-21**	**23-Sep-21**	**23-Sep-21**	**19-Apr-22**	**31-Dec-24**	**06-Jul-23**	**31-Jan-24**	**24-June-24**	**23-Jul-24**

BSA expiration date	26-Jul-26	28-Feb-28	22-March-28	12-Nov-28	19-May-29	03-Jul-43	03-Jul-34	23-Jul-30	24-March-23	18-May-31	June 10-31	27-Sep-29	27-Sep-29	18-Apr-32	May 24-25	05-Jul-33	Check	June 24-34	23-Jul-26
BSA issue price	0,16 €	0,30 €	0,16 €	0,28 €	0,17 €	0,01 €	0,01 €	0,15 €	-	0,16 €	0,14 €	-	-	0,06 €	-	0,07 €	0,05 €	0,09 €	-
BSA exercise price	1,68 €	3,12 €	2,92 €	2,76 €	1,84 €	1.24	1,24 €	1,30 €	-	1,45 €	1,23 €	1,10 €	1,10 €	0,60 €	-	0,65 €	0,46 €	0,38 €	-
Terms and conditions	(6)	(6)	(6)	(6)	(6)	(1)	(2)	(7)	(3)	(7)	(7)	(4)	(5)	(7)	(9)	(7)	(10)	(10)	(9)
Number of warrants exercised at the balance sheet date	-	-	-	-	-	-	-	-	6 000 000	-	-	-	-	-	5 500 000	-	-	480 000	1 930 000
Cumulative number of warrants forfeited or cancelled at the balance sheet date	25 000	-	50 000	-	-	-	-	-	-	122 000	61 000	-	-	200 000	-	-	-	240 000	-
Number of warrants outstanding at the balance sheet date	90 000	55 000	-	40 000	170 000	1 450 000	500 000	135 000	-	122 000	-	2 181 818	2 363 600	200 000	-	320 000	50 000	240 000	3 570 000
Total number of shares that may be subscribed by exercising the warrants at the balance sheet date, taking into account their terms and conditions	90 000	55 000	-	40 000	170 000	1 450 000	500 000	135 000	-	122 000	-	2 181 818	2 363 600	133 333	-	106 667	-	-	3 570 000
Maximum total number of shares that could result from all the warrants outstanding at the date of this document	90 000	55 000	-	40 000	170 000	1 450 000	500 000	135 000	-	122 000	-	2 181 818	2 363 600	200 000	-	320 000	50 000	240 000	3 570 000

(1) BSA "BEI Tranche 1" : Tranche 1 of the financing granted by the European Investment Bank (see section 10.2.2 of this document) is accompanied by the issue of warrants.

(2) BSA "BEI Tranche 2" Tranche 2 of the financing granted by the European Investment Bank (see section 10.2.2 of this document) is accompanied by the issue of share warrants.

(3) Kepler BSAs resulting from the implementation of a financing line: Under the terms of the agreement, Kepler Cheuvreux has undertaken to subscribe for a maximum of 6,000,000 shares at its own initiative, over a maximum period of 24 months, subject to the contractual conditions being met. The shares will be issued on the basis of a volume-weighted average share price over the two trading days preceding each issue, less a maximum discount of 6.0%. These conditions enable Kepler Cheuvreux to guarantee the subscription of shares over the term of the contract. At December 31, 2022, 1,790,000 warrants remained to be exercised. All were exercised in January 2023. As of the date of this document, no Kepler BSAs remain outstanding.

(4) Johnson & Johnson BSAs resulting from an issue of ABSAs reserved for a certain category of people in September 2021.

(5) BSA Armistice Capital Master Fund Ltd resulting from a reserved issue of ABSA in September 2021.

(6) All warrants have become exercisable

(7) One-third of the warrants may be exercised at the end of a twelve-month period, and then in further tranches of one-third at the end of each year that has elapsed, for a period of two years, and are conditional on attendance at 75% of the Board meetings held in each of the three years.

(8) The planned allotments did not become effective as the warrants were not formally subscribed by their beneficiaries. These warrants were considered as cancelled.

(9) Vester warrants resulting from the implementation of a financing line: Under the terms of the agreement, Vester has undertaken to subscribe for a maximum of 5,500,000 shares at its own initiative, over a maximum period of 24 months, subject to the contractual conditions being met. The shares will be issued on the basis of a volume-weighted average share price over the two trading days preceding each issue, less a maximum discount of 6.0%. These conditions enable Vester to guarantee the subscription of shares over the term of the contract. At June 30, 2023, 150,000 warrants had been exercised.

(10) One-third of the warrants may be exercised at the end of a twelve-month period, and a further one-third at the end of each subsequent year.

Preference shares (AP)

Date of general meeting	04-May-16			05-Oct-18				
Date of Board meeting	26-Jul-16	15-Nov-16	17-Oct-17	10-Oct-18	12-Nov-18	19-Sep-19	20-Nov-19	27-Apr-20
Total number of free shares authorized	8 500			9 000				
Total number of free shares granted	7 765	570	2 340	5 700	1 375	150	400	100
Maximum total number of ordinary shares that may be issued on conversion of bonus shares	776 500	57 000	234 000	570 000	137 500	15 000	40 000	10 000
Total number of shares granted to corporate officers	2 875	-	-	5 700	-	-	-	-
Maximum total number of ordinary shares that may be created by conversion of bonus shares by corporate officers (initially)	*287 500*	-	-	*570 000*	-	-	-	-
Including Alexandre LOISEAU	*160 000*	-	-	*450 000*	-	-	-	-
Including Pierre FOREST	*127 500*	-	-	*0*	-	-	-	-
Including Christophe Lamboeuf	*0*	-	-	*120 000*	-	-	-	-
Number of non-agent beneficiaries	*62*	*4*	*4*	*0*	*21*	*1*	*1*	*1*
Vesting date of preference shares (AP)	26-Jul-17	15-Nov-17	17-Oct-18	10-Oct-19	12-Nov-19	19-Sep-20	20-Nov-20	27-Apr-21
End of share retention period and start of share conversion period	26-Jul-20	15-Nov-20	17-Oct-21	10-Oct-21	12-Nov-21	19-Sep-22	20-Nov-22	27-Apr-23
Terms of conversion into ordinary shares	See below			See below				
Deadline for converting vested share subscription rights into ordinary shares	26-Jan-26	15-May-26	17-Apr-27	10-Oct-26	12-Nov-26	19-Sep-25	20-Nov-25	27-Apr-26
Cumulative number of preference shares cancelled or lapsed at balance sheet date	1 850	350	1 990	-	60	150	-	-
Number of preference shares definitively acquired at the balance sheet date	5 915	220	350	-	-	-	400	100
Number of preference shares already converted into ordinary shares at balance sheet date	1 220	150	200	-	-	-	-	-
Number of ordinary shares resulting from conversion at balance sheet date	37 660	4 950	6 600	-	1 980	-	-	-
Number of preference shares acquired but not yet converted into ordinary shares at balance sheet date	4 695	70	150	5 700	1 015	-	400	100
Of which number of potential ordinary shares that could result from conversion at the balance sheet date	145 575	2 310	3 000	188 100	33 170	-	13 200	2 000
Maximum number of potential ordinary shares that could result from conversion at the balance sheet date	145 575	2 310	3 000	188 100	33 170	-	13 200	2 000

Maximum number of potential ordinary shares that could result from conversion at the balance sheet date	145 575	2 310	3 000	188 100	33 170	-	13 200	2 000

Holders of share subscription warrants may sell their shares or request conversion of their shares into new ordinary or existing shares in the Company, in accordance with the terms and conditions set out in the minutes of the General Meeting that approved their allotment.

Free share plans

Date of general meeting	02-Jul-20		03-June-21		02-June-23	06-Jun-24
Date of Board meeting	22-Jul-20	18-May-21	19-Apr-22	Feb-02-23	06-Jul-23	24-June-24
Total number of free shares authorized	500 000		500 000		971 368	5 176 170
Total number of free shares granted (3)	284 300	215 980	497 000	112 000	936 000	4 612 000
Total number of shares granted to corporate officers	1 500	1 400	48 000	-	300 000	1 600 000
Including Alexandre Loiseau	500	*600*	*48 000*	-	*300 000*	*1 600 000*
Including Christophe Lamboeuf	1 000	*800*	-	-	-	-
Number of non-agent beneficiaries	*58*	*58*	*32*	*1*	*1*	*1*
Vesting date (1)	22-Jul-21	18-May-24	19-Apr-25	02-Feb-26	06-Jul-26	June 24-27
End of retention period (2)	22-Jul-23	(2)	(2)	(2)	(2)	(2)
Number of shares definitively allocated at the balance sheet date	283 050	121 880	-	-	-	-
Cumulative number of shares cancelled or lapsed at balance sheet date	1 250	94 100	206 500	-	91 000	-
Free shares still in the vesting period at balance sheet date	-	-	290 500	112 000	845 000	4 612 000

(1) The vesting period for AGA plans granted in 2021 and 2022 begins on the date of the Board of Directors' decision to grant the shares and ends three (3) years after that date.

(2) The AGAs granted in 2021 and 2022, once definitively acquired, will not be subject to a holding period.

(3) The allocation of AGAs on 18/05/2021 used part of the AGAs withdrawn following employee departures (transfer to the pool) from the 22.07.2020 plan.

The allocation of AGAs on 02/02/2023 comes from AGAs withdrawn following employee departures (remittance to the pool) under the 19.04.2022 plan.

Summary of dilutive instruments

	At December 31, 2024
Summary of potential dilution (in number of shares)	**In the event of exercise/conversion and full vesting**
Number of shares outstanding	**67 732 127**
Maximum number of shares to be issued on exercise of BSPCEs	-
Maximum number of shares to be issued on exercise of stock options	1 983 500
Maximum number of shares to be issued on exercise of warrants	11 487 418
Maximum number of shares to be issued on conversion of bonus shares	387 355

Maximum number of shares to be issued upon vesting of bonus shares	5 859 500
Maximum number of shares that may be issued	**19 717 773**
Number of shares making up the diluted capital	**87 449 900**

4.4. Share ownership

4.4.1. Breakdown of theoretical capital and voting rights at April 15, 2025

To the best of the Company's knowledge, and based on the most recent IPT, the breakdown of capital and voting rights at April 15, 2025 is as follows:

Shareholders	Number of shares	% of capital	Theoretical voting rights	% of theoretical voting rights
Alexandre Loiseau	631 740	0,9%	1 252 880	1,8%
Sub-total Board of Directors	**631 740**	**0,9%**	**1 252 880**	**1,8%**
Telix Pharmaceuticals	11 911 852	17,0%	11 911 852	16,8%
Johnson & Johnson Innovation - JJDC Inc	10 811 687	15,5%	10 811 687	15,2%
Other registered shares	557 210	0,8%	1 013 544	1,4%
Other floating	46 019 638	65,8%	46 019 638	64,8%
Total number of shares outstanding	**69 932 127**	**100,0%**	**71 009 568**	**100,0%**

To the best of the Company's knowledge, no shareholders are acting in concert.

The Company is not aware of any other shareholder having exceeded 3% of the capital or voting rights (or any multiple thereof).

4.4.2. Significant shareholders not represented on the Board of Directors

At April 15, 2025, Telix Pharmaceuticals and Johnson & Johnson Innovation - JJDC, Inc. held 17.0% and 15.5% of the capital respectively, and were not represented on the Company's Board of Directors.

4.4.3. Voting rights of major shareholders

At the Annual General Meeting of May 25, 2011, shareholders approved the introduction of double voting rights for all shares held in registered form for at least three years in the name of the same shareholder.

Voting rights attached to shares are proportional to the percentage of capital they represent, and each share carries at least one vote.

However, in accordance with Article 9 of the Articles of Association and the provisions of the French Commercial Code, all fully paid-up shares registered in the name of the same shareholder for at least three years carry double voting rights in relation to the percentage of share capital they represent.

As of April 15, 2025, the following shareholders have double voting rights:

Shareholders	Number of shares	Theoretical voting rights
Telix Pharmaceuticals	11 911 852	11 911 852
Alexandre Loiseau	631 740	1 252 880

Other	557 210	1 013 544
Total shares with double voting rights	**13 242 159**	**14 277 601**

Statutory restrictions on the exercise of voting rights and transfers of shares, or clauses brought to the Company's attention pursuant to Article L. 233-11 of the French Commercial Code.

None.

Direct or indirect shareholdings in the Company's capital of which it is aware pursuant to Articles L. 233-7 and L. 233-12 of the French Commercial Code.

In accordance with the provisions of Article L.225-197-1 of the French Commercial Code, senior executives are required to hold 10% of the shares allotted by the Board of Directors in registered form until they cease to hold office, up to a maximum number of shares whose aggregate value does not exceed one year's gross compensation.

4.4.4. Control of the Company

As of the date of this document, no single shareholder holds a percentage that could give rise to a presumption of control of the Company within the meaning of Article L. 233-3 of the French Commercial Code.

The Company has therefore not had to implement any measures to ensure that this control is not exercised in an abusive manner.

To the best of the Company's knowledge, no shareholders are acting in concert.

4.4.5. Statement of pledges

The Company is not aware of any shareholders who have pledged their shares.

Concerning pledges granted by the Company: Please refer to section 5.3.5 "Other information" of this document - Paragraph Financial commitments.

4.4.6. Related party transactions

The regulated agreements in force to date are mentioned in the special reports of the Statutory Auditors presented below.

Intercompany transactions

There are three main types of intra-group flows.

a) Commercial flows: As all equipment sold worldwide is manufactured in France, the Company has signed an exclusive distribution agreement with its American subsidiary, granting the latter exclusive territorial rights to distribute the Group's products (equipment and consumables) in the United States and Canada.

In 2024, the Company invoiced its subsidiary €1,441,000 for the sale of Cellvizio products.

b) Service re-invoicing: A service agreement was signed on January 1, 2022 between the Company and its US subsidiary for an initial term of five years, renewable annually thereafter. The agreement provides for the Company to assist Mauna Kea Technologies Inc. in five areas:

- subsidiary management ;
- accounting and financial assistance (drawing up and monitoring budgets, implementing control tools, advising on relations with banks, tax assistance, etc.);
- sales assistance (definition of strategic plans, marketing plans, organization of sales events, sales administration, assistance in managing product regulations, etc.);
- technical assistance (sales support, maintenance and quality control improvements) ;

- assistance with human resources management (recruitment of key staff, training, social regulations, dedicated IT tools, HR policy, etc.).

The agreement stipulates that the costs inherent in the assistance services actually rendered will be invoiced by the Company to its subsidiary at actual cost, to which a 5% margin will be applied. From the amounts due will be deducted the costs of any services that the subsidiary could have provided to the Company in these same areas.

In fiscal 2024, the Company and its subsidiary invoiced each other €659,000 and $307,000 respectively.

c) Financial flows: A Group cash management agreement was signed on October 11, 2005. Advances made by either of the two Group entities are remunerated at the legal interest rate in France.

In 2024, the Company billed its subsidiary €3,828,000 in interest.

Related party transactions

See section 3.5. of this document.

4.5. Shareholder participation at the Annual General Meeting

Shareholders' meetings (article 19 of the bylaws)

Shareholders' Meetings are convened and held under the conditions laid down by law.

If the Company wishes to convene a meeting by electronic means instead of by post, it must first obtain the agreement of the shareholders concerned, who must provide their e-mail address.

Meetings are held at the registered office or at any other location specified in the notice of meeting.

The right to attend Shareholders' Meetings is governed by the laws and regulations in force, and is subject to the shares being recorded in the name of the shareholder or the intermediary registered on the shareholder's behalf by midnight (Paris time) on the second business day prior to the Meeting, either in the registered share accounts held by the Company, or in the bearer share accounts held by the authorized intermediary.

Shareholders who are unable to attend the Meeting in person may choose one of the following three options:

- grant a power of attorney under the conditions authorized by law and regulations,
- vote by mail, or
- send a power of attorney to the Company without indicating a mandate,

in accordance with the law and regulations.

Forms giving no voting direction or expressing an abstention are not considered as votes cast.

The Board of Directors may organize, in accordance with applicable laws and regulations, the participation and voting of shareholders at Shareholders' Meetings by any means of telecommunication enabling their identification, in addition to or to the exclusion of any other means of participation. If the Board of Directors decides to exercise this option for a given Shareholders' Meeting, this decision is mentioned in the notice of meeting. However, for Extraordinary General Meetings only, one or more shareholders representing at least 25% of the share capital may object to the exclusive use of a means of telecommunication enabling them to be identified. This right of objection is exercised after publication of the notice of meeting, in accordance with the applicable regulatory provisions.

Shareholders taking part in Shareholders' Meetings by any of the other means of telecommunication referred to above that enable them to be identified are deemed to be present for the purposes of calculating quorum and majority.

Shareholders who use the electronic voting form provided on the website set up by the meeting's centralizing agent are deemed to be present. The electronic form can be entered and signed directly on this site, using a login code and password. Proxies or votes cast before the meeting by this electronic means, as well as the acknowledgement of receipt given, will be considered as non-revocable and binding writings.

Meetings are chaired by the Chairman of the Board of Directors or, in his absence, by the Chief Executive Officer, by a Chief Operating Officer if he is a director, or by a director specially appointed for this purpose by the Board. Failing this, the Meeting elects its own Chairman.

The duties of scrutineer are carried out by the two members of the Meeting present and accepting these duties, who have the greatest number of votes. The officers appoint the secretary, who may be chosen from outside the shareholder body.

An attendance sheet is kept in accordance with the law.

The Ordinary General Meeting convened on first call is valid only if the shareholders present or represented own at least one-fifth of the shares with voting rights. Ordinary General Meetings convened on second call are valid regardless of the number of shareholders present or represented.

Resolutions at the Annual General Meeting are passed by a majority of the votes cast by the shareholders present or represented. The votes cast do not include those attached to shares for which the shareholder did not take part in the vote, abstained or voted blank or invalid.

The Extraordinary General Meeting convened on first call is valid only if the shareholders present or represented own at least a quarter of the shares with voting rights. Extraordinary General Meetings convened on second call are valid only if the shareholders present or represented own at least one-fifth of the shares with voting rights.

Resolutions at the Extraordinary General Meeting require a two-thirds majority of the votes cast by shareholders present or represented. The votes cast do not include those attached to shares for which the shareholder did not take part in the vote, abstained or voted blank or invalid.

Copies or extracts of the minutes of the General Meeting are validly certified by the Chairman of the Board of Directors, by a director acting as Chief Executive Officer or by the secretary of the General Meeting.

Powers of Shareholders' Meetings (Article 19 of the Bylaws)

Ordinary and Extraordinary Shareholders' Meetings exercise their respective powers in accordance with the law.

CHAPTER 5: FINANCIAL AND ACCOUNTING INFORMATION

5.1. Financial information on results and financial position

Readers are invited to read the following information on the Group's financial position and results of operations in conjunction with the Group's IFRS consolidated financial statements for the year ended December 31, 2024, and to refer to the notes to the 2024 consolidated financial statements in this document.

5.1.1. Business review

Sustained Pay-Per-Use (PPU) activity in the United States

In 2024, PPU activity remained buoyant, with quarterly volumes comparable to those of 2023, averaging nearly 1,000 procedures per quarter, confirming the growth seen in relation to 2022 and previous years.

The impact of this dynamic was lessened by a negative price effect resulting from lower Medicare reimbursement rates by CMS (*Centers for Medicare & Medicaid Services*). This reduction was the result of incorrect cost declarations by hospitals, which had an impact on the rates charged by ambulatory surgery centers (ASCs). The Company is working closely with CMS and the hospitals to correct these errors and return to the original reimbursement level.

PPUs billed	T1 2023	T2 2023	T3 2023	T4 2023	T1 2024	T2 2024	T3 2024	T4 2024
Volume of PPU procedures	693	1 013	887	1 361	1 017	1 062	888	831

Launch of CellTolerance

In the second half of 2024, the Group launched *CellTolerance*, a new brand and multidisciplinary program dedicated to the treatment of food intolerances, based on a B2B2C "cash-pay" business model. This strategic initiative enables the Group to penetrate an unprecedented market, estimated at nearly 7 billion euros a year, while freeing itself from the constraints of reimbursement.

A pilot center was inaugurated in the fourth quarter of 2024 to validate the operating model and accelerate deployment from 2025.

This activity generated sales of around €0.5 million in 2024.

JV with Tasly

In 2024, commercial activity in China via the joint venture remained limited, as the subsidiary's operational launch was delayed due to the takeover of Tasly Pharmaceuticals by China Resources, a state-owned pharmaceutical company, announced in August 2024. This acquisition led to a temporary suspension of operations during the transaction finalization period, which is expected to continue until the end of the first quarter of 2025.

By 2023, the Group had recorded revenues of $4.7 million (€4.3 million), comprising an initial payment of $6.5 million (€5.8 million) spread over 3 years and an additional payment of $2.5 million (€2.3 million) for technology transfer.

In 2024, the Group recorded 2 million euros corresponding to the deferral of the initial payment over the second year of the contract.

5.1.2. Analysis of consolidated income

STATEMENT OF COMPREHENSIVE INCOME

(Amounts in thousands of euros)

	31/12/2024	31/12/2023
Operating income		
Sales figures	7 655	10 480
Other income	760	547
Total income	**8 415**	**11 027**
Operating expenses		
Cost of sales	(1 215)	(2 118)
Gross margin	*78%*	*66%*
Research & Development	(3 550)	(3 860)
Sales & Marketing	(4 705)	(5 618)
Overheads	(4 445)	(5 004)
Share-based payment	(549)	(113)
Total expenses	**(14 464)**	**(16 713)**
Current operating income	**(6 049)**	**(5 686)**
Non-current operating income	(34)	6 918
Operating income	**(6 083)**	**1 231**
Share of profit of associates	**(1 683)**	**(2 528)**
Financial income	458	953
Financial expenses	(3 096)	(2 909)
Profit before tax	**(10 404)**	**(3 253)**
Income tax expense	0	(475)
Net income	**(10 404)**	**(3 727)**

- **Sales and other operating revenues**

In 2024, total sales will amount to 7.7 million euros, compared with 10.5 million euros in 2023. This decrease is mainly due to the absence of orders for systems and probes from the joint venture in China, representing a shortfall of around 2 million euros linked to contractual commitments for minimum orders. It was also due to a drop in performance in the United States, particularly in the Pay-Per-Use business, impacted by a 35% to 40% price cut in ambulatory surgery centers. This decline follows the reduction in Medicare reimbursement levels decided by the CMS (Centers for Medicare & Medicaid Services) at the beginning of 2024.

This downward revision of tariffs is due to erroneous cost statements submitted by certain hospitals, which had a negative impact on the reimbursement levels applied to ambulatory surgery centers (ASCs). The Group has made considerable efforts to have these errors corrected, and to obtain a favorable revision of reimbursement levels as quickly as possible.

Sales by revenue category

(Amounts in thousands of euros)	2024	2023	Variation
Systems	1 301	1 171	11%
Consumables	2 917	3 913	-25%
Services	1 429	1 134	26%
Licensing revenues	2 008	4 262	-53%
Sales figures	**7 655**	**10 480**	-27%

Sales by region

(Amounts in thousands of euros)	2024	2023	Variation
United States	3 456	4 493	-23%
Europe and the rest of the world	1 983	1 622	22%
Asia-Pacific	2 216	4 365	-49%
Sales figures	**7 655**	**10 480**	-27%

In the United States, pay-per-use (PPU) business remained buoyant, with quarterly volumes comparable to those of 2023.

This stability was offset by :

- The negative price effect resulting from the reduction in Medicare reimbursement rates by CMS. This reduction resulted from misreporting of costs by hospitals, which had an impact on the rates charged by ambulatory surgery centers (ASCs);
- System sales volume lower than in 2023.

