



# Mauna Kea Technologies

A Public Limited Company (*Société anonyme*) with share capital of 559,701 euros  
Registered office: 9 rue d'Enghien  
75010 Paris, France  
431 268 028 in the Paris Trade and Companies Register

## 2014 Registration Document



Pursuant to its General Regulation, in particular Article 212-13, the *Autorité des marchés financiers* (AMF, French Financial Markets Authority) filed this Registration Document on June 24, 2015 under the number R.15-056. This document may not be used in connection with any financial transaction unless it is supplemented by a securities note approved by the AMF. This document was prepared by the issuer and its signatories are liable for its content.

In compliance with the provisions of Article L.621-8-1-I of the French Monetary and Financial Code, this document was registered after the AMF checked that it is complete and understandable, and that its content is consistent. It does not imply any authentication by the AMF of the accounting and financial information presented.

*This document is available free of charge from the Company's head office. It is also available in electronic form on the AMF (website ([www.amf-france.org](http://www.amf-france.org))) and on the Company's website ([www.maunakeatech.com](http://www.maunakeatech.com)).*

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## GENERAL OBSERVATIONS

### *Definitions*

In this Registration Document, unless otherwise indicated:

- The term "Mauna Kea Technologies" or the "Company" refers to Mauna Kea Technologies S.A.;
- The term "Mauna Kea Technologies Inc." or the "Subsidiary" refers to the American subsidiary Mauna Kea Technologies Inc., wholly owned by Mauna Kea Technologies S.A.;
- The term "Group" refers to Mauna Kea Technologies S.A. and its subsidiary.

## SECTION 1

### PERSONS RESPONSIBLE

#### 1.1. Person responsible for the Registration Document

Mr. Alexandre LOISEAU, CEO of Mauna Kea Technologies.

#### 1.2. Attestation of the person responsible

"Having taken all reasonable measures to this end, I declare that the information contained in this Registration Document is, to my knowledge, in keeping with the facts, and leaves out nothing that might impact on its substance.

The statutory auditors have given me their letter of consent, in which they confirm having verified the information regarding the financial position and the financial statements provided in this Registration Document, as well as having read this Registration Document in its entirety.

The historical financial information for the financial year ended December 31, 2014 provided in this Registration Document was covered by a statutory auditors' report provided on page 162 of said document, which contains no observations.

The historical financial information for the financial year ended December 31, 2013 provided for reference in this Registration Document and provided in the 2013 Registration Document filed with the AMF on August 6, 2014 under No. R.14-050 was covered by a statutory auditors' report, provided on page 163 of said Registration Document, which contains no observations.

The historical financial information for the financial year ended December 31, 2012 provided for reference in this Registration Document and provided in the 2012 annual financial report published on April 26, 2013 on the Company's website (<http://www.maunakeatech.com/en/content/documentation>) was covered by a statutory auditors' report, provided on page 88 of said annual financial report, which contains no observations."

June 23, 2015  
**Alexandre Loiseau**  
 Chief Executive Officer

#### Incorporation by reference

In accordance with Article 28 of the Commission Regulation (EC) No. 809/2004 of April 29, 2004, the following information has been incorporated in this Registration Document as reference

:

##### 1. Regarding the 2013 financial year:

- the management report on the consolidated financial statements, the consolidated financial statements and the statutory auditors' report on the latter are provided respectively in Sections 9 and 20 of the Registration Document filed with the AMF under No. R.14-050 on August 6, 2014.
- the statutory auditors' special report on related party agreements is included in Section 19.3 of said Registration Document.

##### 2. Regarding the 2012 financial year:

- the management report on the consolidated financial statements, the consolidated financial statements and the statutory auditors' report on the latter are provided respectively in pages 5 to 13, 48 to 87 and 88 to 90 of the 2012 annual financial report published on April 26, 2013 on the Company's website (<http://www.maunakeatech.com/en/content/documentation>).
- the statutory auditors' special report on related party agreements is provided in pages 117 to 119 of the 2012 annual financial report published on April 26, 2013 on the Company's website (<http://www.maunakeatech.com/en/content/documentation>)

### 1.3. Persons responsible for the financial information



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**Chief Executive Officer**

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## SECTION 2 STATUTORY AUDITORS

### 2.1. Main statutory auditors

#### **COFIDEC SARL,**

Member of the Regional Company of Auditors of Paris  
Represented by Mr. Thibault Faure  
155 Boulevard Haussmann, 75008 Paris

Date of start of first term of office: June 7, 2006.

Duration of the current term of office: six financial years from June 15, 2012.

Date of expiry of the current term of office: at the end of the general meeting held to approve the financial statements for the year ending December 31, 2017.

#### **Ernst & Young et Autres,**

Member of the Regional Company of Auditors of Versailles  
Represented by Mr. Cédric Garcia  
1/2 Place des Saisons, 92400 Courbevoie - Paris-La Défense 1.