In Asia-Pacific, the decrease in sales reflects a high base in 2023 with the receipt of non-recurring income from the JV technology transfer.

Other income

Other income comprises the Research Tax Credit, which stands at 753 K€ in 2024, up on 2023 due to the increase in working time allocated to the Group's research and development projects, particularly in AI, over the period.

Operating expenses

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Cost of sales	(1 215)	(2 118)
Gross margin (excluding licenses)	78%	*66%*
Research & Development	(3 550)	(3 860)
Sales & Marketing	(4 705)	(5 618)
Overheads	(4 445)	(5 004)
Share-based payment	(549)	(113)
Total expenses	**(14 464)**	**(16 713)**
Current operating income	**(6 049)**	**(5 686)**
Neutralization of net changes in depreciation, amortization and impairment	1 596	**1 810**
EBITDA	**(4 453)**	**(3 876)**

Cost of sales and gross margin

Cost of sales came to 1,215 K€ for 2024, compared with 2,118 K€ for 2023, reflecting the fall in sales over the period.

Gross margin stood at 78% of sales, up 12 points on 2023, mainly due to the end of the depreciation period for older-generation systems used as part of SSPs or leases, and an exceptional accounting restatement.

Research and development expenditure

In 2024, Research and Development expenditure amounted to €3,550,000, compared with €3,860,000 in 2023, down slightly over the period due to changes in headcount.

Sales and marketing expenses

Sales and marketing expenses mainly relate to sales efforts in the United States. Their decrease in 2024 is explained by the reduction of the US sales team from 8 to 5 people at the end of the year, following several voluntary departures.

General and administrative expenses

Overheads fell by 11% to €4,445,000 in 2024. This decrease reflects the significant cost-cutting efforts implemented by the Group over the period, despite a one-off increase in legal fees linked to negotiations on bank loan maturities, in particular with the European Investment Bank (EIB). It also reflects the absence of variable compensation paid to members of the Executive Committee for the year, and a voluntary reduction in the salary of the Chairman and Chief Executive Officer.

Share-based payments

To encourage Group employees to contribute to its performance and align their interests with those of shareholders, the Group has continued to grant stock options and bonus shares to its employees. The total cost of these grants in 2024 amounted to €549,000, compared with €113,000 in 2023, a year marked by significant cancellations of instruments, booked in 2023, following the departure of employees in the United States as part of the Group's strategic reorientation.

EBITDA

EBITDA will be -4,453 K€ in 2024, compared with -3,876 K€ in 2023. The implementation of cost-cutting plans and the reduction of operating expenses have enabled the Company to offset almost 80% of the decline in sales over the period.

- **Net income formation**

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Current operating income	**(6 049)**	**(5 686)**
Non-current operating income	(34)	6 918
Operating income	**(6 083)**	**1 231**
Share of profit of associates	(1 683)	(2 528)
Financial income	458	953
Financial expenses	(3 096)	(2 909)
Profit before tax	**(10 404)**	**(3 253)**
Income tax expense	-	(475)
Net income	**(10 404)**	**(3 727)**

Non-current operating income

Non-current operating income for 2023 corresponded essentially to the Group's share of the capital gain on the sale of patents to the Tasly Mauna Kea Medical Engineering Technology Co. Ltd joint venture, less Cenponts' fees in connection with the creation of this joint venture.

Share of companies accounted for by the equity method

This item reflects the Group's share in the profits of the joint venture Tasly Mauna Kea Medical Engineering Technology Co. Ltd.

Financial income and expense

Financial income amounted to 458 K€ in 2024, compared with 953 K€ in 2023, due to lower foreign exchange gains and interest on cash and cash equivalents, as a result of the decline in the latter over the period.

Financial expenses will reach 3,096 K€ in 2024, compared with 2,411 K€ in 2023. They are mainly non-cash, and their increase is explained by the revaluation of the effective interest rate on the EIB loan, following the restructuring carried out in April 2024 (see note 1.14 in chapter 5.2).

Income tax expense

The tax charge recorded in 2023 resulted from a positive tax result for the year, linked to the exceptional profit generated by the transfer of patents to the JV in China.

5.1.3. Analysis of the consolidated balance sheet

- **Non-current assets**

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Intangible assets	1 472	2 013
Property, plant and equipment	509	621
Right of use	1 082	543
Investments in associates	3 923	5 183
Non-current financial assets	222	250
Total non-current assets	**7 208**	**8 611**

Non-current assets amounted to 7,208 K€ at December 31, 2024, compared with 8,611 K€ at December 31, 2023.

Equity-accounted investments are the main component, and correspond to the Group's 49% interest in the joint venture Tasly Mauna Kea Medical Engineering Technology Co. Ltd. The decrease in the value of these investments is due to the loss for the period and the impact of exchange rates.

Net intangible assets include development costs of €850,000, patents, licenses and trademarks for a net amount of €591,000, with the balance relating to software. The decrease compared with 2023 is mainly due to amortization booked over the period.

Non-current assets also include the right of use (IFRS 16) relating to property leases in France and the United States, which increased over the period due to adjustments made as part of this restatement.

Current assets

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Inventories and work-in-progress	4 261	2 863
Accounts receivable	1 332	1 320
Other current assets	1 427	2 139
Current financial assets	-	36
Cash and cash equivalents	2 017	7 969
Total current assets	**9 037**	**14 327**

At December 31, 2024, current assets totaled €9,037,000, compared with €14,327,000 a year earlier. This decrease is mainly due to the fall in cash and cash equivalents, as the Group benefited at the end of 2023 from a €6 million capital increase subscribed by Telix Pharmaceuticals International Pty. Ltd.

Inventories and work-in-progress increased by €1,398k in 2024, due to an increase in production over the period and, at the same time, the postponement of several system sales in the United States and the absence of system sales to the JV in China.

Other current assets fell by 712 K€, reflecting the repayment in 2024 of research tax credits for the years 2022 and 2023.

Shareholders' equity

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Share capital	2 709	2 464
Additional paid-in capital	9 465	7 622
Reserves	(25 982)	(22 800)
Translation reserves	(177)	(836)
Consolidated net income, Group share	(10 404)	(3 727)
Total shareholders' equity	**(24 389)**	**(17 276)**

The net change in shareholders' equity is mainly due to the net loss for the period.

Non-current liabilities

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Long-term debt	7 158	13 402

Non-current provisions	109	72
Total non-current liabilities	**7 267**	**13 474**

Long-term debt at December 31, 2024 comprises :

- State-guaranteed loans due in more than one year (PGE) for €1.7 million;
- The conditional advance granted by BPI for €4.4 million, including capitalized interest;
- The liability recognized following the application of IFRS 16, relating to lease contracts, for €0.8 million.

Non-current provisions relate to pension commitments.

Current liabilities

(Amounts in thousands of euros)	**31/12/2024**	**31/12/2023**
Short-term borrowings and financial debts	24 773	16 371
Current provisions	38	38
Trade accounts payable	3 274	2 774
Other current liabilities	5 282	7 557
Total current liabilities	**33 367**	**26 740**

Short-term borrowings at December 31, 2024 comprise :

- Tranches 1 and 2 of the loan taken out with the European Investment Bank (EIB) amount to €14.4 million and €7.9 million respectively. Following the restructuring of the loan, a new EIR has been recalculated, taking into account the new principal and interest repayment schedules, as well as additional royalties (see note 1.14 to the financial statements).
  At December 31, 2024, as the Group was unable to comply with one of the conditions stipulated in the contract, the entire debt was reclassified as short-term in view of its potential payability (see note 24 to the financial statements). The safeguard decree dated March 31, 2025 (see note 11 to the financial statements) has suspended this liability.
- The current portion of PGEs for €0.6 million;
- The debt related to the mobilization of the Research Tax Credit for 2024, i.e. 0.5 M€;
- The current portion of the liability recognized following the application of IFRS 16 to lease contracts for €0.3 million.

The increase in trade payables is mainly due to longer payment terms.

Other current liabilities include (i) amounts due to employees, social security bodies and the French government, and (ii) deferred income. Deferred income mainly relates to the licensing agreement with Tasly Pharmaceutical, for which the Company received €6.5 million, recognized on a straight-line basis in sales over 36 months. In fiscal 2024, €2 million was recognized in sales in this respect.

5.1.4. Consolidated cash flow and financing

- **Analysis of cash flow statement**

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Net cash from operating activities (A)	**(6 324)**	**(753)**
Of which cash flow	**(4 038)**	**(5 905)**
Of which change in WCR related to operations	(2 569)	5 152
Net cash used in investing activities (B)	**(149)**	**(354)**
Net cash used in financing activities (C)	**483**	**5 959**
Impact of changes in exchange rates (D)	38	(19)
Net change in cash and cash equivalents (A) + (B) + (C) + (D)	**(5 952)**	**4 832**
Opening cash position	7 969	3 137
Closing cash position	2 017	7 969

Cash flow from operating activities

The Company's cash flow will increase by €1,867,000 in 2024, driven in particular by the reduction in operating expenses resulting from the cost-cutting plans implemented during the year.

The change in working capital requirement (WCR) is negative in 2024, due to the increase in systems inventory. By way of comparison, working capital showed a favorable trend in 2023, driven by the receipt of receivables related to the Tasly licensing agreement, amounting to $6,500,000.

- **Cash flow from investing activities**

Net cash consumption linked to investment activities amounted to 149 K€ in 2024 compared with 354 K€ in 2023, as the number of systems placed under the PPUs in the United States was lower in 2024.

- **Cash flows from financing activities**

Cash flow from financing activities will amount to 483 K€ in 2024, compared with 5,959 K€ in 2023.

In 2024, these flows mainly reflect :

(i) cash receipts of €2 million under the financing facilities set up with Vester ;

(ii) pre-financing of the 2024 research tax credit (crédit d'impôt recherche - CIR) in the amount of €0.5 million;

(iii) offset by cash outflows linked to loan repayments in the amount of €1 million, and interest payments, mainly on debt contracted with the EIB.

As a reminder, financing flows for 2023 were strongly positive thanks to the €6m capital increase reserved for Telix Pharmaceuticals.

Capital financing

Type of operation	Capital (in K€)	Additional paid-in capital (in K€)	Number of shares issued	Number of shares outstanding
At December 31, 2021	**1 784**	**111 920**		**44 595**
AGAP conversion	-	1	6	44 601
BSA conversion (Kepler)	75	774	1 875	46 476
BSA subscription	-	12	-	46 476
Allocation of retained earnings	-	(111 920)	-	46 476
Total at December 31, 2022	**1 859**	**787**	**1 881**	**46 476**
AGAP conversion	-	-	2	46 478
BSA conversion (Kepler)	72	641	1 790	48 268
BSA conversion (Vester)	57	680	1 430	49 698
BSA subscription	-	23	-	49 698
Capital increase	476	5 514	11 912	61 610
Transaction costs	-	(70)	-	61 610
Total at December 31, 2023 (published)	**2 464**	**7 575**	**15 134**	**61 610**
Discount neutralization		47	-	61 610
Total at December 31, 2023	**2 464**	**7 622**	**15 134**	**61 610**
AGAP conversion	5	(5)	122	61 732
BSA conversion (Vester)	240	1 758	6 000	67 732
BSA subscription	-	24	-	67 732
Transaction costs	-	(62)	-	67 732
Discount neutralization	-	128	-	67 732
Total at December 31, 2024	**2 709**	**9 465**	**21 256**	**67 732**

Since its creation and until December 31, 2024, the Company has financed itself mainly through capital increases. The following capital increases have been carried out since 2021:

- Capital increase reserved for Johnson & Johnson Innovation - JJDC, Inc. and the Armistice Capital fund in 2021 for gross proceeds of €12.5 million through the issue of 11,363,545 new ordinary shares with a par value of €0.04 at an issue price of €1.1;

- Equity financing facility with Kepler Cheuvreux via the exercise of 6,000,000 warrants between 2021 and 2023 for gross proceeds of €3,915,000;
- Equity financing line with Vester Finance via the exercise of 1,430,000 warrants in 2023 for gross proceeds of €737,000;
- Capital increase reserved for Telix Pharmaceuticals in 2023 for gross proceeds of €6.0 million, through the issue of 11,911,852 new ordinary shares with a par value of €0.04 at an issue price of €0.5;
- Equity financing line with Vester Finance via the exercise of 6,000,000 warrants in 2024 for gross proceeds of €1,998,000.

Financing through loans and repayable advances

Since its creation, Mauna Kea Technologies has obtained several financing grants, including :

- A loan from IFP Partners in several tranches disbursed in 2017 and 2019 for a total gross amount of 9 million euros, fully repaid in 2019;
- A loan from the European Investment Bank in several tranches to be disbursed in 2019 and 2020 for a total gross amount of 17.5 million euros;
- A repayable advance from BPIFrance as part of the PERSEE project, disbursed in several installments between 2010 and 2021 for a total amount of 3.4 million euros;
- A state-guaranteed loan (PGE) granted in 2020 by BNP Paribas and BPIFrance for 4 million euros, repayment of which began in 2022.

Movements in borrowings and repayable advances during fiscal 2024 are summarized in the table below:

CHANGE IN NON-CURRENT BORROWINGS

(Amounts in thousands of euros)	31/12/2023	Increase.	Decrease	Interest / Discounting	Reclassification from non-current to current	Other	31/12/2024
Conditional advances BPI (ex Oseo)	4 308	-	-	106	-	-	4 414
Lease liability IFRS 16	149	1 184	-	-	(508)	1	826
PGE loan	1 706	95	-	(69)	(16)	-	1 716
EIB loan	7 097	-	(7 097)	-	-	-	-
BSA BEI	28	-	-	13	53	-	94
BSA Vester	98	-	-	(23)	-	-	75
Other	15	5	-	-	12	-	32
Total non-current borrowings	**13 401**	**1 284**	**(7 097)**	**27**	**(459)**	**1**	**7 157**

CHANGE IN CURRENT FINANCIAL DEBT

(Amounts in thousands of euros)	31/12/2023	Increase.	Decrease	Interest / Discounting	Reclassification from non-current to current	Other	31/12/2024
Lease liability IFRS 16	381	-	(557)	-	508	10	342
PGE loan	993	-	(420)	26	4	-	603
EIB loan	14 317	22 098	(15 113)	2 055	-	-	23 357
BSA BEI	53	-	-	-	(53)	-	-
Mobilization CIR / CII	627	471	(627)	-	-	-	471
Total current financial debt	**16 371**	**22 569**	**(16 717)**	**2 081**	**459**	**10**	**24 773**

(See note 11 to the consolidated financial statements).

Research tax credit financing

The Company benefits from the provisions of articles 244 quater B and 49 septies F of the French General Tax Code relating to research tax credits. This credit is recognized in other income.

Movements in the Research Tax Credit during fiscal 2024 are summarized in the table below:

(Amounts in thousands of euros)	31/12/2023	Operating income	Payment received	Other	31/12/2024
Research tax credit	1 171	753	(1 171)		753

The CIRs for 2022 and 2023 were repaid in 2024, but only the 2023 CIR was cashed in during the year, since the 2022 CIR had been pre-financed by the Predirec Innovation 3 fund.

The 2024 CIR amounts to 753 K€ and has been pre-financed in the amount of 471 K€.

(See notes 1.14, 8.2 and 11.4 to the consolidated financial statements).

5.1.5. Recent events and outlook

- **Subsequent events at December 31, 2024**

Artificial intelligence (AI) patents

On January 20, 2025, the Group announced that it had been granted a new US patent for an artificial intelligence technology for enhancing confocal laser endomicroscopy (CLE), significantly strengthening its intellectual property. This new technology represents an innovative solution for AI-assisted real-time interfacing of Cellvizio and physicians, while taking into account their cognitive constraints and user experience data specific to diagnostic procedures. This cutting-edge technology aims to improve the user experience and efficiency of AI-integrated endomicroscopy in clinical settings.

This new patent, named "AURA", complements Mauna Kea's "EVA" (Endomicroscopy Virtual Assistant) portfolio, which already includes 12 patents dedicated to innovative architectures and workflows for AI-based multi-step image processing. The combined capabilities of AURA and EVA will significantly improve the ergonomics, interface and efficiency of Mauna Kea's Cellvizio CLE technology, enhancing the adoption and use of Cellvizio in various medical specialties. This achievement is part of Mauna Kea's recent partnership with UK-based V7, a leader in artificial

intelligence (AI) and data labeling, announced in March 2024, the aim of which is to build large, annotated, high-quality endomicroscopy datasets.

Backup procedure

On March 31, 2025, the Paris Business Court granted the Company's request to open safeguard proceedings, in view of its financial situation.

This is part of a proactive commitment by Mauna Kea Technologies' management to create the most favorable conditions for the success of its transformation, and to maximize the unique value of its technology. During this observation period, the Company will continue to operate under the legal protection afforded by the procedure, while benefiting from more favorable conditions to conclude its strategic and financial negotiations. As such, the Company's pre-proceeding liabilities are frozen for the duration of the proceedings.

Against this backdrop, Mauna Kea Technologies intends to finalize ongoing discussions with several strategic partners and long-term financial investors.

At the same time, the Company will enter into negotiations with its creditors with a view to achieving a balanced financial structure, reducing its debt and securing the liquidity needed to enable it to deploy its strategic plan towards profitability.

In this context, the Paris Business Court has appointed SELARL THEVENOT PARTNERS, in the person of Maître Aurélia Perdereau, as administrator with supervisory responsibility for Mauna Kea Technologies, and SCP BTSG, in the person of Maître Stéphane Gorrias, as judicial representative.

Exclusive negotiation for a license agreement

Also on March 31, 2025, the Company officially entered into exclusive negotiations for a licensing agreement for its Cellvizio technology in a broad therapeutic area, with a major player in the sector.

As part of its broader strategic process initiated at the end of 2024, the Company is also pursuing several licensing discussions covering other therapeutic areas, testifying to the growing interest in Cellvizio technology within multiple medical specialties.

At the same time, and following the opening of the safeguard procedure announced on March 31, 2025, Mauna Kea Technologies intends to intensify its discussions concerning financing options with long-term investors, in order to consolidate its financial position and support its future growth.

- **Main trends**

Business remained brisk at the start of the year, particularly in the United States, despite a reduced sales team. Several systems were sold over the period. Pay-Per-Use business continues the trend observed at the end of 2024.

The CellTolerance business is also expanding rapidly, with the opening of several new centers since the beginning of the year, both in the United States and in Germany. By way of illustration, one of the recently opened centers in Stanford is rapidly gaining momentum: the number of procedures performed there is increasing month by month, already exceeding 70 in the space of four months.

- **Profit forecasts or estimates**

In 2025, Mauna Kea Technologies aims to complete several value-creating initiatives:

- Accelerate CellTolerance's sales momentum, supported by a solid active pipeline of 42 business opportunities;
- Achieve favorable results in the pancreatic cyst indication, including inclusion in EU clinical guidelines in 2025 and results from the 500-patient CLIMB study in the United States;
- Develop patents and AI applications for Cellvizio, in particular the development of a multimodal image database with annotation capabilities;
- Close one or more strategic transactions.

5.2. Consolidated financial statements

5.2.1. IFRS consolidated financial statements for the year ended December 31,

- **Consolidated statement of financial position**

(Amounts in thousands of euros)	Note	31/12/2024	31/12/2023
ASSETS			
Non-current assets			
Intangible fixed assets	**3**	1 472	2 013
Property, plant and equipment	**4**	509	621
Right of use	**4**	1 082	543
Investments in associates	**5**	3 923	5 183
Non-current financial assets	**6**	222	250
Total non-current assets		**7 208**	**8 611**
Current assets			
Inventories and work-in-progress	**7**	4 261	2 863
Accounts receivable	**8**	1 332	1 320
Other current assets	**8**	1 427	2 139
Current financial assets		-	36
Cash and cash equivalents	**9**	2 017	7 969
Total current assets		**9 037**	**14 327**
TOTAL ASSETS		**16 245**	**22 938**

(Amounts in thousands of euros)	Note	31/12/2024	31/12/2023
LIABILITIES			
Shareholders' equity			
Share capital	**10**	2 709	2 464
Additional paid-in capital	**10**	9 465	7 622
Reserves		(25 982)	(22 800)
Translation reserves		(177)	(836)
Consolidated net income, Group share		(10 404)	(3 727)
Total shareholders' equity		**(24 389)**	**(17 276)**
Non-current liabilities			
Long-term debt	**11**	7 158	13 402
Non-current provisions	**12**	109	72
Total non-current liabilities		**7 267**	**13 474**
Current liabilities			
Short-term borrowings and financial debts	**13**	24 773	16 371
Current provisions	**11**	38	38
Trade accounts payable	**13**	3 274	2 774
Other current liabilities	**13**	5 282	7 557
Total current liabilities		**33 367**	**26 740**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		**16 245**	**22 938**

Consolidated income statement

(Amounts in thousands of euros)	Note	31/12/2024	31/12/2023
Operating income			
Sales figures	**15**	7 655	10 480
Other income	**15**	760	547
Total income		**8 415**	**11 027**
Operating expenses			
Cost of sales	**17**	(1 215)	(2 118)
Gross margin (excluding licenses)		*78%*	*66%*
Research & Development	**17**	(3 550)	(3 860)
Sales & Marketing	**17**	(4 705)	(5 618)
Overheads	**17**	(4 445)	(5 004)
Share-based payment	**16**	(549)	(113)
Total expenses		**(14 464)**	**(16 713)**
Current operating income		**(6 049)**	**(5 686)**
Non-current operating income	**18**	(34)	6 918
Operating income		**(6 083)**	**1 231**
Share of profit of associates		(1 683)	(2 528)
Financial income	**19**	458	953
Financial expenses	**19**	(3 096)	(2 909)
Profit before tax		**(10 404)**	**(3 253)**
Income tax expense	**20**	-	(475)
Net income		**(10 404)**	**(3 727)**
Other comprehensive income			
Items not reclassified to net income			
Actuarial gains and losses on defined benefit plans	**12**	1	(3)
Total items not reclassified to net income		**1**	**(3)**
Items subsequently reclassified to net income			
Translation adjustments on foreign entities		659	(1 413)
Total items subsequently reclassified to net income		**659**	**(1 413)**
Other comprehensive income for the year, net of tax		**660**	**(1 415)**

Overall result		**(9 744)**	**(5 142)**
Weighted average number of shares outstanding (in thousands)		64 072	49 302
Earnings per share (€/share)	**23**	**(0.16)**	**(0.08)**
Weighted average number of potential shares (in thousands)		70 073	62 077

Consolidated statement of cash flows

(Amounts in thousands of euros)	Note	31/12/2024	31/12/2023
Cash flow from operating activities			
Consolidated net income		(10 404)	(3 727)
Elimination of depreciation, amortization and provisions		1 980	1 522
Share of profit of associates		1 683	2 528
Calculated income and expenses related to share-based payments	**17**	549	113
Other items excluded from cash flow from operations		2 059	2 026
Income and expenses related to the discounting of repayable advances	**11**	*106*	*103*
Income and expenses related to the discounting of borrowings	**11**	*1 912*	*1 572*
Income and expenses related to the fair value of derivative instruments	**11**	*(10)*	*82*
Net financial interest	**11**	*457*	*269*
Other non-cash items	**11**	*(406)*	-
Capital gains and losses		95	(8 366)
Cash flow		**(4 038)**	**(5 905)**
Change in working capital from operations		(2 569)	5 152
Inventories and work-in-progress	**6**	*(1 186)*	*83*
Accounts receivable	**7**	*45*	*5 867*
Other current assets	**7**	*298*	*(353)*
Trade accounts payable	**13**	*453*	*1 503*
Other current liabilities	**13**	*(2 179)*	*(1 948)*
Taxes paid		283	-
Net cash from operating activities (A)		**(6 324)**	**(753)**
Cash flow from investing activities			
Acquisition of property, plant and equipment and intangible assets	**3/4**	(215)	(382)

Disposal of property, plant and equipment and intangible assets		1	13
Change in loans and advances granted	**5/8**	29	15
Other cash flows from investing activities		36	
Net cash used in investing activities (B)		**(149)**	**(354)**
Cash flows from financing activities			
Amounts received on exercise of stock options, BSAs and BSPCEs	**10**	2 088	1 404
Amounts received from shareholders on capital increases	**10**	-	5 990
Debt issuance and redemption costs	**11**	(420)	(961)
Repayment of lease liability IFRS 16	**11**	(555)	(489)
Other net financial interest paid	**11**	(319)	(278)
CIR financing	**11**	(156)	220
Other cash flows from financing activities		(155)	73
Net cash used in financing activities (C)		**483**	**5 959**
Impact of changes in exchange rates (D)		38	(19)
Net change in cash and cash equivalents (A) + (B) + (C) + (D)		**(5 952)**	**4 832**
Opening cash position	**9**	7 969	3 137
Closing cash position	**9**	2 017	7 969
Change in cash and cash equivalents		**(5 952)**	**4 832**

Consolidated statement of changes in equity

(Amounts in thousands of euros)

(Amounts in thousands of euros)		Capital	Bonus	Treasury shares	Consolidated reserves	Translation reserves	Consolidated net income, Group share	Total consolidated shareholders ' equity
Shareholders' equity at	**31/12/2022**	**1 859**	**787**	**(55)**	**(11 912)**	**577**	**(11 180)**	**(19 925)**
Appropriation of profit		-	-	-	(11 180)	-	11 180	-
Capital transactions		605	6 835	-	-	-	-	7 441
Share-based payments		-	-	-	113	-	-	113
Treasury share transactions		-	-	33	(7)	-	-	26
Total income for the year	31/12/2023	-	-	-	(3)	(1 413)	(3 727)	(5 142)
Other movements		-	-	-	212	-	-	212
Shareholders' equity at	**31/12/2023**	**2 464**	**7 622**	**(21)**	**(22 777)**	**(836)**	**(3 727)**	**(17 276)**
Appropriation of profit		-	-	-	(3 727)	-	3 727	-
Capital transactions		245	1 843	-	-	-	-	2 088
Share-based payments		-	-	-	549	-	-	549
Treasury share transactions		-	-	21	(21)	-	-	-
Total income for the year	**31/12/2024**	-	-	-	-	659	(10 404)	(9 745)
Other movements		-	-	-	(5)	-	-	(5)
Shareholders' equity at	**31/12/2024**	**2 709**	**9 465**	**-**	**(25 981)**	**(177)**	**(10 404)**	**(24 389)**

Other movements during the period relate to the application of IFRS to the JV accounts.

The Company

Founded in 2000, Mauna Kea Technologies is a global medical device company that manufactures and markets Cellvizio®, the real-time in vivo cell imaging platform. This technology offers unique in vivo cellular visualization, enabling physicians to monitor disease progression over time, assess reactions as they occur, classify areas of uncertainty and guide surgical interventions. The Cellvizio platform is used in many countries around the world and in several medical specialties, transforming the way doctors diagnose and treat patients.

Key events of the year

Sales in the United States

Pay-per-use (PPU) activity remained buoyant throughout 2024, with quarterly volumes comparable to those of 2023, averaging almost 1,000 procedures per quarter. This represents a significant increase of almost 50% on 2022 and previous years.

However, the positive impact of this volume growth was offset by a negative price effect resulting from the reduction in Medicare reimbursement rates by CMS (*Centers for Medicare & Medicaid Services*). This reduction resulted from

misreporting of costs by hospitals, which had an impact on the rates charged by ambulatory surgery centers (ASCs). The Group has made considerable efforts to rectify these errors, and has succeeded in raising awareness among 80% of the hospitals that provided erroneous data.

It should be noted that in 2025, reimbursement rates are expected to remain in the same APC classification, as CMS relies on 2023 data to set 2025 rates. However, a favorable adjustment is expected no later than January 2026, when CMS will integrate the corrected 2024 data and take into account the provisional data provided through direct collaboration with the Group. This adjustment should restore reimbursement levels to the highest APC level, representing an increase of over 50% in reimbursement rates for Medicare beneficiaries.

Capital sales amounted to three Cellvizio® systems in 2024, including one sold to *Ohio State University* in Q4, compared with four systems in 2023. This represents a significant shortfall in Q4, when the company was in active negotiations for seven Cellvizio® sales, three of which should be concluded in January.

While capital sales cycles have lengthened, the pipeline remains strong, representing a total of 13 active opportunities in the United States.

CellTolerance

In the second half of the year, the Group launched CellTolerance, a new brand and multidisciplinary program dedicated to the treatment of food intolerances through a B2B2C "cash-pay" business model. This strategic initiative enables the Group to address a very significant and fast-growing market, and to overcome reimbursement barriers.

To support this new strategy, a dedicated pilot center was inaugurated in the fourth quarter of 2024 to validate the operating model and accelerate deployment in complementary networks from 2025.
The launch has been very well received, and the pipeline of active opportunities is already substantial, with 42 activable accounts identified and expectations of continued growth in the months ahead. The Group has achieved sales of around 0.5 million euros in 2024, and is aiming to at least triple sales by 2025.

JV in China

Business activity in China via the Group's joint venture with Tasly Pharmaceutical has so far been very limited, despite the Chinese market's strong interest in endomicroscopy. Due to differing interpretations of the financial obligations to be met by Tasly Pharmaceutical and the joint venture, the loss of revenue opportunity is estimated at around 2 million euros. Mauna Kea is currently evaluating all options to remedy the current difficulties.

Review of strategic options

On November 19, 2024, the Group announced the launch of a strategic process covering a broad spectrum of possibilities, from a merger and acquisition to the conclusion of licensing and/or marketing agreements. As part of this process, the Group has retained the services of RM Global, a US investment bank specializing in the healthcare sector.

This process is designed to ensure the Company's operational stability and secure the financing needed to deploy the long-term commercial potential of its Cellvizio platform.

Notes to the financial statements

Note 1: Accounting principles and methods

1.1 Group accounting policies

The financial statements are presented in thousands of euros. In some cases, rounding may lead to insignificant differences in totals.

They were approved by the Board of Directors on April 22, 2025. These financial statements will not be final until they have been approved by the Annual General Meeting of Shareholders.

The financial statements are prepared under the historical cost convention, with the exception of financial assets measured at fair value. The preparation of financial statements in accordance with IFRS requires the use of estimates and assumptions that affect the amounts and disclosures in the financial statements, notably in connection with the valuation of share-based payment expenses, the valuation of research tax credits, and the values in use taken into account in impairment testing. These assumptions and estimates, which are established on the basis of information or situations existing at the date of preparation of the financial statements, may prove to be different from reality in the future. Where appropriate, a sensitivity analysis may be performed if material.

Over the past few years, the Company has significantly reduced its losses and cash consumption, which now stands at around half a million euros a month, excluding financing repayments. Although it remains dependent on external financing (capital increases, loans or other) at this stage, this dependence is much less pronounced than before. Indeed, based on its business plan, the Company expects to reach profitability by the end of 2026.

In order to ensure sufficient financial visibility in the coming years, on March 31, 2025 the Company obtained the opening of a safeguard procedure. This will first freeze bank repayments for the duration of the procedure (six months, renewable), then allow the debt to be reorganized by spreading repayments over a period of up to ten years, and potentially to obtain debt write-offs.

In view of these factors, as well as the financial resources available at December 31, 2024 (2.0 million euros in cash) and the momentum of commercial activity, the Company estimates that it will be able to finance its operations until the end of the first half of 2025. It also estimates its twelve-month financing requirement at around €5 million, and has several options to cover it.

On the one hand, as part of the strategic process launched at the end of 2024, the Company has initiated several discussions for licensing agreements with strategic partners, likely to give rise to upfront payments on signature, as well as additional payments linked to the achievement of operational and commercial targets. More specifically, on March 31, 2025, the Company announced that it had entered into exclusive negotiations for a licensing agreement in a broad therapeutic area, while at the same time pursuing other strategic discussions. In addition, the Company is studying with several investment banks various dilutive financing solutions (capital increases via public offerings or private placements) or debt financing.

In view of these various options, the Company considers at this stage that the risk of not securing the financing required to continue its activities in the coming months remains moderate. On the basis of these factors, the Board of Directors has adopted the going concern assumption. However, the outcome of these discussions, whether concerning licensing agreements or financing solutions, is not guaranteed. This constitutes a significant uncertainty which could jeopardize the Company's ability to continue as a going concern.

The Group's consolidated financial statements at December 31, 2024 have been prepared in accordance with IFRS (International Financial Reporting Standards) as published by the IASB (International Accounting Standards Board) and adopted by the European Union at that date. All the texts adopted by the European Union are available on the European Commission website.

In preparing its financial statements for the year ended December 31, 2024, the Group has applied the same accounting standards, interpretations and methods as those used in its financial statements for the year ended December 31, 2023, with the exception of the texts that have come into force since January 1, 2024, mentioned in the paragraph below.

New texts with mandatory application on January 1, 2024:

- Amendments to IFRS 16 "Leaseback obligations"; ;
- Amendments to IAS 1 "Classification of liabilities as current and non-current" and "Non-current liabilities with covenants" ;

- Amendments to IAS 7 and IFRS 7 "Vendor financing arrangements".

The financial statements have not been impacted by the application of these amendments and improvements.

New non-mandatory application texts on January 1, 2024 :

- Amendments to IAS 21 "Absence of convertibility". At the balance sheet date, these amendments had not yet been adopted by the European Union. The effective date of application according to the IASB is January 1, 2025;
- Amendments to IFRS 9 and IFRS 7 "Classification and Measurement of Financial Instruments". At the balance sheet date, these amendments had not yet been adopted by the European Union. The effective date of application according to the IASB is January 1, 2026;
- Amendments related to the annual improvements to IFRS standards - Volume 11. At the balance sheet date, these amendments had not yet been adopted by the European Union. The effective date of application according to the IASB is January 1, 2026;
- IFRS 18 "Presentation of financial statements and disclosures". At the balance sheet date, this standard had not yet been adopted by the European Union. The effective date of application according to the IASB is January 1, 2027;
- IFRS 19 "Subsidiaries not subject to public disclosure requirements: disclosures". At the balance sheet date, this standard had not been adopted by the European Union. The effective date of application according to the IASB is January 1, 2027.

These new texts have not been applied in advance by the Group or are not applicable.

1.2 Use of estimates and judgments

The preparation of financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, income and expenses. Actual values may differ from these estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. The impact of changes in accounting estimates is recognized in the period of the change and any subsequent periods affected.

Information on the main sources of uncertainty relating to estimates and assumptions, and the judgments made in applying the accounting policies that have the most significant impact on the amounts recognized in the financial statements, is included in the following notes:

- Note 1.16 - Provisions for pensions and other post-employment benefits ;
- Note 1.13 - Expenses related to bonus shares ;
- Note 1.18 - Research tax credits ;
- Note 1.15 - Conditional advances ;
- Note 1.17 - Sales determined in accordance with IFRS 15 - Revenue from contracts with customers.

1.3 Consolidation methods

Controlled subsidiaries within the meaning of IFRS 10 "Consolidated financial statements" are fully consolidated. The Group controls an entity when it is exposed to, or has a right to, variable returns from its relationship with the entity, and has the ability to influence those returns through its control over the entity. They are deconsolidated from the date on which control ceases to be exercised.

Associates within the meaning of IFRS 10 are accounted for using the equity method. The Group exercises significant influence over these entities when it has the power to participate in decisions relating to the entity's financial and operating policies, but does not control or jointly control these policies.

Intra-group transactions and balances are eliminated. Subsidiaries' accounting policies have been aligned with those of the Company.

1.4 Net investments abroad

In accordance with IAS21 §15, foreign exchange gains and losses on long-term receivables in US dollars held by the Company from its subsidiary have been recorded in shareholders' equity. These receivables are considered as net foreign currency investments in foreign consolidated subsidiaries, given the unforeseeable nature of their settlement.

1.5 Property, plant and equipment

Since January 1, 2019, property, plant and equipment subject to a lease of more than twelve months and involving assets with an individual replacement value of more than USD5,000 are subject to the recognition of an asset representing the right to use the leased asset. The initial measurement of the asset is estimated using the cost model and depreciated over the shorter of the lease term or the right-of-use period, in accordance with IFRS 16.

Purchased property, plant and equipment are recorded at acquisition or production cost. Major renovations and improvements are capitalized, while repairs, maintenance and other renovation costs are expensed as incurred. Subsidies received in respect of capitalized expenditure are deducted from cost.

Property, plant and equipment are depreciated on a straight-line basis over the estimated useful lives of the assets concerned. Leasehold improvements are depreciated over the shorter of their useful life or the lease term.

Cellvizio® entrusted to hospitals with which the Group has partnership agreements (reference centers) and Cellvizio® made available under consignment contracts are recognized as fixed assets.

The depreciation periods used are as follows:

Fixtures and fittings .....7 years

Research and development equipment.....2 to 5 years

Production tooling .....3 to 7 years

Cellvizio entrusted to reference centers, on loan or on consignment ..... 5 years

Research equipment and technical installations ..... 7 years

Office equipment and furniture ..... 5 years

Computer hardware .....3 years

1.6 Recoverable amount of intangible assets and property, plant and equipment

Amortized intangible assets and property, plant and equipment are tested for impairment whenever the recoverability of their carrying amount appears uncertain.

An impairment loss is recognized to the extent that the asset's carrying amount exceeds its recoverable amount. The recoverable amount of an asset is the higher of its fair value less costs to sell and its value in use. With regard to the Group's intangible assets, there is no market data available which would enable fair value net of disposal costs to be determined other than by estimating future cash flows. Consequently, the recoverable amount is essentially equal to the value in use.

Value in use is determined annually, in accordance with IAS 36: it corresponds to the present value of estimated future cash flows expected to arise from the continuing use of assets and from their disposal at the end of their useful life. It does not take into account the impact of the Group's financial structure, the tax effect, or restructuring costs not yet incurred.

1.7 Leases

In application of the standard on leases (IFRS 16), the Company recognizes, in respect of the rights and obligations created by the leases :

- a right of use corresponding to the present value of initial rents and direct costs. This right is amortized and written down if there is any indication of a possible loss;

- a lease liability corresponding to the present value, at the lessee's marginal borrowing rate, of payments due to the lessor over the term of the contract.

The lease term corresponds to the non-cancellable period plus any renewal options whose exercise by the Company is reasonably certain.

Contracts restated by the Group correspond mainly to leases for the head office in France and offices in Boston, as well as leases for motor vehicles.

1.8 Financial assets

The Company's financial assets comprise loans and receivables, and cash and cash equivalents.

The measurement and recognition of financial assets and liabilities are defined by IFRS 9 - Financial Instruments.

Loans and receivables

This category includes trade receivables, other loans and receivables, and deposits and guarantees, classified in the balance sheet under Financial investments.

These instruments are initially recognized at fair value, and subsequently at amortized cost calculated using the EIR method. Short-term receivables with no stated interest rate are valued at the original invoice amount, unless the application of an implicit interest rate has a material effect. For variable-rate loans and receivables, a periodic re-estimation of cash flows to reflect changes in market interest rates modifies the effective interest rate and consequently the valuation of the loan or receivable.

The Group analyzes each of its overdue trade receivables to determine whether any impairment needs to be recognized.

Loans and receivables are monitored for objective indications of impairment. A financial asset is impaired if its carrying amount is greater than its recoverable amount, as estimated during impairment tests. The impairment loss is recognized in the income statement.

Assets at fair value through profit or loss

Assets considered as held for trading include assets which the Group intends to resell in the near future in order to realize a capital gain, which belong to a portfolio of financial instruments managed together and for which there is a short-term disposal practice.

1.9 Inventories and work-in-progress

Inventories are stated at the lower of cost and net realizable value. In the latter case, a corresponding impairment loss is recognized in the income statement.

Raw materials inventories are valued using the weighted average cost method.

Inventories of semi-finished and finished products are valued at standard cost, taking into account the cost of materials used, the cost of labor and a proportion of overheads.

1.10 Cash and cash equivalents

Cash equivalents are held for the purpose of meeting short-term cash commitments, rather than for investment or other purposes. They are readily convertible into a known amount of cash and are subject to an insignificant risk of change in value. Cash and cash equivalents comprise immediately available cash, immediately callable term deposits and short-term marketable securities. They are valued according to the IFRS 9 categories to which they belong.

Short-term investment securities are readily convertible to a known amount of cash and are subject to an insignificant risk of changes in value. They are measured at fair value, with changes in value recognized in the income statement.

1.11 Share capital

The cost of capital transactions directly attributable to the issue of new shares or options is recognized in shareholders' equity as a deduction from the proceeds of the issue, net of tax.

1.12 Liquidity contract

Following its IPO on the Euronext Paris regulated market, the Company signed a liquidity contract with a specialist institution to limit the daily volatility of the Mauna Kea Technologies share.

The portion of the contract invested in the Company's own shares by this service provider is deducted from consolidated shareholders' equity at the end of each financial year. The cash portion of the contract is presented as an asset under Financial assets.

1.13 Share-based payments

Since its creation, the Company has set up several equity-settled compensation plans in the form of "Bons de Souscription de Parts de Créateur d'Entreprise" (BSPCE) granted to employees and/or managers, in the form of "Bons de Souscription d'Actions" (BSA) granted to non-employee members of the Board of Directors or Supervisory Board, in the form of stock options (SO) granted to employees of the subsidiary Mauna Kea Technologies Inc. and in the form of preferred shares (AP) and bonus shares (AGA) allocated free of charge to employees and/or managers.

In accordance with IFRS 2, the cost of transactions settled in equity instruments is recognized as an expense with a corresponding increase in equity over the period in which the rights to benefit from the equity instruments vest.

Since 2002, the Group has applied IFRS 2 to all equity instruments granted to employees, members of the Board of Directors or Supervisory Board, individuals or companies.

The fair value of stock options or performance shares granted to employees is determined by applying the Black-Scholes option pricing model. The same applies to options granted to other individuals providing similar services, as their market value is not determinable.

The determination of the fair value of converted instruments takes into account the vesting conditions as described in Note 17: Share-based payments. Other factors taken into consideration are also presented in Note 17: Share-based payments.

1.14 Measurement and recognition of financial liabilities

Financial liabilities at amortized cost

Borrowings and other financial liabilities are initially measured at fair value and subsequently at amortized cost, calculated using the effective interest rate ("EIR"). Transaction costs directly attributable to the acquisition or issue of a financial liability are deducted from that liability. These costs are then amortized actuarially over the life of the liability, based on the EIR. The EIR is the rate that equates the expected future cash outflows with the current net carrying amount of the financial liability, in order to deduct its amortized cost.

The Research Tax Credit ("CIR") receivable for 2024 has been pre-financed in the amount of €471,000 in 2024. In accordance with the IAS 39 decision tree on derecognition of financial assets, it was concluded that the Group had not transferred substantially all the risks and rewards inherent in the CIR 2024 receivable transferred. The receivable has therefore not been derecognized, and the funds received from the mobilization of the receivable are recognized in current borrowings.

Restructuring of financing agreement with the European Investment Bank

The quantitative and qualitative tests required by the standard led the Group to classify the restructuring of the loan as a substantial modification and to apply the appropriate accounting treatment:

- extinction of original debt ;

- recognition of a new loan at its fair value on the renegotiation date, discounted at the new EIR taking into account (i) the revised maturity schedule and (ii) the impact of royalties on sales scaled according to the Group's forecasts.

The difference between the net carrying amount of the original debt at the extinguishment date and the fair value of the new loan is recognized in the income statement, representing net financial income of €113,000.

Liabilities at fair value through profit or loss

Liabilities at fair value through profit or loss are measured at fair value.

In accordance with the provisions of the new IFRS 9 and the clarifications issued in 2017 by the IFRS Interpretations Committee on the treatment of changes in debt deemed not to be derecognizable, the Group immediately restates in the income statement the effect of changes in the contractual borrowing conditions. The effective interest rate is thus maintained over the residual maturity of the debt.

As part of the financing agreed with the European Investment Bank (EIB), the Group issued share warrants. This issue was analyzed in accordance with IFRS 9 criteria. The existence of a put option and the variable nature of the number of shares to which the warrants will give entitlement result in the recognition of a derivative instrument which must be measured at fair value at the grant date. It is subsequently remeasured at each balance sheet date, with a corresponding adjustment to income.

1.15 Conditional advances

Historically, the Company has received aid in the form of subsidies or conditional advances. Details of these grants are provided in Note 11: Borrowings.

An unconditionally repayable loan is treated as a government grant if there is reasonable assurance that the company will meet the conditions for waiving repayment of the loan. Otherwise, it is classified as a liability.

The amount resulting from the rate advantage obtained when interest-free repayable advances are granted is considered as a subsidy. This benefit is determined by applying a discount rate equal to the contractual rate, if known, or to the market rate.

1.16 Provisions

Provisions for contingencies and charges

Provisions for liabilities and charges correspond to commitments arising from litigation and other risks, the timing and amount of which are uncertain, and which the Group may encounter in the course of its business.

A provision is recognized when there is a legal or constructive obligation to a third party as a result of a past event, which is probable or certain to result in an outflow of resources to the third party, without at least equivalent consideration being received from the third party, and the future outflow of resources can be reliably estimated.

The amount recognized as a provision is the best estimate of the expenditure required to settle the obligation, discounted if necessary to the balance sheet date.

Pension and other post-employment benefit obligations

Group employees are entitled to the pension benefits provided for by French law:

- receive a retirement allowance, paid by the Group, when they retire (defined-benefit plan);
- payment of retirement pensions by Social Security organizations, which are financed by contributions from companies and employees (defined-contribution state schemes).

For defined-benefit plans, the cost of retirement benefits is estimated using the projected unit credit method. Under this method, pension costs are recognized in the income statement so as to spread them evenly over the service lives of employees. Retirement benefit obligations are measured at the present value of estimated future payments, using the market rate based on the long-term bonds of leading companies with a duration corresponding to that estimated for the plan.

The Company calls on qualified actuaries to carry out an annual review of the valuation of these plans.

In accordance with IAS 19 "Employee Benefits", service cost and net interest are recognized in operating income, with remeasurements in other comprehensive income.

Group payments for defined contribution plans are expensed in the income statement in the period to which they relate.

1.17 Income from ordinary activities

The Group recognizes revenue in accordance with IFRS 15.

Revenue corresponds to the fair value of the consideration received or receivable for goods sold in the ordinary course of the Group's business. Revenue is stated net of value-added tax, product returns, rebates and discounts, and after deduction of intra-Group sales.

The Group recognizes revenue when the transfer of promised goods or services to a customer is completed, at an amount which reflects the payment which the entity expects to receive in return for these goods or services. For product sales, revenue is recognized either when the products are made available or when they are delivered, depending on the terms of the order.

In the case of the Group's ordinary sales, and in the case of a system rental contract, the Cellvizio is recognized as a Group asset, and sales are recognized on the sale of consumables or on a fee-for-service basis by the healthcare professional, insofar as the system remains the property of the Group.

Sales of systems previously leased under "Pay-Per-Use" (PPU) contracts are classified under "Sales" in the income statement.

Sales generated by the joint venture Tasly Mauna Kea Medical Engineering Technology Co.

Following the creation of Mauna Kea Medical Enginering Technology Co, the Group signed two contracts with this JV

- A technology transfer agreement dated November 30, 2022;
- A license agreement dated December 23, 2022.