Date of start of first term of office: May 25, 2011

Duration of the current term of office: six financial years from May 25, 2011.

Date of expiry of the current term of office: at the end of the general meeting held to approve the financial statements for the year ending December 31, 2016.

### 2.2. Alternate statutory auditors

#### **ATA SARL,**

Member of the Regional Company of Auditors of Paris  
155 Boulevard Haussmann, 75008 Paris

Date of start of first term of office: June 7, 2006.

Duration of the current term of office: six financial years from June 15, 2012.

Date of expiry of the current term of office: at the end of the general meeting held to approve the financial statements for the year ending December 31, 2017.

#### **Auditex,**

Member of the Regional Company of Auditors of Versailles  
1/2 Place des Saisons, 92400 Courbevoie - Paris-La Défense 1.

Date of start of first term of office: May 25, 2011

Duration of the current term of office: six financial years from May 25, 2011.

Date of expiry of the current term of office: at the end of the general meeting held to approve the financial statements for the year ending December 31, 2016.

During the period covered by the historical financial information, there have been no resignations or terminations of statutory auditors.

## SECTION 3

### SELECTED FINANCIAL INFORMATION

The key financial information presented below was taken from the consolidated financial statements prepared according to IFRS [International Financial Reporting Standards]. It should be read together with the information contained in Sections 9 "Review of results and the financial situation," 10 "Cash and capital," and 20 "Financial information concerning the assets, financial situation and earnings of the issuer".

#### Simplified consolidated balance sheet

Consolidated data audited in €K

	As at December 31		
	2014	2013	2012
Non-current Assets	4,440	4,309	3,807
Including intangible assets	3,542	3,713	3,163
Including tangible assets	794	519	571
Including non-current financial assets	105	77	73
Current Assets	23,098	35,235	42,251
Including cash and cash equivalents	15,018	27,792	37,638
<b>TOTAL OF ASSETS</b>	<b>27,538</b>	<b>39,544</b>	<b>49,058</b>
Equity	18,150	30,159	40,162
Non-current Liabilities	3,124	3,108	2,843
Including long-term debt	2,606	2,643	2,362
Current liabilities	6,264	6,276	6,053
Including short-term borrowings and debts	638	659	756
<b>TOTAL OF EQUITY AND LIABILITIES</b>	<b>27,538</b>	<b>39,544</b>	<b>49,058</b>

#### Simplified consolidated income statement

Consolidated data audited in €K

	As at December 31		
	2014	2013	2012
Total sales of "equipment"	7,175	6,835	6,172
Total sales of "consumables" (probes)	2,958	2,603	2,003
Total sales of "services"	882	538	634
<b>Total sales</b>	<b>11,016</b>	<b>9,977</b>	<b>8,810</b>
Other income	1,267	939	1,472
<b>Total of revenue</b>	<b>12,282</b>	<b>10,915</b>	<b>10,282</b>
Cost of sales	(3,675)	(3,042)	(2,705)
Gross margin	67%	70%	69%
<b>Total operating expenses</b>	<b>(26,106)</b>	<b>(22,437)</b>	<b>(23,251)</b>
<b>Operating profit</b>	<b>(13,823)</b>	<b>(11,521)</b>	<b>(12,969)</b>
<b>Profit before tax</b>	<b>(13,991)</b>	<b>(11,516)</b>	<b>(13,054)</b>
Other comprehensive income	99	(73)	(52)
<b>Comprehensive income</b>	<b>(13,892)</b>	<b>(11,589)</b>	<b>(13,108)</b>

## SECTION 3 - SELECTED FINANCIAL INFORMATION

### Simplified consolidated cash-flow statements

Consolidated data audited in €K	As at December 31		
	2014	2013	2012
Net cash flows from operating activities	(12,731)	(9,612)	(13,280)
Of which self-financing capacity	(11,751)	(10,016)	(11,207)
Of which change in WCR related to business activities	(980)	405	(2,073)
Net cash flows from investing activities	(567)	(1,146)	(429)
Net cash flows from financing activities	483	923	2
Cash flows variation	<u>(12,774)</u>	<u>(9,846)</u>	<u>(13,709)</u>

### Net cash position

Consolidated data audited in €K	2014	of which under 1 year	of which over 1 year
Financial debts			
BPI-Coface advances	3,244	638	2,606
Cash and cash equivalents	15,018	15,018	
Net cash balances (*)	<u>11,774</u>	<u>14,380</u>	<u>(2,606)</u>

(\*) This amount does not take into account the capital increase through private placement carried out in May 2015 for a gross amount of €4.7 million.