(i) Technology transfer agreement

The Group was to take the necessary steps to transfer ownership of the patents to the joint venture (JV), in return for a payment of USD 2.5 million from the latter.

All the patents were transferred on February 17, 2022. However, the contract included a condition precedent, which was lifted on April 20, 2023.

Consequently, the corresponding sales were fully recognized on the date the suspensive condition was lifted.

(ii) License agreement

Under the terms of the agreements signed with the JV, the Company :

- grants the JV an exclusive 8-year license to :
    - (i) market certain Cellvizio indications in China,
    - (ii) develop and market Cellvizio internationally in the fields of neurology and neurosurgery,
    - (iii) manufacture Cellvizio units for the Chinese market;
- undertakes to provide the JV with technical support and know-how transfer, in order to make the JV fully autonomous.

In return, the JV undertakes to pay the Company :

- an upfront license payment of USD 6.5 million, to be received in January 2023;
- an additional payment ("technology transfer material fee") of 0.5 million USD, conditional on the completion

of a first phase of technology transfer;

- a second license payment of USD 0.5 million, to be paid on completion of the transfer to the JV of part of the inventory held by a local distributor;
- royalties equivalent to 7.5% of sales generated by the JV, subject to certain conditions.
  During the technology transfer phase, the JV also undertakes to purchase minimum volumes of Cellvizio systems and probes from Mauna Kea Technologies for a period of 5 years.

During the local *product* phase in China, Mauna Kea Technologies will receive royalties of 7.5% on JV sales, subject to certain conditions.

Accounting treatment

The Company considers that the license granted to the JV consists of two distinct phases:

1. an initial phase of know-how transfer and support, at the end of which the JV will become autonomous,

2. a phase of autonomous operation by the JV.

This first phase is estimated to last 36 months, after which the JV will be able to manufacture the systems itself.

As a result, the payments of 6.5 million USD (upfront) and 0.5 million USD (technology transfer) are considered as consideration for the transfer of know-how and support. Sales are therefore recognized on a straight-line basis over the 36 months following signature of the license agreement.

Sales recognition :

- Fiscal 2023: 4.3 million euros
    - 2.0 million euros (MUSD 2.5) related to the transfer of patents, completed in the 1st half of 2023;
    - 2.3 million euros (US$2.2 million) under the license agreement, corresponding to initial payments spread over 36 months.
- Fiscal 2024: 2.0 million euros (2.2 MUSD) of sales recognized in respect of the continued deferral of the license agreement.

1.18 Research tax credit

Research Tax Credits ("CIR") are granted to companies by the French government to encourage them to carry out technical and scientific research. Companies that can prove that they have incurred the expenditure required to benefit from the CIR can use it to pay their corporate income tax for the year in which the expenditure was incurred, and for the three following years. If the amount of tax due is not sufficient to cover the total amount of the tax credit at the end of the three-year period, the difference is reimbursed by the State in cash.

The Group uses the CIR for research expenditure incurred during each financial year, and recognizes the amount in "Other income" for the same year. The CIR is subject to verification by the French tax authorities.

1.19 Other operating income and expenses

These are very limited, unusual and infrequent items of income or expense - of significant amount - which the company presents separately in its income statement to facilitate understanding of current operating performance and provide the reader of the financial statements with useful information for forecasting results.

1.20 Cost of goods sold

Cost of sales comprises expenses directly linked to products sold, i.e. consumption of raw materials, direct labor costs and provisions for inventory depreciation. It also includes the amortization of systems made available to customers under Pay-Per-Use contracts.

1.21 Income tax

Income tax (expense or income) comprises current tax expense (income) and deferred tax expense (income).

Deferred tax is determined and recognized for all temporary differences between the carrying amount of assets and liabilities and their tax bases. Tax losses that can be carried forward or back can also be recognized as deferred tax assets.

The tax rates applicable at the balance sheet date are used to determine deferred taxes.

A deferred tax asset is recognized only to the extent that it is probable that the Group will have sufficient future taxable profits to recover it. The Group has not recorded any net deferred tax assets in its financial statements.

1.22 Segment reporting

To date, the Group has not identified any distinct business segments. It operates in a single business segment: endomicroscopy.

1.23 Other comprehensive income

Income and expense items for the period recognized directly in equity are presented, where appropriate, under "Other comprehensive income". These mainly comprise :

- EUR/USD translation adjustments of the subsidiary Mauna Kea Technologies Inc. ;
- the change in the provision for retirement commitments due to changes in actuarial assumptions.

Note 2: Company and scope of consolidation

Founded in May 2000, Mauna Kea Technologies SA ("the Company") develops and markets medical devices, in particular optical instruments for medical imaging.

As part of its expansion in the United States, the Company created Mauna Kea Technologies Inc. on January 3, 2005.

The joint venture Tasly Mauna Kea Medical Engineering Technology Co Ltd was created on November 03, 2022. The Group holds 49% of its capital, while Tasly Pharmaceutical owns the remaining 51%.

The Group has analyzed the role played in the management of the JV with regard to IAS.28. As a result, Mauna Kea Technologie has significant influence over this JV, which is accounted for by the equity method in the Group's financial statements.

In the second half of 2024, the Group set up Celltolerance, a company dedicated to the field of food intolerance.

	31/12/2024		31/12/2023		Consolidation method
Companies	**% interest**	**% control**	**% interest**	**% control**	
Mauna Kea Technologies SA (1)	100%	100%	100%	100%	Full consolidation
Mauna Kea Technologies Inc.	100%	100%	100%	100%	Full consolidation
Celltolerance SAS	100%	100%	-	-	Full consolidation
Tasly Mauna Kea Medical Technology Co Ltd	49%	49%	49%	49%	Equity method

Note 3: Intangible assets

Movements in intangible assets can be analyzed as follows:

(Amounts in thousands of euros)	31/12/2023	Increase	Decrease	31/12/2024
Development costs	6 050	-	-	6 050
Patents, licenses and trademarks	1 714	11	(8)	1 717
Software	957	8	(21)	944
Patents, licenses and trademarks	397	10	-	407
Total intangible assets, gross	**9 118**	**29**	**(29)**	**9 118**
Amort. / dep. of development costs	(4 715)	(485)	-	(5 200)
Amort. / dep. of patents, licenses and trademarks	(1 461)	(80)	8	(1 533)
Amort. / dep. of software	(929)	(5)	21	(913)
Total amortization/depreciation of intangible assets	**(7 105)**	**(570)**	**29**	**(7 646)**
Total net intangible assets	**2 013**	**(541)**	**-**	**1 472**

(Amounts in thousands of euros)	31/12/2022	Increase	Decrease	31/12/2023
Development costs	6 050	-	-	6 050
Patents, licenses and trademarks	1 859	-	(145)	1 714
Software	955	9	(7)	957
Patents, licenses and trademarks	420	15	(38)	397
Total intangible assets, gross	**9 284**	**24**	**(190)**	**9 118**
Amort. / dep. of development costs	(4 230)	(485)	-	(4 715)
Amort. / dep. of patents, licenses and trademarks	(1 467)	(81)	87	(1 461)
Amort. / dep. of software	(886)	(51)	7	(929)
Total amortization/depreciation of intangible assets	**(6 582)**	**(617)**	**94**	**(7 105)**
Total net intangible assets	**2 702**	**(593)**	**(96)**	**2 013**

All development costs relating to the third-generation Cellvizio (GEN III) have been capitalized between 2019 and 2021 for a total of €2,427,000. They have been amortized from the date of commercialization, i.e. October 1, 2021.

An impairment test was carried out at December 31, 2024, in accordance with the methodology described in Note 1.6, and the Group did not recognize any impairment.

Note 4: Property, plant and equipment and right of use

Movements in property, plant and equipment and rights of use break down as follows:

(Amounts in thousands of euros)	31/12/2023	Increase	Decrease / Scrapping	Exchange differences	Other movements	31/12/2024
Industrial equipment	3 700	156	(853)	2	197	3 202
Building fixtures and fittings	51	-	(1)	-	-	50
Other property, plant and equipment	1 367	31	(103)	7	-	1 302
Property, plant and equipment in progress	-	-	-	-	-	-
Gross value of property, plant and equipment	**5 118**	**186**	**(957)**	**9**	**197**	**4 553**
Depreciation of industrial equipment	(3 258)	(382)	839	(3)	(21)	(2 825)
Depreciation of building fixtures and fittings	(51)	-	1	-	-	(50)
Depreciation/depreciation of other tangible fixed assets	(1 188)	(73)	99	(7)	-	(1 169)
Total depreciation of tangible fixed assets	**(4 497)**	**(455)**	**939**	**(10)**	**(21)**	**(4 044)**
Total net property, plant and equipment	**621**	**(269)**	**(18)**	**(1)**	**176**	**509**
Rights of use	5 086	1 611	(24)	24	(287)	6 410
Amort. / dep. of rights of use	(4 543)	(916)	(54)	(19)	204	(5 328)
Total net rights of use	**543**	**695**	**(78)**	**5**	**(83)**	**1 082**

(Amounts in thousands of euros)	31/12/2022	Increase	Decrease / Scrapping	Exchange differences	Other movements	31/12/2023
Industrial equipment	3 718	279	(291)	(6)	-	3 700
Building fixtures and fittings	51	-	-	-	-	51
Other property, plant and equipment	1 316	79	(32)	(4)	-	1 367

Property, plant and equipment in progress	8	-	-	-	-	-
Gross value of property, plant and equipment	**5 093**	**358**	**(323)**	**(10)**	**-**	**5 118**
Depreciation/depreciation of industrial equipment	(3 163)	(350)	248	8	-	(3 258)
Depreciation of building fixtures and fittings	(51)	-	-	-	-	(51)
Depreciation/depreciation of other tangible fixed assets	(1 093)	(126)	27	4	-	(1 188)
Total depreciation of tangible fixed assets	**(4 307)**	**(476)**	**275**	**12**	**-**	**(4 497)**
Total net property, plant and equipment	**786**	**(118)**	**(49)**	**2**	**-**	**621**
					-	
Rights of use	5 656	104	(661)	(13)	-	5 086
Amort. / dep. of rights of use	(4 715)	(434)	598	9	-	(4 543)
Total net rights of use	**941**	**(329)**	**(63)**	**(4)**	**-**	**543**

Note 5: Investments in

(Amounts in thousands of euros)	31/12/2023	Results	Change in scope of consolidation	Exchange differences	Other	31/12/2024
Investments in associates	5 183	(1 683)	-	426	(3)	3 923
Total investments in associates	**5 183**	**(1 683)**	**-**	**426**	**(3)**	**3 923**

(Amounts in thousands of euros)	31/12/2022	Results	Change in scope of consolidation	Exchange differences	Other	31/12/2023
Investments in associates	-	(2 528)	8 737	(1 238)	213	5 183
Total investments in associates	**-**	**(2 528)**	**8 737**	**(1 238)**	**213**	**5 183**

Investments in associates correspond to the 49% share in the equity of the joint venture Tasly Mauna Kea Medical Enginnering Technology Co. Ltd.

Note 6: Non-current financial assets

Non-current financial assets at December 31, 2024 mainly comprise guarantee deposits paid in connection with operating leases and collective holdbacks relating to sales of Research Tax Credit receivables.

Note 7: Inventories

Inventories and work-in-progress break down as follows:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Raw materials inventories	2 124	1 668

Inventories of finished goods	2 585	1 733
Total gross inventories	**4 709**	**3 389**
Raw materials dep.	(241)	(332)
Expenditure on inventories and work-in-progress of finished goods	(207)	(194)
Total dep. of inventories and work-in-progress	**(448)**	**(526)**
Total net inventories	**4 261**	**2 863**

In 2024, inventories of raw materials and finished goods are higher than in 2023 due to an increase in production during the year.

Impairment mainly concerns slow-moving inventory and older generations of Cellvizio.

Note 8: Trade receivables and other current assets

8.1 Trade accounts receivable

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Accounts receivable	1 472	1 434
Impairment of trade receivables	(140)	(114)
Net trade accounts receivable	**1 332**	**1 320**

The allowance for doubtful debts represents 10% of gross receivables in 2024 and breaks down as follows:

(Amounts in thousands of euros)	31/12/2024	Less than one year	More than a year old
Accounts receivable	1 472	1 472	-
Impairment of trade receivables	(140)	(140)	-
Net trade accounts receivable	**1 332**	**1 332**	**-**

Provisions for receivables relate to a clinical trial project whose implementation is uncertain.

8.2 Other assets

Other current assets break down as follows:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Personnel and related accounts	4	9
Research tax credits	753	1 171
Other tax receivables	165	198
Other receivables	138	372
Prepaid expenses	367	390
Gross total of other current assets	**1 427**	**2 139**
Other receivables	-	-
Total net other current assets	**1 427**	**2 139**

Changes in the research tax credit (crédit d'impôt recherche - CIR) receivable were as follows:

(Amounts in thousands of euros)	31/12/2023	Operating income	Payment received	Other	31/12/2024
Research tax credit	1 171	753	(1 171)		753

The Research Tax Credit receivable corresponds to CIR 2024 amounting to 753 K€. Receivables for 2022 and 2023 have been reimbursed.

Other tax receivables relate to deductible VAT and the refund of VAT credit claimed, representing a total of €165,000 compared with €198,000 at December 31, 2023.

Other receivables mainly comprise prepayments to suppliers of €118,000, compared with €294,000 at December 31, 2023.

Note 9: Cash and cash equivalents

The item breaks down as follows:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Current accounts in EURO	1 081	1 174
Current accounts in USD	752	594
Current accounts in JPY	84	1
Short-term accounts in EURO	-	6 100
Locked account	100	100
Total cash and cash equivalents	**2 017**	**7 969**

Note 10:

10.1 Issued capital

The share capital is set at two million seven hundred and nine thousand two hundred and eighty-five euros and eight cents (€2,709,285.08). It is divided into 67,732,127 fully subscribed and paid-up shares with a par value of €0.04.

This number excludes "Bons de Souscription d'Actions" (BSA), "Bons de Souscription de Parts de Créateur d'Entreprise" (BSPCE), stock options (SO) granted to certain investors and individuals, whether or not employees of the Company, performance shares (AP) and bonus shares (AGA).

The table below shows the history of the Company's capital since December 31, 2023:

Type of operation	Capital (in K€)	Additional paid-in capital (in K€)	Number of shares issued	Number of shares outstanding (in thousands)
Total at December 31, 2022	**1 859**	**787**	**1 881**	**46 476**
AGAP conversion	-	-	2	46 478
BSA conversion (Kepler)	72	641	1 790	48 268
BSA conversion (Vester)	57	680	1 430	49 698
BSA subscription	-	23	-	49 698
Capital increase	476	5 514	11 912	61 610
Transaction costs	-	(70)	-	61 610
Total at December 31, 2023 (published)	**2 464**	**7 575**	**15 134**	**61 610**
Discount neutralization	-	47	-	61 610
Total at December 31, 2023	**2 464**	**7 622**	**15 134**	**61 610**
AGAP conversion	5	(5)	122	61 732
BSA conversion (Vester)	240	1 886	6 000	67 732
BSA subscription	-	24	-	67 732
Transaction costs	-	(62)	-	67 732
Total at December 31, 2024	**2 709**	**9 465**	**21 256**	**67 732**

On June 24, 2024, the Board of Directors acknowledged the end of the vesting period for bonus shares granted in 2021.

Vester Finance subscribed 4,070,000 shares in fiscal 2024 as part of the capital financing line set up in 2023. This transaction resulted in a share capital increase of 162,800 euros, accompanied by a share premium of 1,322,735 euros. As this contract expired in July 2024, a new equity financing line was set up with Vester Finance. Under this new line, 1,930,000 shares were subscribed, generating a share capital increase of 77,200 euros, together with a share premium of 436,333 euros.

This new contract enables Vester Finance to subscribe for up to 5,500,000 warrants (parity of 1 warrant for 1 share) at an exercise price based on the weighted average unit cost (CUMP) of the last 2 trading days, including a maximum discount of 6%. On the issue date, Vester paid a subscription price of €500,000, broken down into a nominal value and an issue premium.

Considering that the cash to be paid by Vester to exercise the warrants is not fixed, as it is indexed to the Company's share price, this contract falls within the scope of IFRS 9, as recommended by IAS 32.16(b)(ii). The contract also stipulates that Mauna Kea Technologies will have the right to modify the exercise conditions once a minimum capital increase of €750,000 has been reached. Analysis of the contract has led the Company to consider the subscription price paid as a prepayment on the subscription date. Up to the amount of €1,500,000, the capital increase is accounted for on a gross basis, with the 6% discount recognized as a financial expense. Once the 1,500 K€ has been reached, Mauna Kea Technologies will be able to modify the terms of exercise, and the contract will then fall outside the scope of IFRS.9. The residual warrants will be considered as equity instruments and will be recorded when they are exercised.

At December 31, 2024, 1,930,000 warrants had been exercised, resulting in a capital increase of €77,000. As the €1,500k threshold had not been reached at the balance sheet date, the residual warrants fall within the scope of IFRS and are recognized as financial derivatives at fair value (see note 12). The change in fair value with the issue date is recognized in financial income (see note 21).

10.2 Warrants, stock options and preferred shares

Since its creation, the Company has issued "Bons de Souscription d'Actions" (BSAs), employee share subscription warrants ("BSPCEs" and others), as well as stock options (SOs), performance shares (APs) and bonus shares (AGAs), details of which are given below since December 31, 2023.

		Options	Nb of potential actions
At December 31, 2023		**14 315 328**	**14 690 553**
Created over the period			
SO	31/01/2024	20 000	20 000
BSA	31/01/2024	50 000	50 000
SO	05/04/2024	50 000	50 000
AGA	24/06/2024	4 612 000	4 612 000
SO	24/06/2024	1 580 000	1 580 000
BSA	24/06/2024	240 000	240 000
BSA	23/07/2024	5 500 000	5 500 000
Exercised/converted during the period		(6 121 880)	(6 121 880)
Lost over the period		(902 900)	(902 900)

At December 31, 2024	**19 342 548**	**19 717 773**

The new instruments issued in 2024 are as follows:

- January 31, 2024: 20,000 options were issued to an employee;
- January 31, 2024: 50,000 warrants were issued to an external service provider;
- On April 05, 2024, 50,000 options were issued to an employee;
- On June 24, 2024, 4,612,000 bonus shares were issued to 43 employees and to the Chairman and Chief Executive Officer;
- On June 24, 2024, 1,580,000 options were issued to 11 employees;
- On June 24, 2024, 240,000 warrants were issued to a director;
- on July 23, 2024, 5,500,000 warrants were issued to Vester Finance.

The terms and conditions governing the exercise of preference shares and bonus shares are described in Note 16: Share-based payments.

10.3 Acquisition by the Company of its own shares

As part of its liquidity program with Gilbert Dupont, the Group bought back several of its own shares during the year, as summarized below:

	2024				
	1st quarter	**2nd quarter**	**3rd quarter**	**4th quarter**	**Total**
Securities purchased	654 939	580 205	725 705	261 578	2 222 427
Price	0.45	0.40	0.38	0.28	
Total amount (in K euros)	**294**	**232**	**273**	**73**	**872**
Securities sold	650 429	551 612	740 868	331 006	2 273 915
Price	0.44	0.40	0.38	0.25	
Total amount (in K euros)	**288**	**221**	**283**	**83**	**874**

At December 31, 2024, this contract was terminated and the Company no longer held any treasury shares.

Note 11: Borrowings and financial liabilities

(Amounts in thousands of euros)	**31/12/2023**	**Increase.**	**Decrease**	**Interest / Discounting**	**Reclassification from non-current to current**	**Other**	**31/12/2024**
Conditional advances BPI (ex Oseo)	4 308	-	-	106	-	-	4 414
Lease liability IFRS 16	530	1 184	(557)	-	-	11	1 168
PGE loan	2 699	95	(420)	(43)	(12)	-	2 319
EIB loan	21 414	22 098	(22 210)	2 055	-	-	23 357

BSA BEI	83	-	-	13	-	-	96
CIR mobilization	627	471	(627)	-	-	-	471
BSA Vester	98	-	-	(23)	-	-	75
Other	15	5	-	-	12	-	32
Total borrowings	**29 774**	**23 853**	**(23 814)**	**2 108**	**-**	**11**	**31 930**

Total financial debt amounted to 31,932 thousand euros, mainly comprising loans from the European Investment Bank (EIB) under the financing agreement signed in 2019 and restructured in 2024, an innovation grant from BPI France in 2010, and two government-guaranteed loans granted in 2020.

The restructuring of the EIB loan in 2024 led the Group to record the extinguishment of the initial loan and a new loan (see terms and conditions in paragraph 11.2).

The impact of the restructuring (see note 11.3 below) of the two EMPs was an increase in the fair value of financial debt and a new breakdown between current and non-current liabilities.

The breakdown between non-current and current financial debt at December 31, 2024 is as follows :

CHANGE IN NON-CURRENT BORROWINGS

(Amounts in thousands of euros)	**31/12/2023**	**Increase.**	**Decrease**	**Interest / Discounting**	**Reclassification from non-current to current**	**Other**	**31/12/2024**
Conditional advances BPI (ex Oseo)	4 308	-	-	106	-	-	4 414
Lease liability IFRS 16	149	1 184	-	-	(508)	1	826
PGE loan	1 706	95	-	(69)	(16)	-	1 716
EIB loan	7 097	-	(7 097)	-	-	-	-
BSA BEI	28	-	-	13	53	-	94
BSA Vester	98	-	-	(23)	-	-	75
Other	15	5	-	-	12	-	32
Total non-current borrowings	**13 401**	**1 284**	**(7 097)**	**27**	**(459)**	**1**	**7 157**

CHANGE IN CURRENT FINANCIAL DEBT

(Amounts in thousands of euros)	**31/12/2023**	**Increase.**	**Decrease**	**Interest / Discounting**	**Reclassification from non-current to current**	**Other**	**31/12/2024**
Lease liability IFRS 16	381	-	(557)	-	508	10	342

PGE loan	993	-	(420)	26	4	-	603
EIB loan	14 317	22 098	(15 113)	2 055	-	-	23 357
BSA BEI	53	-	-	-	(53)	-	-
Mobilization CIR / CII	627	471	(627)	-	-	-	471
Total current financial debt	**16 371**	**22 569**	**(16 717)**	**2 081**	**459**	**10**	**24 773**

At December 31, 2024, the Company had not obtained a formal *waiver* from the EIB concerning one of the clauses of the financing agreement, namely the obligation to maintain a cash position in excess of 4 million euros (see note 21). In the absence of this waiver agreement, the Company was potentially in *breach of* its contractual obligations, which could have rendered the debt payable, requiring it to be reclassified as a current liability at that date.

However, the opening of safeguard proceedings in favor of the Company on March 31, 2025 (see note 24) has had the effect of freezing the liabilities and suspending all commitments relating to this financing contract.

11.1 BPI advances (formerly OSEO Fi)

On May 31, 2010, Mauna Kea Technologies received reimbursable innovation funding from OSEO for its PERSEE project. The aim of this project was to develop, validate and market a device capable of improving diagnostic techniques and pre-operative extension assessments for cancer patients.

The project was closed at the end of 2020, and the fifth installment of the €504,000 repayable advance was received in December 2021. The advances bear interest at 2.45%.

The contract signed between OSEO, now BPIFrance, and the Company in 2010 stipulates that the first repayment is to be made once sales of €2,500,000 have been achieved on the new products developed. The amount to be repaid, based on the new repayment schedule, will be €4,724,000, including the discounting charge. If no repayment is made within 10 years of the last grant payment, Mauna Kea will be released from any obligation to pay financial returns. In addition, if cumulative sales exceed €50,000,000, 2% of the sales generated must be repaid over a period of 15 years.

11.2 EIB loans

The Company entered into a €22.5 million financing agreement with the European Investment Bank (EIB) on June 20, 2019, initially comprising three tranches. Only two tranches were ultimately drawn down by the Company, the third tranche no longer being available to the Company:

- A first tranche of 11,500 K€, cashed on July 3, 2019, bearing capitalized interest of 5%;
- A second tranche of €6,000,000, redeemed on July 8, 2020, with capitalized interest of 4% and cash interest of 3%.

The initial maturity of these tranches was five years, with repayment due in July 2024 for Tranche 1 and July 2025 for Tranche 2.

In view of these approaching maturities, the Company undertook a restructuring of the loan, finalized in April 2024. Under the terms of the new agreement, the EIB has agreed to defer final repayments of principal and interest to July 2028 for Tranche 1, and July 2029 for Tranche 2. The amended schedule provides for progressive repayments of principal as follows (i) €1.0 million in 2025, (ii) €2.5 million in 2026, (iii) €5.0 million in 2027. In addition, the agreement includes a commitment by the Company to pay annual royalties of 2% on certain revenues, over a period of six years from January 30, 2024, for a total minimum amount of €8 million, capped at €10 million.

Instruments are also attached to each of the tranches: (i) 1,450,000 share subscription warrants (BSA) under Tranche 1 entitling their holders to subscribe for a maximum of 1,450,000 shares in the Company at an exercise price of €1.24031 (initially €1.8856, lowered as part of the renegotiation), (ii) 500,000 BSA under Tranche 2 entitling their holders to subscribe for a maximum of 500,000 shares in the Company at an exercise price of €1.24031.

Finalization of the restructuring agreement remained conditional on (i) the revaluation of the exercise price of Tranche 1 warrants to €1.24031, approved at the 2024 Annual General Meeting, and (ii) the raising of €7 million in financing before April 30, 2025.

At the date of this document, the latter condition has not yet been met, resulting in a 4% increase in interest rates on all tranches from October 1, 2024.

Lastly, the opening of a safeguard procedure in favor of the Company on March 31, 2025, having the effect of freezing liabilities, suspends all commitments linked to this agreement, which are now being renegotiated with the EIB (see note 24).

In accordance with IFRS, the Group performed quantitative and qualitative tests to determine the accounting treatment to be applied following this restructuring. As a result, the Group recognized the extinguishment of the old loan and a new debt whose fair value was measured by applying a new effective interest rate. (See note 1.14)

11.3 PGE loans

On July 17, 2020, the Company obtained financing of 4 million euros from BNP Paribas and Bpifrance in the form of a Loan Guaranteed by the French State (PGE). BNP Paribas and Bpifrance have each granted a loan of 2 million euros at fixed interest rates of 0.25% and 1.75% respectively. These non-dilutive loans will be 90% guaranteed by the French state (ministerial orders of March 23 and April 17, 2020 granting state guarantees to credit institutions and financial companies, pursuant to article 6 of law no. 2020-289 of March 23, 2020). Each loan has an initial term of one year. At the end of the first year, repayment of the principal due may be deferred again, at the Company's discretion, for a maximum period of 5 years.

In 2021, the loans have been renegotiated and the new maturities are as follows: June 24, 2026 and August 31, 2026 with fixed interest rates of 0.75% and 2.25% respectively. BNP Paribas' principal repayment is monthly, while Bpifrance's is quarterly.

In 2024, the Group obtained a restructuring of the two loans:

- The maturity of the PGE BNP has been extended by 12 months from June 24, 2026 to June 24, 2027, with monthly amortization and interest resuming from May 24, 2025. The interest rate has been raised to 4%;
- The maturity of the PGE BPI has been extended by 12 months to August 31, 2027, with maturities resuming on June 1, 2025. The interest rate has been raised to 5.25%;
- A capital repayment waiver has been granted to the Group for the period from June 1, 2024 to May 31, 2025 inclusive, for both loans.

11.4 Mobilization of the CIR claim

The receivable of €753,000 relating to the CIR for 2024 was pre-financed by €471,000 in October 2024.

11.5 Derivative financial instruments

<u>BSA BEI</u>

As part of the financing agreed with the European Investment Bank (EIB), the Group issued share warrants. This issue was analyzed in accordance with IFRS 9 criteria. The existence of a put option and the variable nature of the number of shares to which the warrants will give entitlement result in the recognition of a derivative instrument which must be measured at fair value at the grant date. It is subsequently remeasured at each balance sheet date, with a corresponding adjustment to income.

Tranche 1 is accompanied by the issue of share subscription warrants (BSA) entitling the holder, if exercised, to subscribe for a maximum of 1,450,000 shares in the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These BSAs were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of October 5, 2018. The exercise price of the BSAs, initially equal to the volume-weighted average of the last three trading sessions prior to their issue, less a 5% discount i.e. €1.8856 per BSA, was reduced to €1.24031 following the restructuring in 2024. The warrants may be exercised until July 3, 2043 (initially until July 3, 2039).

Tranche 2 is also accompanied by the issue of share subscription warrants (BSA) entitling the holder, in the event of exercise, to subscribe for a maximum of 500,000 shares in the Company (i.e. 1.6% of the share capital on a non-diluted basis). These BSAs were issued on the basis of the twenty-fourth resolution adopted by the Combined General Meeting of July 2, 2020. The exercise price of the warrants is equal to the volume-weighted average of the last three trading sessions preceding their issue, less a 5% discount, i.e. €1.24031 per warrant. The warrants may be exercised until July 3, 2044 (initially until July 3, 2039).

These issues were analyzed in accordance with IFRS 9 criteria, and gave rise to the recognition of derivative instruments measured at fair value at the grant date. They are subsequently revalued at each balance sheet date, with a corresponding adjustment to income.

At December 31, 2024, these derivatives were revalued on the basis of the following assumptions:

	BSA Tranche 1	**BSA Tranche 2**
Valuation at December 31, 2024	73 K€	24 K€
Theoretical maturity	19.5 years	20.5 years
Probable maturity	5.5 years	5.5 years
Volatility	55% at 4.5 years 45% at age 19	55% at 4.5 years 45% at age 19
Repo rate	4.0% per annum	4.0% per annum
Reference price	0,20 €	0,20 €

The change in value between December 31, 2023 and December 31, 2024 is recognized in financial income in the income statement.

BSA Vester

In July 2024, an equity financing line was set up with Vester Finance.

The exercise procedures are described in Note 10.1 - Issued capital.

11.6 Debt maturity

Debt maturity at December 31, 2024 is as follows :

(Amounts in thousands of euros)	**Gross amount**	**Less than one year**	**One to three years**	**Three to five years**	**More than five years**
Long-term debt	7 157	-	1 715	5 442	-
Short-term borrowings and financial debts	24 773	24 773	-	-	-

Trade accounts payable	3 274	3 274	-	-	-
Other current liabilities	5 282	5 282	259	-	-
Total financial liabilities	**40 486**	**33 329**	**1 974**	**5 442**	**-**

Note 12: provisions

Non-current provisions break down as follows:

(Amounts in thousands of euros)	31/12/2023	Endowments	Unused reversals	Used reversals	Other	31/12/2024
Pension commitments	47	16	(1)	-	-	62
Provisions for litigation	25	47	-	(25)	-	47
Total non-current provisions	**72**	**63**	**(1)**	**(25)**	**-**	**109**

(Amounts in thousands of euros)	31/12/2022	Endowments	Unused reversals	Used reversals	Other	31/12/2023
Pension commitments	80	15	(13)	-	(35)	47
Provisions for litigation	26	25	-	(26)	-	25
Restructuring provisions	13	-	(13)	-	-	-
Total non-current provisions	**119**	**40**	**(26)**	**(26)**	**(35)**	**72**

commitments

For the purposes of estimating retirement commitments, the following assumptions have been made for all employee categories (employees, supervisors and managers):

- Retirement age: 64,
- Departure terms: voluntary departure,
- Mortality table: INSEE 2024
- Collective bargaining agreement: metallurgy,
- Staff rotation :
    - 18-25 years: 0% of sales
    - 26-35 years: 18
    - 36-45 years: 16
    - 46-55 years old: 24
    - > 56 years old: 0% of sales
- Employer contribution rate: 47% (identical to 2023)
- Salary increase rate: 2.5% (identical to 2023)
- Discount rate: 3.35% (versus 3.20% 2023) corresponding to the iBoxx Corporate AA10+ rate

The Group does not finance its retirement benefit obligations.

Termination benefits amounted to €100,000 at the close of the 2024 financial year.

Note 13: Trade payables and other current liabilities

No discounting has been applied to trade payables and other current liabilities, as they mature in less than 1 year at the end of each year in question.

13.1 Trade payables and accounts

Trade accounts payable break down as follows:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Trade accounts payable	3 274	2 774

The increase in trade payables is due to longer payment terms.

13.2 Other current liabilities

Other current liabilities break down as follows:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Tax liabilities	449	578
Social debts	1 732	1 438
Other liabilities	109	235
Deferred income	2 992	5 306
Total other current liabilities	**5 282**	**7 557**

Tax liabilities mainly concern :

- payroll, sales and value-added taxes,
- and the balance of corporate income tax due in 2023.

Social security liabilities mainly comprise provisions for paid vacations, provisions for bonuses and commissions, and amounts due to social security bodies. The increase is due to a payment schedule negotiated with the social security bodies and the tax authorities.

Deferred income mainly corresponds to service contracts and extended warranties whose recognition in sales is deferred under IFRS 15. At December 31, 2022, this item had been increased by $6.5 million receivable under the licensing agreement with Tasly Pharmaceutical. This amount is recognized in sales over the estimated duration of the Group's support of the JV teams, i.e. 36 months. In fiscal 2024, 2.2 million euros were therefore recognized in this respect. The remaining balance is due within one year.

Note 14: On-balance sheet financial instruments

At December 31, 2024 (in thousands of euros)	Balance sheet value	Fair value through profit or loss	Fair value through equity	Loans and receivables	Debt at amortized cost
Assets					
Non-current financial assets	222	-	-	222	-
Accounts receivable	1 332	-	-	1 332	-
Other current assets (1)	1 060	-	-	1 060	-
Current financial assets	-	-	-	-	-
Treasury	2 017	2 017	-	-	-
Total assets	**4 631**	**2 017**	**-**	**2 614**	**-**
Liabilities					
Long-term debt	7 158	169	-	-	6 989
Short-term borrowings and financial debts	24 773	-	-	-	24 773
Trade accounts payable	3 274	-	-	-	3 274
Other current liabilities (1)	2 290	-	-	-	2 290
Total liabilities	**37 495**	**169**	**-**	**-**	**37 326**

(1) Advances and deposits received which are not repayable in cash, and deferred income and expenses which do not meet the definition of a financial liability, have not been included.

Note 15: Sales and operating income

Sales and operating income break down as follows:

15.1

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Sales figures	7 655	10 480
Operating subsidies	7	11
Research tax credits and other tax credits	753	536
Total income	**8 415**	**11 027**

Group sales in 2024 will be made up of :

- sales of Cellvizio® systems, consumables and related services;
- revenues from the strategic agreement signed with Tasly Pharmaceutical. For 2024, the Group recognized 2.2 million euros in sales linked to the recognition over 3 years of the 6.5 million dollar payment relating to the licensing agreement. In 2023, these revenues also included upfront income of $2.5 million from the JV in respect of know-how relating to the transferred patents (see note 1.18).

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Sales by geographical segment at December 31, 2024 were as follows:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
EMEA (Europe, Middle East, Africa)	1 983	1 622
USA and Canada	3 456	4 493
Asia	2 216	4 365
Total sales by geographic area	**7 655**	**10 480**

For the purposes of geographical analysis, Group Management allocates sales according to the place of delivery of products or, in the case of services, according to the location of the customer's head office.

15.2 Tax credits

The Research Tax Credit amounts to 753 thousand euros for 2024, up on 2023 due to the increase in eligible expenses, mainly personnel costs.

Note 16 Share-based payments

Share-based payments concern all warrants (BSA/BSPCE/SO), preference shares (AP) and bonus shares (AGA) granted to employees, service providers and members of the Board of Directors. The terms and conditions of exercise are detailed in the minutes of the Annual General Meetings.

The main other assumptions used to determine the expense arising from share-based payments using the Black-Scholes valuation model were as follows:

- Risk-free interest rate: government bond rate (GFRN index),
- Dividend: none,
- Turnover: 20%,
- Volatility: 55% for BSAs, BSPCEs and SOs granted in 2024.

The volatility used corresponds to the average of the historical volatilities of a panel of listed companies in the same business sector as the Company and/or with a market capitalization and trading volumes comparable to those of the Company. Listed companies whose shares were traded for less than €1 were excluded from the panel.

The exercise price, estimated life and fair value of the underlying shares at the grant date were used to value each category of share-based compensation.

In 2024, the impact of share-based payments resulted from the issue of 6,552,000 instruments giving rights to the capital, representing almost 9.7% of the capital at December 31, 2024. These instruments were allocated to employees, directors and external service providers, with a view to aligning their interests with those of the shareholders.

Note 17 External expenses

17.1 Cost of sales

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Purchases consumed	890	918
Personnel expenses	568	549
External expenses	110	108
Taxes	18	21
Net changes in depreciation, amortization and impairment	486	504
Change in work-in-progress and finished goods	(869)	(13)
Other	12	32
Total Cost of sales	**1 215**	**2 118**

In 2024, the cost of goods sold fell due to an increase in inventoried production with the postponement of system sales in the United States and the absence of minimum orders by the JV in China.

17.2 Research and costs

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Purchases consumed	41	2
Personnel expenses	2 271	2 586
External expenses	584	521
Taxes	34	37
Net changes in depreciation, amortization and impairment	610	702
Change in work-in-progress and finished goods	11	31
Other operating income and expenses	(1)	12
Total Research & Development	**3 550**	**3 860**

Personnel expenses include all payroll costs for R&D staff. Their decrease is explained by the change in headcount over the period.

External expenses mainly comprise research costs, costs of maintaining patent protection and consultancy fees.

17.3 Sales & Marketing costs

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Purchases consumed	(13)	(43)
Personnel expenses	3 394	3 945
External expenses	1 202	1 707
Taxes	18	18
Net changes in depreciation, amortization and impairment	91	(48)
Other	13	40
Total Sales & Marketing	**4 705**	**5 618**

Personnel expenses include all payroll costs for sales and marketing staff. The decrease is due to a reduction in the sales force following several departures, as well as a reduction in variable remuneration in line with the decline in sales in the United States;

External expenses mainly comprise travel expenses for sales staff, and costs related to trade shows and other marketing events. These expenses fell over the period, reflecting the implementation of an active cost-cutting policy.

17.4 Overhead costs

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Purchases consumed	56	38
Personnel expenses	1 640	1 868
External expenses	2 248	2 632
Taxes	206	105
Net changes in depreciation, amortization and impairment	591	556
Other	(296)	(195)
Total overheads	**4 445**	**5 004**

Personnel expenses include all payroll costs relating to general management and support functions (human resources, legal affairs, finance, etc.). They fell over the period, mainly reflecting the absence of variable compensation paid to members of the Executive Committee for the year, as well as a voluntary reduction in compensation for the Chairman and Chief Executive Officer.

External expenses also fell, despite a one-off increase in legal fees linked to loan renegotiations. This reduction is the result of an active policy of cost control and reduction.

Note 18 Non-current operating income

At December 31, 2023, non-recurring operating income and expenses amounted to 6,918 thousand euros, corresponding to the Group's share of the capital gain on the sale of patents to the Tasly Mauna Kea Medical Engineering Technology Co. Ltd joint venture, less the fees paid to Cenponts in connection with the transaction.

Note 19 Financial income and expense

Financial income and expenses break down as follows:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Foreign exchange gains	219	585
Other financial income	239	359
Total financial income	**458**	**944**
Foreign exchange losses	(365)	(602)
Interest expense	(457)	(270)
Other financial expenses	(238)	(79)
Depreciation of financial assets	-	(8)
Losses on cash equivalents	-	1
Discounting expenses	(2 036)	(1 943)
Total financial expenses	**(3 096)**	**(2 900)**
Total financial income and expense	**(2 638)**	**(1 956)**

Financial income consists mainly of :

- foreign exchange gains and interest on short-term accounts, down sharply over the period ;
- the impact under IFRS of the renegotiation of the EIB loan for 112 K€ (see note 1.14).

Financial expenses mainly include discounting charges corresponding to interest on the loan granted by the EIB and the repayable advance from BPI France.

Note 20 Income tax expense

For reasons of prudence, the Group has not activated its tax losses in France and the United States.

The accounting impact of the introduction of the J.V. and French tax legislation have led to the recognition of a tax charge for the 2023 financial year.

(Amounts in thousands of euros)	31/12/2024	31/12/20223
Net income of consolidated companies	(10 404)	(3 727)
Share of profit of associates	1 683	2 528
Income tax expense	-	475

Profit before tax of consolidated companies	**(8 721)**	**(725)**
Theoretical income tax expense 25% of sales	**(2 180)**	**(181)**
Other non-deductible expenses and non-taxable income	(44)	(45)
Tax rate differential	(528)	(459)
Limitation of deferred tax assets not capitalized	2 752	1 160
Actual tax expense	**0**	**475**

Note 21 Commitments

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Share - 1 year	671	1 280
Share 1 to 5 years	3 123	1 989
Share over 5 years	-	-
Total Commitments Other contracts	**3 794**	**3 269**

At December 31, 2024, commitments are as follows:

EIB loan obligations

Following the EIB financing restructuring agreement signed on April 24, 2024, the obligations have been updated. Firstly, the agreement stipulates that finalization will be definitively acquired as soon as the Group has raised 7 million euros through licensing agreements, partnerships, fundraising or other means between January 1, 2024 and April 30, 2025. In addition, the agreement includes a commitment to pay annual royalties of 2% on certain revenues over a period of six years from January 30, 2024, capped at 10 million euros.

The guarantees given by the EIB on inventories and trade receivables, and on the pledge of certain patents, have been extended to cover the new maturities.

Financial covenants are also included in the contractual obligations:

- A cash position in excess of 4 million euros;

- Debt coverage ratio greater than 2.0:1.0;

- A debt-to-equity ratio of 1.0:1.0 ;

- A minimum level of income and EBITDA.

Obligations under other contracts

The Group subcontracts the manufacture of certain subassemblies required for its products to suppliers. In order to secure its operations, it has undertaken to purchase a certain quantity of sub-assemblies from certain suppliers.

Collateral

In order to guarantee its financial obligations towards a service provider essential to the continuity of its operations, the Company has set up a stand-by letter of credit. In return for this commitment, a €100,000 interest-bearing bank account has been pledged, and will remain blocked until March 24, 2025.

Note 22 Related party transactions

The following remuneration granted to members of the Executive Board and other Group related parties was expensed in the years presented:

(Amounts in thousands of euros)	31/12/2024	31/12/2023
Salaries and wages of key executives	197	211
Share-based payments to key executives	136	40
Pension commitments for key executives	4	1
Directors' fees Corporate officers	54	76
Share-based payments Corporate officers	48	33
	439	**361**

Note 23 Earnings per share

	31/12/2024	31/12/2023
Net income (in K€)	**(10 404)**	**(3 727)**
Weighted average number of shares outstanding (in thousands)	64 072	49 302
Earnings per share (in €)	**(0.16)**	**(0.08)**
Weighted average number of potential shares (in thousands)	70 073	62 077

Basic earnings per share are calculated by dividing net income attributable to Group shareholders by the weighted average number of ordinary and preference shares outstanding during the year.

Note 24 Post-balance sheet events

On March 31, 2025, the Tribunal des activités économiques de Paris (Paris Economic Activities Court) granted the Company's request to open safeguard proceedings, in view of its financial situation. This move is part of a proactive commitment by Mauna Kea Technologies' management to create the most favorable conditions for the success of its transformation, and to maximize the unique value of its technology. During this observation period, the Company will continue to operate under the legal protection afforded by the procedure, while benefiting from more favorable conditions to conclude its strategic and financial negotiations. As such, the Company's pre-proceeding liabilities are frozen for the duration of the proceedings.

Also on March 31, 2025, the Company officially entered into exclusive negotiations for a licensing agreement for its Cellvizio technology in a broad therapeutic area, with a major player in the sector.

5.2.2. Statutory auditors' reports on the consolidated financial statements

Statutory auditor's report on the consolidated financial statements

To the Annual General Meeting of Mauna Kea Technologies,

Opinion

In compliance with the assignment entrusted to us by your Annual General Meeting, we have audited the accompanying consolidated financial statements of Mauna Kea Technologies for the year ended December 31, 2024.

In our opinion, the consolidated financial statements give a true and fair view of the financial position and the assets and liabilities of the Group as at December 31, 2009 and of the results of its operations for the year then ended in accordance with IFRSs as adopted by the European Union.

Basis of opinion

- **Audit framework**

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under these standards are set out in the section of this report entitled "Statutory Auditors' Responsibilities Relating to the Audit of the Consolidated Financial Statements".

- **Independence**

We conducted our audit in accordance with the rules of independence set out in the French Commercial Code (Code de commerce) and in the Auditors' Code of Ethics, covering the period from January 1 2024 to the date of issue of our report.

Significant going concern uncertainty

Without qualifying the opinion expressed above, we draw your attention to the significant uncertainty relating to events or circumstances that may call into question the going concern assumption described in note 1.1 "Group accounting policies" to the consolidated financial statements.

Justification of assessments

In accordance with the requirements of articles L. 821-53 and R. 821-180 of the French Commercial Code (Code de commerce) relating to the justification of our assessments, we hereby inform you that, in addition to the matter described in the section entitled "Significant uncertainty relating to the going concern assumption", the most significant assessments we made, in our professional judgment, concerned the appropriateness of the accounting policies applied.

These assessments were made in the context of our audit of the consolidated financial statements taken as a whole, and of the formation of our opinion expressed above. We do not express an opinion on any individual component of these consolidated financial statements.

Specific checks

In accordance with professional standards applicable in France, we have also verified the information given in the Board of Directors' management report relating to the Group.

We have no matters to report as to its fair presentation and consistency with the consolidated financial statements.

Responsibilities of management and those charged with corporate governance in relation to the consolidated financial statements

It is the responsibility of management to prepare consolidated financial statements that give a true and fair view in accordance with IFRS as adopted by the European Union, and to implement such internal control procedures as it determines are necessary to ensure that the consolidated financial statements are free from material misstatement, whether due to fraud or error.

When preparing the consolidated financial statements, it is the responsibility of management to assess the company's ability to continue as a going concern, to present in these statements, where appropriate, the necessary going concern information and to apply the going concern accounting policy, unless the company is to be wound up or cease trading.

The consolidated financial statements have been approved by the Board of Directors.

Statutory auditor's responsibilities relating to the audit of consolidated financial statements

Our responsibility is to issue a report on the consolidated financial statements. Our objective is to obtain reasonable assurance about whether the consolidated financial statements, taken as a whole, are free from material misstatement. Reasonable assurance refers to a high level of assurance, without however guaranteeing that an audit performed in accordance with professional standards would systematically detect any material misstatement. Misstatements may be the result of fraud or error and are considered material when it is reasonable to expect that they could, individually or in aggregate, influence the economic decisions made by users of the financial statements.

As stipulated by Article L. 821-55 of the French Commercial Code, our role in auditing the financial statements is not to guarantee the viability or quality of your company's management.

In the context of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit. In addition :

- identifies and assesses the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, designs and implements audit procedures to address these risks, and obtains audit evidence that it believes to be sufficient and appropriate to provide a basis for its opinion. The risk of not detecting a material misstatement resulting from fraud is higher than that of a material misstatement resulting from error, as fraud may involve collusion, falsification, deliberate omission, misrepresentation or circumvention of internal controls;

- it obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, and not for the purpose of expressing an opinion on the effectiveness of internal control ;

- it assesses the appropriateness of the accounting methods used and the reasonableness of the accounting estimates made by management, as well as the related disclosures in the consolidated financial statements;

- It assesses the appropriateness of management's application of the going concern accounting policy and, based on the information gathered, whether or not there is any significant uncertainty related to events or circumstances that could call into question the company's ability to continue as a going concern. This assessment is based on information gathered up to the date of his report, bearing in mind that subsequent events or circumstances could call into question the company's ability to continue as a going concern. If it concludes that there is a material uncertainty, it draws the attention of the readers of its report to the information provided in the consolidated financial statements concerning this uncertainty or, if this information is not provided or is not relevant, it issues a qualified opinion or a refusal to certify;

- It assesses the overall presentation of the consolidated financial statements, and whether they give a true and fair view of the underlying transactions and events;

- concerning the financial information of the persons or entities included in the scope of consolidation, it gathers information that it considers sufficient and appropriate to express an opinion on the consolidated financial statements. He is responsible for directing, supervising and performing the audit of the consolidated financial statements, and for expressing an opinion on these financial statements.

Paris-La Défense, April 30, 2025

The Statutory Auditor
ERNST & YOUNG et Autres

Franck Sebag

5.3. Parent company financial statements

5.3.1. Parent company financial statements for the year ended December 31, 2024

Balance sheet assets

Sections	Gross amount	Amort. Prov.	Net 31/12/2024	Net 31/12/2023
INTANGIBLE ASSETS				
Concessions, patents and similar rights	909 983	(891 613)	18 371	7 043
Other intangible assets	45 278	(22 291)	22 986	21 420
Advance payments on intangible assets Intangible			-	-
PROPERTY, PLANT AND EQUIPMENT				
Buildings	49 715	(49 715)	-	-
Plant, machinery and equipment	1 073 057	(1 015 390)	57 667	83 734
Other property, plant and equipment	1 176 289	(1 051 337)	124 952	169 189
LONG-TERM INVESTMENTS				
Other investments	16 924 039	(1 950 077)	14 973 962	16 433 962
Receivables from investments	81 189 736	(74 974 338)	6 215 398	6 134 558
Other long-term investments	212 310	-	212 310	298 322
FIXED ASSETS	**101 580 405**	**(79 954 760)**	**21 625 646**	**23 148 228**
INVENTORIES AND WORK-IN-PROGRESS				
Raw materials and supplies	1 953 126	(241 388)	1 711 737	1 214 251
Intermediate and finished products	2 823 599	(830 426)	1 993 174	1 381 826
Advances and deposits paid on orders	111 708	-	111 708	294 445
RECEIVABLES				
Accounts receivable	1 075 197	(28 294)	1 046 903	1 120 454
Other receivables	924 358	-	924 358	777 812
MISCELLANEOUS				
Availability	1 273 546	-	1 273 546	7 540 327
ACCRUALS AND DEFERRALS				
Prepaid expenses	367 196	-	367 196	389 663
CURRENT ASSETS	**8 528 730**	**(1 100 108)**	**7 428 622**	**12 718 777**
Deferred debt issuance costs	112 956		112 956	

Cumulative translation adjustment	61 049	-	61 049	7 143
GENERAL TOTAL	**110 283 141**	**(81 054 868)**	**29 228 273**	**35 874 148**

- **Balance sheet liabilities**

Sections	Exercise 2024	Exercise 2023
Share or individual capital (of which paid-in: 2,709,285)	2 709 285	2 464 410
Additional paid-in capital	9 290 794	7 575 178
Other reserves	53 975	53 975
Retained earnings	(18 225 742)	(28 628 034)
RESULT FOR THE YEAR (profit or loss)	**(13 839 043)**	**10 402 292**
SHAREHOLDERS' EQUITY	**(20 010 731)**	**(8 132 179)**
Proceeds from issues of redeemable shares		
Conditional advances	4 414 104	4 308 575
OTHER EQUITY	**4 414 104**	**4 308 575**
Provisions for contingencies	107 837	32 143
Provisions for charges	-	-
PROVISIONS	**107 837**	**32 143**
FINANCIAL LIABILITIES		
Borrowings from credit institutions	2 244 717	2 661 156
Borrowings and other financial liabilities	24 297 693	21 334 820
OPERATING LIABILITIES		
Trade accounts payable	3 068 111	2 965 361
Tax and social security liabilities	2 126 511	1 942 553
MISCELLANEOUS LIABILITIES		
Other liabilities	15 608	28 959
ACCRUALS AND DEFERRALS		
Deferred income	2 225 339	4 587 591
DEBTS	**33 977 978**	**33 520 439**
Translation adjustment liabilities	10 739 085	6 145 169
GENERAL TOTAL	**29 228 273**	**35 874 148**

 Income statement

Sections	Fiscal 2024			Exercise
	France	Exports	Total	2023
Sales of merchandise	-	-	-	75
Sales of goods	360 703	2 611 635	2 972 338	3 820 940
Sales of services	105 368	3 217 133	3 322 501	5 328 649
NET SALES	**466 071**	**5 828 768**	**6 294 839**	**9 149 665**
Stocked production			854 069	89 995
Operating subsidies			6 500	10 667
Write-backs of dep. (and depreciation), expense transfers			486 739	222 529
Other products			282 702	345 716
OPERATING INCOME			**7 924 849**	**9 818 571**
Purchases of raw materials and other supplies)			(1 463 295)	(1 036 658)
Change in inventories (raw materials and supplies)			408 391	(38 528)
Other purchases and external charges			(4 189 670)	(4 628 503)
Taxes and similar payments			(264 578)	(171 472)
Wages and salaries			(3 956 654)	(4 338 021)
Social security charges			(1 777 449)	(1 921 961)
Operating allowances :				
On fixed assets: depreciation and amortization			(124 952)	(254 178)
On fixed assets: impairment losses			-	-
On current assets: impairment charges			(474 286)	(408 819)
Provisions			-	-
Other expenses			(64 832)	(172 900)
OPERATING EXPENSES			**(11 907 326)**	**(12 971 039)**
OPERATING INCOME			**(3 982 477)**	**(3 152 468)**
FINANCIAL PRODUCTS			**3 955 445**	**2 716 199**
Other interest and similar income			3 926 755	2 326 291
Reversals of provisions and expense transfers			8 485	9 316
Positive exchange rate differences			20 205	380 592
FINANCIAL EXPENSES			**(14 437 181)**	**(4 389 492)**

Depreciation, amortization and provisions		(11 462 929)	(2 603 211)
Interest and similar expenses		(2 962 582)	(1 353 070)
Negative exchange differences		(11 670)	(433 211)
Net expenses on disposals of marketable securities			
FINANCIAL RESULT		**(10 481 736)**	**(1 673 293)**
INCOME FROM ORDINARY ACTIVITIES BEFORE TAX		**(14 464 213)**	**(4 825 761)**
EXTRAORDINARY INCOME		**31 888**	**16 775 139**
Extraordinary income from management operations		5 581	305
Extraordinary income from capital transactions		1 308	16 762 227
Reversal of provisions and expense transfers		25 000	12 608
EXCEPTIONAL EXPENSES		**(160 111)**	**(1 607 978)**
Exceptional expenses on management operations		(13 197)	(8 577)
Exceptional expenses on capital transactions		(100 126)	(1 574 400)
Exceptional depreciation, amortization and provisions		(46 788)	(25 000)
EXTRAORDINARY RESULT		**(128 223)**	**15 167 162**
Income tax		753 393	60 892
TOTAL REVENUE		**11 912 182**	**29 309 910**
TOTAL EXPENSES		**(25 751 225)**	**18 907 617**
PROFIT OR LOSS		**(13 839 043)**	**10 402 292**

- **Company activity**

Founded in 2000, Mauna Kea Technologies is a global medical device company that manufactures and markets Cellvizio®, the real-time in vivo cell imaging platform. This technology offers unique in vivo cellular visualization, enabling physicians to monitor disease progression over time, assess reactions as they occur, classify areas of uncertainty and guide surgical interventions. The Cellvizio® platform is used in many countries around the world and in several medical specialties, transforming the way doctors diagnose and treat patients.

- **Key events of the year**

Sales in the United States

Pay-per-use (PPU) activity remained buoyant throughout 2024, with quarterly volumes comparable to those of 2023, averaging almost 1,000 procedures per quarter. This represents a significant increase of almost 50% on 2022 and previous years.

However, the positive impact of this volume growth was offset by a negative price effect resulting from the reduction in Medicare reimbursement rates by CMS (*Centers for Medicare & Medicaid Services*). This reduction resulted from misreporting of costs by hospitals, which had an impact on the rates charged by ambulatory surgery centers (ASCs).

The Group has made considerable efforts to rectify these errors, and has succeeded in raising awareness among 80% of the hospitals that provided erroneous data.

It should be noted that in 2025, reimbursement rates are expected to remain in the same APC classification, as CMS relies on 2023 data to set 2025 rates. However, a favorable adjustment is expected no later than January 2026, when CMS will integrate the corrected 2024 data and take into account the provisional data provided through direct collaboration with the Group. This adjustment should restore reimbursement levels to the highest APC level, representing an increase of over 50% in reimbursement rates for Medicare beneficiaries.

Capital sales amounted to three Cellvizio® systems in 2024, including one sold to *Ohio State University* in Q4, compared with four systems in 2023. This represents a significant shortfall in Q4, when the company was in active negotiations for seven Cellvizio® sales, three of which should be concluded in January.

While capital sales cycles have lengthened, the pipeline remains strong, representing a total of 13 active opportunities in the United States.

CellTolerance

In the second half of the year, the Group launched CellTolerance, a new brand and multidisciplinary program dedicated to the treatment of food intolerances through a B2B2C "cash-pay" business model. This strategic initiative enables the Group to address a very significant and fast-growing market, and to overcome reimbursement barriers.

To support this new strategy, a dedicated pilot center was inaugurated in the fourth quarter of 2024 to validate the operating model and accelerate deployment in complementary networks from 2025.
The launch has been very well received, and the pipeline of active opportunities is already substantial, with 42 activable accounts identified and expectations of continued growth in the months ahead. The Group has achieved sales of around 0.5 million euros in 2024, and is aiming to at least triple sales by 2025.

JV in China

Commercial activity in China via the Group's joint venture with Tasly Pharmaceutical has so far been very limited, despite the Chinese market's strong interest in endomicroscopy. Due to differing interpretations of the financial obligations to be met by Tasly Pharmaceutical and the joint venture, the loss of revenue opportunity is estimated at around 2 million euros. Mauna Kea is currently evaluating all options to remedy the current difficulties.

Review of strategic options

On November 19, 2024, the Group announced the launch of a strategic process covering a broad spectrum of possibilities, from a merger and acquisition to the conclusion of licensing and/or marketing agreements. As part of this process, the Group has retained the services of RM Global, a US investment bank specializing in the healthcare sector.

This process is designed to ensure the Company's operational stability and secure the financing needed to deploy the long-term commercial potential of its Cellvizio platform.

Events since the year-end

On March 31, 2025, the Paris Business Court granted the Company's request to open a safeguard procedure, in view of its financial situation. This move is part of a proactive commitment by Mauna Kea Technologies' management to create the most favorable conditions for the success of its transformation, and to maximize the unique value of its technology. During this observation period, the Company will continue to operate under the legal protection afforded by the procedure, while benefiting from more favorable conditions to conclude its strategic and financial negotiations. As such, the Company's pre-proceeding liabilities are frozen for the duration of the proceedings.

Also on March 31, 2025, the Company officially entered into exclusive negotiations for a licensing agreement for its Cellvizio technology in a broad therapeutic area, with a major player in the sector.

Accounting rules and methods

Note 1: Accounting principles

The Company's annual financial statements have been prepared in accordance with the standards, principles and methods of the general chart of accounts appended to regulation 2016-07 of the French Accounting Standards Authority (Autorité des Normes Comptables) of November 4, 2016, approved by the decree of November 2016, in compliance with the provisions of French law, in compliance with the principle of prudence, in accordance with the basic assumptions and in compliance with the general rules governing the preparation and presentation of annual financial statements :

1. Consistency of accounting policies from one year to the next ;
2. Exercise independence ;
3. Continuity of operation.

Over the past few years, the Company has significantly reduced its losses and cash consumption, which now stands at around half a million euros per month, excluding financing repayments. Although it remains dependent on external financing (capital increases, loans or other) at this stage, this dependence is much less pronounced than before. Indeed, based on its business plan, the Company expects to reach profitability by the end of 2026.

In order to ensure sufficient financial visibility over the next few years, on March 31, 2025 the Company obtained the opening of a safeguard procedure. This will first freeze bank repayments for the duration of the procedure (six months, renewable), then allow the debt to be reorganized by spreading repayments over a period of up to ten years, and potentially to obtain debt write-offs.
In view of these factors, as well as the financial resources available at December 31, 2024 (2.0 million euros in cash and cash equivalents, including the US subsidiary) and the momentum of commercial activity, the Company estimates that it will be able to finance its operations until the end of the first half of 2025. It also estimates its twelve-month financing requirement at around 5 million euros, including its US business, and has several options to cover it.

On the one hand, as part of the strategic process launched at the end of 2024, the Company has initiated several discussions for licensing agreements with strategic partners, likely to give rise to upfront payments on signature, as well as additional payments linked to the achievement of operational and commercial targets. More specifically, on March 31, 2025, the Company announced that it had entered into exclusive negotiations for a licensing agreement in a broad therapeutic area, while at the same time pursuing other strategic discussions. In addition, the Company is studying with several investment banks various dilutive financing solutions (capital increases via public offerings or private placements) or debt financing.

In view of these various options, the Company considers at this stage that the risk of not securing the financing required to continue its activities in the coming months remains moderate. On the basis of these factors, the Board of Directors has adopted the going concern assumption. However, the outcome of these discussions, whether concerning licensing agreements or financing solutions, is not guaranteed. This constitutes a significant uncertainty which could jeopardize the Company's ability to continue as a going concern.

The most significant accounting principles and methods used to prepare the parent company financial statements are summarized below:

Note 2: Fixed assets

Tangible and intangible fixed assets

Patents and in-house research and development costs are expensed as incurred.

Other property, plant and equipment and intangible assets are recognized at acquisition cost and depreciated over their estimated useful lives.

The depreciation method and duration by asset category are summarized below:

Category	Duration	Mode
Software	1 to 3 years	Linear
Patents, Licenses, Trademarks	20 years	Linear
Other property, plant and equipment :		
- fittings	7 years	Linear
- tooling	2 to 7 years	Linear
- computer equipment	3 years	Linear
- furniture	5 years	Linear

Long-term investments and marketable securities

Fixed assets have been valued using the historical cost method, which is characterized by the use of nominal costs expressed in current euros. The gross value is the purchase cost excluding incidental expenses. When the inventory value is lower than the gross value, a provision for depreciation is booked for the difference.

Note 3: Inventory valuation

Inventories are valued at acquisition cost using the following methods:

Designations	Methods
Raw materials	Weighted average cost
Work in progress	Cost of work-in-progress
Finished products	Cost of goods sold, excluding marketing costs

The acquisition cost comprises :

- of the purchase price, including customs duties and other non-recoverable taxes,
- after deduction of trade discounts, rebates, cash discounts and similar items,
- transport, handling and storage costs (if justified by specific operating conditions),
- and other costs directly attributable to the acquisition.

Production costs include consumption of raw materials, direct expenses and depreciation of assets used in production.

Demonstration equipment intended for short-term sale is recorded in inventory.

Where necessary, inventories have been written down to reflect their realizable value at the balance sheet date.

Note 4: Receivables

Receivables are valued at their face value. A provision for impairment is recorded when the inventory value is lower than the book value.

Note 5: Provisions

In accordance with the principle of prudence, provisions for liabilities and charges are set aside to cover probable outflows of resources to third parties for which the Company has no counterpart. These provisions are estimated on the basis of the most probable assumptions at the balance sheet date.

The Company has not opted to recognize a provision for retirement commitments.

Note 6: Foreign currency transactions

Income and expenses in foreign currencies are recorded at their exchange value on the transaction date.

Foreign currency receivables and payables at year-end are translated at the exchange rate prevailing at that date. Translation differences are recorded in the balance sheet under "Translation adjustments".

Unrealized foreign exchange losses that have not been offset are covered by a provision for risks.

Cash accounts in foreign currencies at year-end are translated at the exchange rate prevailing at that date. Foreign exchange gains and losses arising on translation are recognized in the income statement.

Note 7: Subsidies

The Company has received a number of grants and conditional advances. Details of these grants are provided in the Financial Debts note in paragraph 5.3.3.

Grants are recognized when there is reasonable assurance that the Company will comply with the conditions attached to them and that they will be received.

Subsidies are therefore recognized when the file justifying the research and development expenses incurred has been accepted by the funding organization.

Note 8: Research tax credit

Companies that can prove they have incurred expenses that meet the required criteria are entitled to a tax credit, which can be offset against their corporate income tax. This tax credit is booked under "Corporate income tax".

The Company has benefited from the research tax credit since its creation.

A framework agreement for the assignment of receivables was signed in 2024 between Mauna Kea Technologies SA (the Assignor), the Predirec Innovation 3 securitization fund (the Assignee) and Neftys Conseil (the Arranger), enabling the assignment of receivables in 2024. The amount transferred was charged with the 7.5% holdback, the 7.028% initial deduction and the 0.25% structuring fee. The assignments of these receivables were recognized at the time of transfer of ownership, and resulted in their deletion from the balance sheet in consideration for the cash received.

Note 9: Exceptions to the general principles

Change in valuation method

There were no significant changes in valuation methods during the year.

Changes in presentation methods

There were no significant changes in presentation methods during the year.

Note 10: Sales recognition

The Company's sales are made up of :

1. Sales of Cellvizio systems, consumables (probes) and associated services (maintenance and repair).

The Company recognizes sales of systems and consumables as sales when ownership is transferred. This transfer of ownership is evidenced by a contract, a purchase order and a delivery note.

Whereas sales of maintenance services covering a period exceeding the accounting period are recorded as deferred income. This deferred income is therefore spread over time according to the duration of the services contracted with the customer.

2. Revenues from the strategic agreement signed with Tasly Pharmaceutical in 2022.

Following the creation of Mauna Kea Medical Enginering Technology Co, the Group signed two contracts with this JV

- A technology transfer agreement dated November 30, 2022;
- A license agreement dated December 23, 2022.

(i) Technology transfer agreement

The Group was to take the necessary steps to transfer ownership of the patents to the joint venture (JV), in return for a payment of USD 2.5 million from the latter.

All the patents were transferred on February 17, 2022. However, the contract included a condition precedent, which was lifted on April 20, 2023.

Consequently, the corresponding sales were fully recognized on the date the suspensive condition was lifted.

(ii) License Agreement

Under the terms of the agreements signed with the JV, the Company :

- grants the JV an exclusive 8-year license to :
    - (i) market certain Cellvizio indications in China,
    - (ii) develop and market Cellvizio internationally in the fields of neurology and neurosurgery,
    - (iii) manufacture Cellvizio units for the Chinese market;
- undertakes to provide the JV with technical support and know-how transfer, in order to make the JV fully autonomous.

In return, the JV undertakes to pay the Company :

- an upfront license payment of USD 6.5 million, to be received in January 2023;
- an additional payment ("technology transfer material fee") of 0.5 million USD, conditional on the completion of a first phase of technology transfer;
- a second license payment of USD 0.5 million, to be paid on completion of the transfer to the JV of part of the inventory held by a local distributor;
- royalties equivalent to 7.5% of JV sales, under certain conditions.

During the technology transfer phase, the JV also undertakes to purchase minimum volumes of Cellvizio systems and probes from Mauna Kea Technologies for a period of 5 years.

During the local *product* phase in China, Mauna Kea Technologies will receive royalties of 7.5% on JV sales, subject to certain conditions.

Accounting treatment

The Company considers that the license granted to the JV consists of two distinct phases:

3. an initial phase of know-how transfer and support, at the end of which the JV will become autonomous,
4. a phase of autonomous operation by the JV.

This first phase is estimated to last 36 months, after which the JV will be able to manufacture the systems itself.

As a result, the payments of 6.5 million USD (upfront) and 0.5 million USD (technology transfer) are considered as consideration for the transfer of know-how and support. Sales are therefore recognized on a straight-line basis over the 36 months following signature of the license agreement.

Sales recognition :

- Fiscal 2023: 4.3 million euros
    - 2.0 million euros (MUSD 2.5) related to the transfer of patents, completed in the 1st half of 2023;
    - 2.3 million euros (US$2.2 million) under the license agreement, corresponding to initial payments spread over 36 months.
- Fiscal 2024: 2.0 million euros (2.2 MUSD) of sales recognized in respect of the continued deferral of the license agreement.

5.3.2. Balance sheet information

Property, plant and equipment and intangible assets

Acquisitions and disposals for the year

Figures in euros	At 12/31/2023	Acquisitions	Disposals	At 12/31/2024
Concessions, patents and similar rights	922 588	17 057	(29 662)	909 983
Other intangible assets	43 025	2 253	-	45 278
Total intangible Intangible assets	**965 613**	**19 310**	**(29 662)**	**955 261**
Buildings, fittings and fixtures.....	51 090	-	(1 375)	49 715

General fixtures and fittings	499 811	1 247	(24 474)	476 584
Plant, machinery and equipment	1 364 730	19 587	(311 260)	1 073 057
Office and computer equipment, furniture	751 342	27 010	(78 648)	699 704
Total intangible assets Property, plant and equipment	**2 666 973**	**47 844**	**(415 757)**	**2 299 060**
Property, plant and equipment in progress	-	-	-	-
Total tangible assets	**-**	**-**	**-**	**-**
TOTAL	**3 632 586**	**67 154**	**(445 419)**	**3 254 321**

Changes in property, plant and equipment and intangible assets from one year to the next are due to acquisitions and disposals of assets carried out by the Company in the course of its business.

Depreciation schedule

Amortization of intangible assets and property, plant and equipment is calculated on a straight-line or declining-balance basis, depending on the nature of the asset and its expected useful life.

Technical depreciation schedule

Figures in euros	At 12/31/2023	Endowments	Decreases or reversals	At 12/31/2024
Concessions, patents and similar rights	915 546	5 729	(29 662)	891 613
Other intangible assets	21 605	686	-	22 291
Total Amort. Intangible Intangible	**937 151**	**6 415**	**(29 662)**	**913 904**
Buildings	51 090	-	(1 375)	49 715
General fixtures and fittings	433 896	18 948	(23 517)	429 327
Plant, machinery and equipment	1 280 995	45 157	(310 763)	1 015 389
Office computer equipment, furniture	648 069	49 363	(75 422)	622 010
Total Amort. Depo. Tangible	**2 414 050**	**113 468**	**(411 077)**	**2 116 441**
TOTAL	**3 351 201**	**119 883**	**(440 739)**	**3 030 345**

Provision for depreciation of fixed assets

See paragraph 5.3.3, Statement of provisions.

Long-term investments

Movements for the year :

Figures in euros	Gross value at 12/31/2023	Acquisitions and item-to-item transfers	Sales and transfers from one item to	Gross value at 12/31/2024	Provision	Net value at 12/31/2024

			another			
MKT Inc. shares and MKT Inc. current account. *	71 200 093	12 252 793	(2 240 074)	81 212 812	(74 997 415)	6 215 398
Securities Tasly Maun Kea Medical Engineering Technology Co. **	16 890 962	-	-	16 890 962	(1 927 000)	14 963 962
CellTolerance *** equity securities		10 000		10 000	-	10 000
Loans and other non-current financial assets	299 664	110 065	(197 418)	212 310	-	212 310
TOTAL	**88 390 719**	**12 372 858**	**(2 437 493)**	**98 326 084**	**(76 924 415)**	**21 401 670**

* MKT Inc. shares represent 23,077 euros at the end of 2023 and 2024 and are fully depreciated. The MKT Inc. current account is impaired to the extent of the subsidiary's net worth.

** Tasly Mauna Kea Medical Engineering Technology Co. Ltd was established on November 3, 2022.

*** CellTolerance, a 100% subsidiary of Mauna Kea Technologies, was created in 2024.

Inventories of goods and work in progress

At the close of each financial year, finished goods inventories and work-in-progress include certain assets relating tò products no longer included in the catalog. These identified assets are retained by the Company for use by the After-Sales Service department, and are depreciated by 80%.

Cellvizio® entrusted to hospitals with which the Group has partnership agreements, and older generation Cellvizio® are depreciated on a straight-line basis over 5 years.

Inventories break down as follows

Figures in euros	Gross amount	Depreciation	Balance at 12 31 2024
Raw materials	1 953 126	(241 388)	1 711 737
Finished products	2 823 599	(830 426)	1 993 174
TOTAL	**4 776 725**	**(1 071 814)**	**3 704 911**

Finished products include finished and semi-finished products.

The increase in write-downs concerns slow-moving inventory and old-generation Cellvizio®.

Provisions for impairment of inventories and receivables

See paragraph 5.3.3, Provisions.

Statement of receivables maturities

Receivables held by the Company amounted to €83,768,796 in gross value at 12/31/2024 and break down as follows:

Figures in euros	Gross amount	Within one year	More than a year old
FIXED ASSETS :	**81 402 045**	**-**	**81 402 045**
Receivables from investments	81 189 736	-	81 189 736
Other long-term investments	212 310	-	212 310
CURRENT ASSETS :	**2 366 751**	**2 336 114**	**30 637**
Customers	1 046 903	1 046 903	-
Doubtful customers	28 294	-	28 294
Personnel and related accounts	6 481	6 481	-
Social organizations	2 432	2 432	-
State: various taxes	912 446	912 446	-
Sundry debtors	3 000	3 000	-
Prepaid expenses	367 196	364 853	2 343
TOTAL	**83 768 796**	**2 336 114**	**81 432 683**

Loans granted during the year	-
Repayments received during the year	-
Loans and advances to associates (individuals)	-

Receivables from associates correspond to the current account granted to the subsidiary Mauna Kea Technologies Inc, and their sharp rise is linked to the change in the USD/EUR exchange rate.

Accounts receivable

RECEIVABLES	Gross amount	Amort. Prov.	Net 31/12/2024	Net 31/12/2023
Accounts receivable	1 075 197	28 294	1 046 903	1 120 454
Other receivables	924 358	-	924 358	777 812
TOTAL	**1 999 555**	**28 294**	**1 971 261**	**1 898 265**

Other receivables have increased due to the higher research tax credit receivable compared with 2023.

Provisions are calculated as described in paragraph 5.3.1, Note 4: Receivables.

Of which Group receivables :

Figures in euros	2024	2023
Customers of consolidated affiliates	804 123	719 247
TOTAL	**804 123**	**719 247**

Accrued income

Accrued income included in the following balance sheet items amounts to :

Figures in euros	At 12/31/2024	At 12/31/2023
Customers - Unbilled revenue	659 686	573 966
Accrued income	2 432	17 730
TOTAL	**662 118**	**591 696**

Marketable securities

At December 31, 2024, the Company held no money-market UCITS.

Accruals and deferred income

Prepaid expenses

Figures in euros	At 12/31/2024	At 12/31/2023
Operating expenses	327 097	389 663
Financial expenses	40 099	-
Extraordinary expenses	-	-
TOTAL	**367 196**	**389 663**

Currency translation adjustments

ASSET BALANCE		LIABILITIES	
	Euros		**Euros**
Decrease in receivables	-	Debt reduction	5 697
Increase in debt	61 049	Increase in receivables	10 733 388
TOTAL	**61 049**	**TOTAL**	**10 739 085**

The translation adjustment mainly relates to receivables in US dollars from the subsidiary Mauna Kea Technologies Inc.

5.3.3. Balance sheet liabilities

- **Shareholders' equity**

Share capital

The share capital is set at two million seven hundred and nine thousand two hundred and eighty-five euros.

(2 709 285 €). It comprises 67,732,127 shares with a par value of €0.04 each.

This number excludes "Bons de Souscription d'Actions" (BSA), "Bons de Souscription de Parts de Créateur d'Entreprise" (BSPCE) and stock options granted to certain investors and individuals, whether or not employees of the Company.

The table below shows the Company's share capital since December 31, 2023, in thousands of euros:

Nature of operations	Capital in euros	Share premium in euros	Number of shares issued	Number of shares outstanding
At December 31, 2023	**2 464 410**	**7 574 628**	**15 133 772**	**61 610 247**
AGM Plan 2021	4 875	(4 875)	121 880	61 732 127
BSA conversion (Vester)	240 000	1 758 068	6 000 000	67 732 127
BSA subscription	-	24 100	-	67 732 127
Transaction costs	-	(62 227)	-	67 732 127
Total at December 31, 2024	**2 709 285**	**9 289 694**	**21 255 652**	**67 732 127**

On June 24, 2024, the Board of Directors noted the end of the vesting period of an ordinary bonus share plan, resulting in a capital increase of 4,875 euros and the creation of 121,880 ordinary shares.

6,000,000 shares were subscribed under the equity line of credit set up in 2023 and renewed in July 2024 with Vester Finance, resulting in a share capital increase of €240,000 and a share premium of €1,758,068.

Dilutive instruments giving access to capital

Since its creation, the Company has issued "Bons de Souscription d'Actions" (BSAs), employee share subscription warrants ("BSPCEs" and others), as well as stock options (SOs), performance shares (AGAPs) and bonus shares (AGAs), details of which are given below since December 31, 2023.

		Options	Nb of potential actions
At December 31, 2023		**14 315 328**	**14 690 553**
Created over the period :			
SO	31/01/2024	20 000	20 000
BSA	31/01/2024	50 000	50 000
SO	05/04/2024	50 000	50 000
BSA	24/06/2024	240 000	240 000
SO	24/06/2024	1 580 000	1 580 000
AGA	24/06/2024	4 612 000	4 612 000
BSA	23/07/2024	5 500 000	5 500 000
Exercised/converted during the period		(6 121 880)	(6 121 880)
Lost over the period		(902 900)	(902 900)
At December 31, 2024		**19 342 548**	**19 717 773**

The new instruments issued in 2024 are as follows:

- On January 31, 2024, 20,000 options were issued to an employee;
- On January 31, 2024, 50,000 warrants were issued to a consultant;
- On April 05, 2024, 50,000 options were issued to an employee;
- On June 24, 2024, 240,000 warrants were issued to the directors of Mauna Kea Technologies SA ;
- On June 24, 2024, 1,580,000 options were issued to 11 employees;
- On June 24, 2024, 4,612,000 bonus shares were issued to 43 employees and to the Chairman and Chief Executive Officer;
- On July 23, 2024, 5,500,000 warrants were issued to Vester Finance.

Acquisition by the Company of its own shares

On November 20, 2024, the Company terminated its liquidity contract with Gilbert Dupont, and no longer held any treasury shares at December 31, 2024.

Statement of provisions

The breakdown of provisions by type is as follows:

Provisions for contingencies and charges

Figures in euros	At 12/31/2023	Endowments	Reversals	At 12/31/2024

Provisions for contingencies and litigation	25 000	-	(25 000)	-
Provisions for contingencies - fines and penalties	-	46 788	-	46 788
TOTAL	**25 000**	**46 788**	**(25 000)**	**46 788**

The provision for 2023 related to a dispute with a service provider, which was settled in 2024.

The provision recognized in 2024 concerns late penalties on tax and social security debts currently being negotiated.

Provisions for contingencies

Figures in euros	At 12/31/2023	Endowments	Reversals	At 12/31/2024
Provisions for exchange losses	7 143	61 049	(7 143)	61 049
TOTAL	**7 143**	**61 049**	**(7 143)**	**61 049**

Provision for depreciation of fixed assets

Figures in euros	At 12/31/2023	Endowments	Reversals	At 12/31/2024
Provision immob. Financial	65 522 535	11 401 880	-	76 924 415
Other long-term investments	1 342	-	(1 342)	-
TOTAL	**65 523 877**	**11 401 880**	**(1 342)**	**76 924 415**

These impairments mainly concern :

- shares in the subsidiary Mauna Kea technologies SA, depreciated at 100%, i.e. 23 K€;
- Joints-Venture shares for €1,927,000;
- advances granted to the subsidiary Mauna Kea Technologies Inc, written down to the amount of the subsidiary's negative net assets, i.e. €74,974,000.

An additional impairment loss of €1,470,000 was recognized on the shares in the joint venture in 2024, following a downward revision of the subsidiary's sales projections.

Provisions for inventory write-downs

Figures in euros	At 12/31/2023	Endowments	Reversals	At 12/31/2024
Raw materials	331 925	173 274	(263 811)	241 388
Finished products	599 932	272 718	(42 225)	830 426
TOTAL	**931 857**	**445 992**	**(306 036)**	**1 071 814**

Provisions for impairment of receivables

Figures in euros	At 12/31/2023	Endowments	Reversals	At 12/31/2024
Impairment of trade receivables	12 000	28 294	(12 000)	28 294
TOTAL	**12 000**	**28 294**	**(12 000)**	**28 294**

- **Financial liabilities**

Figures in euros	31/12/2023	+	-	31/12/2024
BPI (formerly OSEO) repayable advance	3 407 529	-	-	3 407 529
Accrued interest on conditional advances	901 046	105 529	-	1 006 575
Conditional advances	**4 308 575**	**105 529**	**-**	**4 414 104**
PGE BNP/BPI	2 658 521	-	(419 749)	2 238 772
Accrued interest on PGE loan	2 635	5 946	(2 635)	5 946
EIB loans	20 723 901	968 739		21 692 640
Accrued interest on EIB loan	588 806	776 781	(588 806)	776 781
Other similar liabilities	-	471 471	-	471 471
Interest on other borrowings	-	1 333 333	-	1 333 333
Deposits received	22 113	1 355	-	23 468
Borrowings and other financial liabilities	**23 995 976**	**3 557 625**	**(1 011 191)**	**26 542 410**

BPI advances (formerly OSEO Fi)

On May 31, 2010, Mauna Kea Technologies received reimbursable innovation funding from OSEO for its PERSEE project. The aim of this project was to develop, validate and market a device capable of improving diagnostic techniques and pre-operative extension assessments for cancer patients.

The project was closed at the end of 2020, and the fifth installment of the €504,000 repayable advance was received in December 2021. The advances bear interest at 2.45%.

The contract signed between OSEO, now BPIFrance, and the Company in 2010 stipulates that the first repayment is to be made once sales of €2,500,000 have been achieved on the new products developed. The amount to be repaid, based on the new repayment schedule, will be €4,724,000, including the discounting charge. If no repayment is made within 10 years of the last grant payment, Mauna Kea will be released from any obligation to pay financial returns. In addition, if cumulative sales exceed 50,000 K€, 2% of the sales generated must be repaid over a period of 15 years.

EIB loan

The Company entered into a €22.5 million financing agreement with the European Investment Bank (EIB) on June 20, 2019, initially comprising three tranches. Only two tranches were ultimately drawn down by the Company, the third tranche no longer being available to the Company:

- A first tranche of 11,500 K€, cashed on July 3, 2019, bearing capitalized interest of 5%;

- A second tranche of €6,000,000, redeemed on July 8, 2020, with capitalized interest of 4% and cash interest of 3%.

The initial maturity of these tranches was five years, with repayment due in July 2024 for Tranche 1 and July 2025 for Tranche 2.

In view of these approaching maturities, the Company undertook a restructuring of the loan, finalized in April 2024. Under the terms of the new agreement, the EIB has agreed to defer final repayments of principal and interest to July 2028 for Tranche 1, and July 2029 for Tranche 2. The amended schedule provides for progressive repayments of principal as follows (i) €1.0 million in 2025, (ii) €2.5 million in 2026, (iii) €5.0 million in 2027.

In addition, the agreement includes a commitment by the Company to pay annual royalties of 2% on certain revenues, over a period of six years from January 30, 2024, for a total minimum amount of €8 million and a maximum of €10 million. The share recognized for 2024 amounts to €1.3 million.

Instruments are also attached to each of the tranches: (i) 1,450,000 share subscription warrants (BSA) under Tranche 1 entitling holders to subscribe to a maximum of 1,450,000 shares in the Company at an exercise price of €1.24031 (initially €1.8856, lowered as part of the renegotiation), (ii) 500,000 BSA under Tranche 2 entitling holders to subscribe to a maximum of 500,000 shares in the Company at an exercise price of €1.24031.

Finalization of the restructuring agreement remained conditional on (i) the revaluation of the exercise price of Tranche 1 warrants to €1.24031, approved at the 2024 Annual General Meeting, and (ii) the raising of €7 million in financing before April 30, 2025.

At the date of this document, the latter condition has not yet been met, resulting in a 4% increase in interest rates on all tranches from October 1, 2024.

Lastly, the opening of a safeguard procedure in favor of the Company on March 31, 2025, having the effect of freezing liabilities, suspends all commitments linked to this agreement, which are now being renegotiated with the EIB (see paragraph *Post-balance sheet events*).

Borrowings PGE

On July 17, 2020, the Company obtained financing of 4 million euros from BNP Paribas and Bpifrance in the form of a Loan Guaranteed by the French State (PGE). BNP Paribas and Bpifrance have each granted a loan of 2 million euros at fixed interest rates of 0.25% and 1.75% respectively. These non-dilutive loans will be 90% guaranteed by the French state (ministerial orders of March 23 and April 17, 2020 granting state guarantees to credit institutions and financial companies, pursuant to article 6 of law no. 2020-289 of March 23, 2020). Each loan has an initial term of one year. At the end of the first year, repayment of the principal due may be deferred again, at the Company's discretion, for a maximum period of 5 years.

In 2021, the loans have been renegotiated and the new maturities are as follows: June 24, 2026 and August 31, 2026 with fixed interest rates of 0.75% and 2.25% respectively. BNP Paribas' principal repayment is monthly, while Bpifrance's is quarterly.

In 2024, the Group obtained a restructuring of the two loans:

- The maturity of the PGE BNP has been extended by 12 months from June 24, 2026 to June 24, 2027, with monthly amortization and interest resuming from May 24, 2025. The interest rate has been raised to 4%;
- The maturity of the PGE BPI has been extended by 12 months to August 31, 2027, with maturities resuming on June 1, 2025. The interest rate has been raised to 5.25%;

- A capital repayment waiver has been granted to the Group for the period from June 1, 2024 to May 31, 2025 inclusive, for both loans.

Debt maturity schedule

DEBTS	Gross amount end ex.	Less than 1 year	1 to 5 years	Over 5 years
Borrowings from credit institutions :				
to a maximum of 1 year	2 244 717	630 106	1 614 612	-
Borrowings and other financial liabilities	24 297 693	24 297 693	-	-
Trade accounts payable	3 068 111	3 068 111	-	-
Personnel and related accounts	588 188	588 188	-	-
Social security and other social organizations	1 087 251	1 087 251	-	-
State and other public bodies :				
Income tax	340 662	340 662	-	-
Other taxes and related accounts	110 409	110 409	-	-
Group and associates	5 000	-	-	5 000
Other liabilities	10 608	10 608	-	-
Deferred income	2 225 339	2 225 339	-	-
TOTAL	**33 977 978**	**32 358 367**	**1 614 612**	**5 000**
Borrowings taken out during the year	-			
Borrowings repaid during the year	419 749			

Trade accounts payable

Figures in euros	Visit 31/12/2024	Visit 31/12/2023
Suppliers France	756 617	630 324
Foreign Suppliers	221 190	122 662
Suppliers invoices not yet received	2 090 304	2 212 376
Total trade payables	**3 068 111**	**2 965 361**

- **Accrued expenses**

Accrued expenses included in the following balance sheet items amount to :

Sections	Exercise 2024	Exercise 2023
OPERATING LIABILITIES		
Trade accounts payable	2 090 304	2 212 376
Tax and social security liabilities	949 150	1 248 891
FINANCIAL LIABILITIES		
Borrowings from credit institutions	3 122 634	1 492 487
MISCELLANEOUS LIABILITIES		
Other liabilities	-	-
DEBTS	**6 162 088**	**4 953 754**

The increase in financial debts corresponds mainly to a share of the minimum amount of royalties on sales contractually due to the EIB as part of the renegotiation of the loan finalized in April 2024.

- **Accruals and deferred income**

Deferred income

Deferred income breaks down as follows:

Figures in euros	Visit 31/12/2024	Visit 31/12/2023
Operating income	2 225 339	4 587 591
Financial income	-	-
Extraordinary income	-	-
TOTAL	**2 225 339**	**4 587 591**

Deferred income relates mainly to the licensing agreement signed with Tasly Pharmaceutical, for which the Company received 6.5 million euros recognized on a straight-line basis in sales over 36 months. In fiscal 2024, 2 million euros were recognized in sales in this respect.

- **Currency translation adjustments**

Please refer to paragraph 5.3.2, Translation adjustments.

- **Amounts owed to affiliated companies**

At December 31, 2024, the Company had no debt to its subsidiary. Only an outstanding invoice of €296,000 has been recognized in respect of MKT Inc.

5.3.4. Information on the income statement

- **Breakdown of net sales**

Sales for fiscal 2024 break down as follows:

Figures in euros	Fiscal 2024			Fiscal 2023
	France	CEE + Export	Total	Total
Sales of merchandise	-	-	-	75
Sales of finished products	360 703	2 611 635	2 972 338	3 820 940
Sales of services	105 368	3 217 133	3 322 501	5 328 649
Sales figures	**466 071**	**5 828 768**	**6 294 839**	**9 149 665**
%	7%	93%	100%	

- **Other operating income**

Other income mainly concerns the Company's sublease of part of its premises on rue d'Enghien. These leases were put in place during 2022. Income recognized in this respect in 2024 corresponds to a full year.

Figures in euros	Visit 31/12/2024	Visit 31/12/2023
Stocked production	854 069	89 995
Other miscellaneous operating income and subsidies	6 500	10 667
Write-backs of depreciation and provisions, expense transfers and other income	486 739	222 529
Other products	282 702	345 716
TOTAL	**1 630 010**	**668 906**

- **Operating expenses**

Figures in euros	Visit	Visit

	31/12/2024	31/12/2023
Purchases of raw materials and other supplies	(1 463 295)	(1 036 658)
Change in raw materials and other supplies	408 391	(38 528)
Other purchases and external charges	(4 189 670)	(4 628 503)
Taxes	(264 578)	(171 472)
Wages and salaries	(3 956 654)	(4 338 021)
Social security charges	(1 777 449)	(1 921 961)
Depreciation and amortization	(124 952)	(254 178)
Impairment losses	(474 286)	(408 819)
Provisions	-	-
Other expenses	(64 832)	(172 900)
TOTAL	**(11 907 326)**	**(12 971 039)**

The reduction in external expenses and salaries and social security charges is the result of the cost-cutting policy implemented by the Company.

Statutory Auditors' remuneration

Statutory auditors' fees for the year and the previous year, in accordance with their engagement letters, can be summarized as follows:

Amount in euros	**Exercise 2024**	**Exercise 2023**	
	EY	EY	EXCO
Audit			
Statutory audit, certification and review of individual and consolidated financial statements			
- Mauna Kea Technologies SA & fully consolidated subsidiaries	128 000	85 000	50 000
Subtotal	**128 000**	**85 000**	**50 000**
Other services provided by networks to fully consolidated subsidiaries			
Services other than account certification (SACC)	-	-	-
Subtotal	**-**	**-**	**-**
Total	**128 000**	**85 000**	**50 000**

 Net financial income

Net financial income for the year amounted to (10,482 K€) and breaks down as follows:

Sections	Exercise 2024	Exercise 2023
FINANCIAL PRODUCTS	**3 955 445**	**2 716 199**
Other interest and similar income	3 926 755	2 326 291
Reversals of provisions and expense transfers	8 485	9 316
Positive exchange rate differences	20 205	380 592
FINANCIAL EXPENSES	**(14 437 181)**	**(4 389 492)**
Depreciation, amortization and provisions	(11 462 929)	(2 603 211)
Interest and similar expenses	(2 962 582)	(1 353 070)
Negative exchange differences	(11 670)	(433 211)
FINANCIAL RESULT	**(10 481 736)**	**(1 673 293)**

Interest income recognized in 2024 corresponds to :

- Interest on the US subsidiary's current account of 3.8 million euros in 2024, compared with 2.1 million euros in 2023. This sharp rise is linked to the increase in the legal interest rate applied to calculate this interest (5.07% and 4.92% respectively for the first and second half of 2024, compared with 2.06% and 4?22% for 2023);
- Interest on term deposits.

Depreciation, amortization and provisions mainly relate to :

- impairment of the US subsidiary's current account advance of €9,932,000 for 2024. This depreciation varies according to the amount of the advance granted, the amount of the subsidiary's equity and the exchange rate. The sharp rise in 2024 is explained by the change in the USD/EUR parity.
- Impairment of joint venture shares of €1,470,000, in addition to the €457,000 provision recognized at December 31, 2023.

Interest expense relates mainly to the EIB loan. The sharp increase is due to the recognition in 2024 of a share of the minimum amount of royalties to be paid to the EIB over the renegotiated term of the loan.

 Net exceptional income

Extraordinary income for the year breaks down as follows:

Sections	Exercise 2024	Exercise 2023

EXTRAORDINARY INCOME	**31 888**	**16 775 139**
Extraordinary income from management operations	5 581	305
Extraordinary income from capital transactions	1 308	16 762 227
Reversals of provisions and expense transfers	25 000	12 608
EXCEPTIONAL EXPENSES	**(160 111)**	**(1 607 978)**
Exceptional expenses on management operations	(13 197)	(8 577)
Exceptional expenses on capital transactions	(100 126)	(1 574 400)
Exceptional depreciation, amortization and provisions	(46 788)	(25 000)
EXTRAORDINARY RESULT	**(128 223)**	**15 167 162**

Exceptional items for the year ended December 31, 2024 mainly comprise :

- The reversal of a provision for a dispute settled in 2024 ;
- The recognition of a provision for potential penalties ;
- Non-recurring consulting fees.

The exceptional result for fiscal 2023 was mainly due to the creation of the joint venture in China:

- The recognition of the shares in this company received as consideration for the transfer of patents represented exceptional income of 16.8 million euros;
- Fees for strategic consulting services provided by Cenponts were recognized as an exceptional expense in the amount of 1.6 million euros.

Income tax

Tax status

At December 31, 2024, the Company had retained earnings of €101,849,111.

Deferred taxation

BASES (in euros)	At the start of the 2024 financial year	Changes in net income for the year	At year-end 2024
Differences between tax treatment and accounting treatment of certain income or expenses :			
Other provisions for contingencies	7 143	53 906	61 050
TOTAL	**7 143**	**53 906**	**61 050**

Tax credits

The Company benefits from the provisions of articles 244 quater B and 49 septies F of the French General Tax Code relating to research tax credits. The research tax credit for the 2024 financial year amounts to €753,393.

5.3.5. Miscellaneous information

Number of salaried and temporary employees

At December 31, 2024, the average number of employees was as follows:

Average headcount	2024	2023 (average headcount)	2023 published (effective at year-end)
Executives	47.3	53.4	48.0
Non-executives	5.6	0.5	8.0
TOTAL	**52.9**	**53.9**	**56.0**

List of subsidiaries and affiliates

Companies concerned	Capital	Capital held	Shareholders' equity including net income	Net income
Mauna Kea Technologies Inc (*)	30 000	100%	(77 890 840)	(6 018 923)
Tasly Mauna Kea Medical Engineering Technology Co(**)	250 000 000	49%	204 484 804	(15 481 542)
CellTolerance(***)	10 000	100%	-	-

(*) Amounts are presented in US Dollars

(**) Amounts are presented in RMB

(***) Amounts are shown in €.

Related party disclosures

No information on related party transactions, as current transactions are excluded from the list of related party transactions.

Directors' remuneration

Management remuneration is not provided, as this would lead to individual remuneration.

Financial commitments

Commitments given

- Towards European Investment Bank (EIB)

Following the EIB financing restructuring agreement signed on April 24, 2024, the obligations have been updated. Firstly, the agreement stipulates that finalization will be definitively acquired as soon as the Group has raised 7 million euros through licensing agreements, partnerships, fundraising or other means between January 1, 2024 and April 30,

2025. In addition, the agreement includes a commitment to pay annual royalties of 2% on certain revenues for a period of six years from January 30, 2024, with a minimum of 8 million euros and a maximum of 10 million euros.

The guarantees given by the EIB on inventories and trade receivables, and on the pledge of certain patents, have been extended to cover the new maturities.

Financial covenants are also included in the contractual obligations:

- A cash position in excess of 4 million euros;
- Debt coverage ratio greater than 2.0:1.0;
- A debt-to-equity ratio of 1.0:1.0 ;
- A minimum level of income and EBITDA.

In view of the opening of a safeguard procedure in favor of the Company on March 31, 2025, which has the effect of freezing liabilities (see Events since the balance sheet date), all these commitments have been suspended and are being renegotiated with the EIB.

- Towards partners

Commitments given	Total	-1 year	1 to 5 years	+5 years
Rental-related	1 087 886	255 700	832 186	-
Related to supply contracts	953 820	671 248	282 572	-
Against bank guarantee	2 840 343	-	2 840 343	-
	4 882 049	**926 948**	**3 955 101**	**-**

In order to guarantee its financial obligations towards a service provider essential to the continuity of its operations, the Company has set up a stand-by letter of credit. In return for this commitment, a €100,000 interest-bearing bank account has been pledged, and will remain blocked until March 24, 2025.

Commitments received

The Prêt Garanti par l'État (PGE) granted by BPI and BNP benefits from a 90% state guarantee under the Fonds National Garantie État Coronavirus.

Employee-related commitments

Retirement benefit commitment

For the purposes of estimating retirement commitments, the following assumptions have been made for all employee categories (employees, supervisors and managers):

- Retirement age: 64
- Departure terms: voluntary departure
- Mortality table: INSEE 2024
- Collective bargaining agreement: metallurgy
- Staff rotation :
    - 18-25 years: 0% of sales
    - 26-35 years: 18

- 36-45 years: 16
- 46-55 years old: 24
- > 56 years old: 0% of sales

- Employer contribution rate: 47% (identical to 2023)
- Salary increase rate: 2.5% (identical to 2023)
- Discount rate: 3.35% (versus 3.20% in 2023) corresponding to the iBoxx Corporate AA10+ rate.

Termination benefits amounted to €100,000 at December 31, 2024, not recognized in the parent company financial statements.

The Company does not finance its retirement benefit obligations.

Customer and supplier payment terms

In accordance with article L. 441-6-1 of the French Commercial Code, the Company is required to publish a breakdown, at the year-end, of the balance of its payables to suppliers and receivables from customers, by due date.

EXERCISE 2024

	Invoices received but not settled at balance sheet date						
In K€	**Total**	**No delay**	**1 to 30 days**	**31 to 60 days**	**61 to 90 days**	**91 days and over**	**Total 1 day or more**
Number of invoices concerned	216	87					129
Total amount of invoices concerned (incl. VAT)	922	434	106	76	122	184	488
Percentage of invoices concerned (incl. VAT)		47%	11%	8%	13%	20%	53%
Percentage of total purchases for the year		8%	2%	1%	2%	4%	9%

	Invoices issued but not paid at year-end						
In K€	**Total**	**No delay**	**1 to 30 days**	**31 to 60 days**	**61 to 90 days**	**91 days and over**	**Total 1 day or more**
Number of invoices concerned	21	12					9
Total amount of invoices concerned (incl. VAT)	415	188	103	96	-	28	227

Percentage of invoices concerned (incl. VAT)	45%	25%	23%	-	7%	55%
Percentage of total invoices issued for the year	4%	2%	2%	-	1%	5%

- **Five-year financial summary under French GAAP**

	31/12/2024	31/12/2023	31/12/2022	31/12/2021	31/12/2020
Capital at year-end					
Share capital	2 709 285	2 464 410	1 859059	1 783 803	1 223 558
Number of shares issued	6 121 880	15 133 772	1 881 400	14 005 375	17 960
Transactions and income for the year					
Sales excluding tax	6 294 839	9 149 665	5 332 370	6 992 787	4 403 044
Earnings before tax, depreciation, amortization and provisions	(2 835 001)	13 388 892	(7 515 570)	(8 039 041)	(9 364 852)
Income tax	(753 393)	(60 892)	(626 810)	(635 110)	(710 870)
Profit after tax but before depreciation, amortization and provisions	(2 081 608)	13 449 784	(6 888 760)	(7 403 931)	(8 923 982)
Income after tax, depreciation, amortization and provisions	(13 839 043)	10 402 292	(12 876 699)	(16 033 905)	(9 444 555)

Distributed earnings (for the year)	-	-	-	-	-
Employee profit-sharing	-	-	-	-	-
Earnings per share (in euros)					
Income after tax and before depreciation, amortization and provisions	-	-	-	-	-
Income after tax, depreciation, amortization and provisions	-	-	-	-	-
Staff					
Number of employees	54	55	56	67	75
Total payroll for the year	3 956 654	4 338 021	4 409 869	5 018 361	5 132 959
Amounts paid in employee benefits	1 777 449	1 921 691	1 969 813	2 122 404	2 107 782

5.4. Statutory auditors' reports on the financial statements

Mauna Kea Technologies

Year ending December 31, 2024

Statutory auditor's report on the financial statements

To the Annual General Meeting of Mauna Kea Technologies,

Opinion

In compliance with the assignment entrusted to us by your Annual General Meeting, we have audited the accompanying financial statements of Mauna Kea Technologies for the year ended December 31, 2024.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and of the financial position of the Company as at December 31, 2009 and of the results of its operations for the year then ended in accordance with the accounting rules and principles applicable in France.

Basis of opinion

Audit framework

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under these standards are set out in the section of this report entitled "Statutory Auditors' Responsibilities Relating to the Audit of the Financial Statements".

Independence

We conducted our audit in accordance with the rules of independence set out in the French Commercial Code (Code de commerce) and in the Auditors' Code of Ethics, covering the period from January 1 2024 to the date of issue of our report.

Significant going concern uncertainty

Without qualifying the opinion expressed above, we draw your attention to the significant uncertainty relating to events or circumstances that may call into question the going concern assumption described in Note 1 "Basis of preparation" to the financial statements.

Justification of assessments

In accordance with the requirements of Articles L. 821-53 and R. 821-180 of the French Commercial Code (Code de commerce) relating to the justification of our assessments, we hereby inform you that, in addition to the matter described in the section entitled "Significant Uncertainties Relating to Going Concern", the most significant assessments we have made, in our professional judgment, relate to the appropriateness of the accounting policies used, the reasonableness of the significant estimates made and the overall presentation of the financial statements.

These assessments were made in the context of our audit of the financial statements taken as a whole, and of the formation of our opinion expressed above. We do not express an opinion on any individual component of these financial statements.

Specific checks

In accordance with professional standards applicable in France, we have also performed the specific procedures required by law.

Information provided in the management report and other documents on the financial situation and financial statements sent to shareholders

We have no matters to report as to the fair presentation and the conformity with the financial statements of the information given in the management report of the Board of Directors, and in the other documents addressed to the shareholders with respect to the financial position and the financial statements, with the exception of the following matter.

We have the following observation to make regarding the fair presentation and consistency with the financial statements of the information on supplier payment terms provided for under Article D.441-6 of the French Commercial Code: this information does not match the due dates shown on invoices.

Information on corporate governance

We attest that the information required by Article L. 225-37-4 of the French Commercial Code has been properly disclosed in the Corporate Governance section of the Board of Directors' management report.

Other information

In accordance with French law, we have ensured that the required information concerning the identity of shareholders and holders of voting rights has been properly disclosed in the management report.

Responsibilities of management and those charged with governance in relation to the financial statements

It is the responsibility of management to prepare financial statements that give a true and fair view in accordance with French generally accepted accounting principles, and to implement any internal control procedures that it considers necessary to ensure that the financial statements are free from material misstatement, whether due to fraud or error.

When preparing the annual financial statements, it is the responsibility of management to assess the company's ability to continue as a going concern, to present in these statements, where appropriate, the necessary going concern information and to apply the going concern accounting policy, unless the company is to be wound up or cease trading.

The annual financial statements have been approved by the Board of Directors.

Statutory auditors' responsibilities in relation to the audit of annual financial statements

Our responsibility is to express an opinion on these financial statements based on our audit. Our objective is to obtain reasonable assurance about whether the financial statements, taken as a whole, are free from material misstatement. Reasonable assurance refers to a high level of assurance, without however guaranteeing that an audit performed in accordance with professional standards would systematically detect any material misstatement. Misstatements may be the result of fraud or error and are considered material when it is reasonable to expect that they could, individually or in aggregate, influence the economic decisions made by users of the financial statements.

As stipulated by Article L. 821-55 of the French Commercial Code, our role in auditing the financial statements is not to guarantee the viability or quality of your company's management.

In an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit. In addition :

- identifies and assesses the risks of material misstatement of the financial statements, whether due to fraud or error, designs and implements audit procedures to address these risks, and obtains audit evidence that it believes to be sufficient and appropriate to provide a basis for its opinion. The risk of not detecting a material misstatement resulting from fraud is higher than that of a material misstatement resulting from error, as fraud may involve collusion, falsification, deliberate omission, misrepresentation or circumvention of internal control;

- it obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, and not for the purpose of expressing an opinion on the effectiveness of internal control;

- it assesses the appropriateness of the accounting methods used and the reasonableness of the accounting estimates made by management, as well as the related disclosures in the financial statements;

- it assesses the appropriateness of management's application of the going concern accounting policy and, based on the information gathered, whether or not there is any significant uncertainty linked to events or circumstances that could call into question the company's ability to continue as a going concern. This assessment is based on information gathered up to the date of his report, bearing in mind that subsequent events or circumstances could call into question the company's ability to continue as a going concern. If the auditor concludes that there is a material uncertainty, he draws the attention of the readers of his report to the information provided in the annual financial statements concerning this uncertainty or, if this information is not provided or is not relevant, he issues a qualified opinion or a refusal to certify;

- assesses the overall presentation of the annual financial statements, and whether they give a true and fair view of the underlying transactions and events.

Paris-La Défense, April 30, 2025

The Statutory Auditor
ERNST & YOUNG et Autres

Franck Sebag

CHAPTER 6: RESPONSIBLE PERSONS

6.1. Person responsible for the document

Alexandre LOISEAU, Chairman and CEO of Mauna Kea Technologies SA.

6.2. Certification by the responsible person

"I hereby certify that, having taken all reasonable care to ensure that such is the case, the information contained in this Document is, to the best of my knowledge, in accordance with the facts and contains no omission likely to affect its import.

I certify that, to the best of my knowledge, the financial statements have been prepared in accordance with applicable accounting standards and give a true and fair view of the assets and liabilities, financial position and results of the Company and all the companies included in the consolidation, and that the management report, the information on which is listed in section 9.2 "Analysis of results", presents a true and fair view of the development of the business, results and financial position of the Company and all the companies included in the consolidation, and describes the main risks and uncertainties they face."

Paris, April 24, 2025

Alexandre Loiseau
Chairman and Chief Executive Officer

6.3. Responsible for financial information

Côme de La Tour du Pin

Chief Financial Officer

9 rue d'Enghien

75010 Paris

E-mail: investors@maunakeatech.com

6.4. Auditors

6.4.1. Statutory Auditors

Ernst & Young et Autres

Member of the Compagnie régionale des commissaires aux comptes de Versailles

Represented by Mr Franck Sebag

1/2 Place des Saisons, 92400 Courbevoie - Paris La Défense 1

Appointed by the Annual General Meeting of June 2, 2023, to hold office until the Annual General Meeting called to approve the financial statements for the year ending December 31, 2028.

6.4.2. Alternate Auditors

None

6.5. Declaration of experts and declaration of interest

None.

6.6. Third-party information

None.

6.7. Declaration by the competent authority regarding approval of the Document

See the cover page of this document.

6.8. Documents available to the public

Copies of this Document are available free of charge from the Company's registered office at 9 rue d'Enghien 75010 Paris, France. It can also be consulted on the Company's website (www.maunkeatech.com) and on the AMF website (www.amf-france.org).

The Company's bylaws, minutes of Shareholders' Meetings and other corporate documents, as well as historical financial information and any valuation or statement drawn up by an expert at the Company's request that must be made available to shareholders, in accordance with applicable legislation, may be consulted, free of charge, at the Company's registered office.

Regulated information within the meaning of the AMF General Regulations is also available on the Company's website (www.maunakeatech.com).

CHAPTER 7: CROSS-REFERENCE TABLES

7.1. Cross-reference table in the annual financial report

Information required in the Annual Financial Report	Paragraphs
1 - Declaration by the individuals responsible for the Financial Report	6.1
2 - 2024 parent company financial statements	5.3
3 - 2024 consolidated financial statements	5.2

4 - Statutory auditors' reports on the 2024 parent company financial statements	5.4
5 - Statutory auditors' reports on the 2024 consolidated financial statements	5.2.2
6 - Management report pursuant to article 222-3-3° of the AMF General Regulations	7.2

7.2. Management report cross-reference table

The following table identifies and locates the mandatory information in the Board's report to the Annual General Meeting in this Document.

Information required in the Management Report	RFA requirements	Paragraphs
1) COMPANY ACTIVITY		
- Situation of the Company and the Group during the year just ended		1.1 and 5
- Foreseeable evolution		5
- Significant events since the balance sheet date		5
- Activities of subsidiaries and affiliates by business segment		5.2.1 and 5.3.2
- Company and Group results		5
- Objective and exhaustive analysis of the Company's business trends, results and financial situation, in particular the Company's and Group's debt position.	FRG	5
- Key financial performance indicators for the Company and the Group	FRG	5
- Non-financial key performance indicators for the Company and the Group		5
- Main risks and uncertainties facing the Company and the Group	FRG	2.1

- Internal control and risk management procedures relating to the preparation and processing of the Company's and the Group's accounting and financial information	RFA	2.2
- Hedging objective and policy for transactions for which hedge accounting is used by the Company and the Group	RFA	N/A
- Exposure to price, credit, liquidity and cash flow risks of the Company and the Group		2.1
- Use of Company and Group financial instruments		N/A
- Financial risks related to the effects of climate change and presentation of measures taken to reduce them (low-carbon strategy) by the Company and the Group	FRG	N/A
- Research and development activities of the Company and the Group		1.2
- Mention of existing branches		5.2.1 - 5.3.2 - 5.3.5
2) LEGAL, FINANCIAL AND TAX INFORMATION ABOUT THE COMPANY		
- Shareholder structure and trends		4.4.1
- Names of controlled companies and percentage of the Company's capital held by them		5.2.1 - 5.3.2 - 5.3.5
- Significant investments during the year in companies headquartered in France		N/A
- Cross-participation		N/A
- Employee share ownership		N/A
- Acquisition and sale by the Company of its own shares	FRG	4.3.4
- Adjustment of securities giving access to the capital in the event of financial transactions		N/A
- Adjustment of securities giving access to the capital and stock options in the event of a share buyback		N/A
- Dividends distributed for the last three years		N/A

- Non-deductible expenses		5.3.4
- Where applicable, injunctions or fines imposed by the Competition Council for anti-competitive practices		N/A
- Information on supplier and customer payment terms		5.3.5
- Inter-company loans		5.3.2
- Information on the operation of a SEVESO facility		N/A
3) INFORMATION CONCERNING CORPORATE OFFICERS		
- Directors' securities transactions		N/A
4) EXTRA-FINANCIAL PERFORMANCE STATEMENT (information provided on a voluntary basis)		
5) ENCLOSED DOCUMENTS		
- Report on payments to governments		N/A
- 5-year financial summary		5.3.5
- Report on corporate governance		3

7.3. Cross-reference table for the headings in annexes 1 and 2 of European Regulation 2019/980

References	Titles	Paragraphs
SECTION 1	**RESPONSIBLE PERSONS, THIRD-PARTY INFORMATION, EXPERT REPORTS AND AND APPROVAL FROM THE COMPETENT AUTHORITY**	
Point 1.1	Persons responsible for the information	6.1 and 6.3
Point 1.2	Certification by those responsible for the document	6.2

Point 1.3	Expert statement	6.5
Point 1.4	Other certificates for third-party information	6.6
Point 1.5	Declaration of document approval	6.7
SECTION 2	**STATUTORY AUDITORS**	
Point 2.1	Contact	6.4
Point 2.2	Changes	N/A
SECTION 3	**RISK FACTORS**	
Point 3.1	Description of major risks	2.1
SECTION 4	**INFORMATION ABOUT THE ISSUER**	
Point 4.1	Company and trade name	4.1.1
Point 4.2	RCS registration and identifier (LEI)	4.1.2
Point 4.3	Date of incorporation and duration	4.1.3
Point 4.4	Registered office - legal form - applicable legislation - website - other	4.1.4
SECTION 5	**BUSINESS OVERVIEW**	
Point 5.1	Main activities	1.1
Point 5.1.1	Nature of operations and main activities	1.1
Point 5.1.2	New products and/or services	1.1
Point 5.2	Main markets	1.1
Point 5.3	Important events	5.1.5 - 5.2.1 - 5.3.1
Point 5.4	Financial and non-financial strategy and objectives	1.1.4
Point 5.5	Degree of dependence	N/A
Point 5.6	Competitive position	1.1.4

Point 5.7	Investments	5.1.4
Point 5.7.1	Major investments made	5.1.4
Point 5.7.2	Major investments in progress or firm commitments	N/A
Point 5.7.3	Joint ventures and significant shareholdings	5.2.1 and 5.3.2
Point 5.7.4	Environmental impact of the use of property, plant and equipment	N/A
SECTION 6	**ORGANIZATIONAL STRUCTURE**	
Point 6.1	Brief description of the Group / Organization chart	5.2.1 and 5.3.2
Point 6.2	List of major subsidiaries	5.2.1 and 5.3.2
SECTION 7	**REVIEW OF FINANCIAL POSITION AND RESULTS**	
Point 7.1	Financial situation	5.1
Point 7.1.1	Business performance and results	5.1.1
Point 7.1.2	Future developments and research and development activities	1.2
Point 7.2	Results of operations	5.1.2
Point 7.2.1	Important factors	5.1
Point 7.2.2	Significant changes in net sales or revenues	5.1
SECTION 8	**CASH AND CAPITAL**	
Point 8.1	Issuer's capital	5.2.1 Note 11
Point 8.2	Cash flow	5.1.4
Point 8.3	Financing requirements and structure	5.1.4
Point 8.4	Restrictions on the use of capital	N/A
Point 8.5	Expected sources of financing	5.2.1

SECTION 9	**REGULATORY ENVIRONMENT**	
Item 9.1	Description of the regulatory environment and external influencing factors	2.1.1
SECTION 10	**TREND INFORMATION**	
Item 10.1	a) Main recent trends	5.1
	b) Significant changes in the Group's financial performance since the balance sheet date	5.1
Item 10.2	Fact likely to have a material impact on the outlook	2.1
SECTION 11	**PROFIT FORECASTS OR ESTIMATES**	
Item 11.1	Forecast or estimate of current profit	5.1.5
Item 11.2	Main assumptions	5.1.5
Item 11.3	Confirmation of profit forecast or estimate	N/A
SECTION 12	**ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND SENIOR MANAGEMENT**	
Item 12.1	Information concerning members of the Company's administrative and management bodies	3.1.1
Item 12.2	Conflicts of interest	3.1.2
SECTION 13	**COMPENSATION AND BENEFITS**	
Item 13.1	Compensation and benefits paid or granted	N/A
Item 13.2	Provisions for pensions and other post-employment benefits	5.2.1 Note 13.1
SECTION 14	**OPERATION OF ADMINISTRATIVE AND MANAGEMENT BODIES**	
Item 14.1	Term of office	3.1.1
Item 14.2	Service contracts	N/A
Item 14.3	Committees	3.2.2

Item 14.4	Compliance with corporate governance rules	3.2.3
Item 14.5	Potential significant impacts and future changes in governance	N/A
SECTION 15	**EMPLOYEES**	
Item 15.1	Breakdown of employees	N/A
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Item 15.3	Employee shareholding agreement	N/A
SECTION 16	**MAJOR SHAREHOLDERS**	
Item 16.1	Capital breakdown	4.4.1
Item 16.2	Different voting rights	4.4.3
Item 16.3	Transmitter control	4.4.4
Item 16.4	Shareholder agreement	4.4.4
SECTION 17	**TRANSACTIONS WITH RELATED PARTIES**	
Item 17.1	Transaction details	4.4.6
SECTION 18	**FINANCIAL INFORMATION CONCERNING THE ISSUER'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND RESULTS OF OPERATIONS**	
Item 18.1	Historical financial information	5.1 - 5.2 - 5.2
Point 18.1.1	Audited historical financial information	5.1 - 5.2 - 5.2
Point 18.1.2	Change of accounting reference date	N/A
Point 18.1.3	Accounting standards	5.2.1 note 1.1 5.3.1 note 1
Point 18.1.4	Change in accounting standards	N/A
Point 18.1.5	Minimum content of audited financial information	5.3

Point 18.1.6	Consolidated financial statements	5.2
Point 18.1.7	Date of latest financial information	5.2
Item 18.2	Interim and other financial information	N/A
Point 18.2.1	Quarterly or half-yearly financial information	N/A
Item 18.3	Audit of historical annual financial information	5.2 and 5.3
Point 18.3.1	Audit report	5.2.2 and 5.4
Point 18.3.2	Other audited information	N/A
Point 18.3.3	Unaudited financial information	N/A
Item 18.4	Proforma financial information	N/A
Point 18.4.1	Significant change in gross values	N/A
Item 18.5	Dividend policy	N/A
Point 18.5.1	Description	N/A
Point 18.5.2	Dividend per share	N/A
Item 18.6	Legal and arbitration proceedings	N/A
Point 18.6.1	Significant procedures	N/A
Item 18.7	Significant change in the issuer's financial position	5.1
Point 18.7.1	Significant changes since year-end	5.1
SECTION 19	**ADDITIONAL INFORMATION**	
Item 19.1	Share capital	4.3
Point 19.1.1	Issued capital	4.3.1
Point 19.1.2	Shares not representing capital	4.3.2
Point 19.1.3	Treasury shares	4.3.4
Point 19.1.4	Securities	4.3.5

Point 19.1.5	Conditions of acquisition right and/or any obligation	4.3
Point 19.1.6	Option or agreement	4.3
Point 19.1.7	History of share capital	4.3
Item 19.2	Memorandum and articles of association	4.2
Point 19.2.1	Registration and corporate purpose	4.1 - 4.2
Point 19.2.2	Existing share classes	4.3
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SECTION 20	**MAJOR CONTRACTS**	
Point 20.1	Summary of each contract	1.2.3 - 5.2.1 note 1.17
SECTION 21	**AVAILABLE DOCUMENTS**	
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