### 2015 Q1 sales: recovery in the United States, regulatory delays in China, stable growth in the EMEA region

The Company reported its quarterly sales for 2015:

Consolidated data audited in €K	As at March 31		
	2015	2014	Change
Total sales of "equipment"	1,222	1,383	-12%
Total sales of "consumables" (probes)	479	589	-19%
Total sales of "services"	154	192	-20%
<b>Total sales</b>	<b><u>1,855</u></b>	<b><u>2,164</u></b>	<b><u>-14%</u></b>

Sales for the first quarter of 2015 came to €1,855K (-14%). The breakdown by business shows strong growth of the preclinical business (€581K, +160%), which does not compensate for the fall of the clinical business to €1,274K (-34%). Sales to hospitals and clinics accounted for 69% of activity in the quarter (versus 90% in Q1 2014).

The breakdown of sales by product and nature highlights the drop in sales of systems to €1,222K and of consumables to €479K (-12% and -19% respectively). Services also moved down to €154K (-20%).

In terms of volume, in the quarter the Company recorded the sale of 12 systems and 134 probes (versus 16 and 157 in Q1 2014, respectively), equal to a decrease of 25% for systems and of 15% for probes. In the first quarter of 2015, 12 systems were added to the net installed base of Cellvizio in the clinical segment, with the overall installed base (including preclinical systems) reaching 456 systems as at March 31, 2015.

## SECTION 4

# RISK FACTORS

*Investors are asked to take into consideration all the information contained in this Registration Document, including the risk factors described in this Section, before deciding whether to purchase or subscribe for the Company's shares.*

### 4.1. Risks related to the markets in which the Group operates

**There are alternative technologies and the appearance of new competing technologies cannot be ruled out.**

The products developed by the Company are positioned in markets in which, in some cases, alternative solutions already exist (traditional biopsy for example), the use of which is sometimes very widespread in the practices of physicians and other medical personnel.

Even though the Company considers that the other solutions available do not perform as well as the Cellvizio and its confocal miniprubes, particularly to the extent that they are more invasive and do not enable microscopic visualization *in vivo*, it cannot guarantee that other alternative or competing technologies showing similar or even superior characteristics in part or in full, compared to those of the Cellvizio, will not be developed.

Such technologies could take significant market share and hinder the Group's ability to market its products successfully. They could also prevent the technology which the Company integrated into the Cellvizio (fiber-optic laser scanning) from becoming established as the benchmark for optical biopsy.

The leaders of the endoscopy market in particular are major players in relation to the Company and have substantial financial resources, which could 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.

The business, financial situation, earnings, growth and prospects of the Group in the medium and long term might be materially affected by the materialization of one or more of these risks.

In addition to its intellectual property protection policy (see Section 11.2.1 Intellectual property protection policy), to protect itself against this risk, the Group devotes considerable effort to improving its existing products and to developing new products and solutions adapted to new areas of medicine and to new pathologies in order to maintain its technological edge.

As of end of December 2014, the R&D department had 30 associates and the budget devoted to R&D in 2014 came to more than €4.6 million.

**The Group might be unable to carry out the necessary growth transactions or they could bring about integration difficulties, monopolize the management team to the detriment of its commitment to the Group's operations, dilute the existing shareholders or negatively impact the financial earnings of the Group.**

The Group's long-term success depends in part on its ability to improve and constantly expand the products it offers, so as to respond to the constantly changing demands of the market, withstand strong competitive and technological pressures, and broaden its geographic coverage.

The Group might be unable, in its current configuration, to satisfy these demands. As a result, the Company could, in the near future, make selective acquisitions of new or complementary technologies. The implementation of this strategy depends, in part, on the Company's ability to identify attractive targets, carry out such acquisitions on satisfactory conditions, and integrate them successfully into its operations or technology.

The Company cannot ensure that it will be able to identify the best opportunities or to make these acquisitions. Moreover, their completion could result in difficulties in integrating new entities or technologies and mobilize the management team and distract it from the Group's operations.

Furthermore, the acquisition of technologies, as well as the entering into of other external growth transactions, could cause the Group to incur significant costs. The Company might have to finance such acquisitions by taking out loans or issuing new equity securities, which could cause it to take financial risks and result in the imposition of certain restrictions or have a dilutive effect on its shareholders.

The business, financial situation, earnings, growth and prospects of the Group in the medium and long term might be materially affected by the materialization of one or more of these risks.

### 4.2. Risks related to the business of the Group

#### 4.2.1. Risks related to the commercial expansion of the Group

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

The Group believes that healthcare professionals will not use its products widely until they are convinced, based on clinical data or scientific publications, that its products offer advantages or are an interesting alternative to equipment already on the market, which they are already experienced in using.

In spite of the compelling results from clinical trials already conducted, the support of numerous specialty societies throughout the world, multiple scientific publications reporting the contributions of the solution proposed by the Company compared to technologies existing to date and the installed base of the Company's products, these same professionals could be reluctant to change their medical treatment practices in favor of the Cellvizio, particularly for the following reasons:

- their lack of experience in using the Cellvizio;
- a significantly insufficient amount of favorable clinical data published;
- fear of their possible liability for using new products and new operating procedures;
- limitations on reimbursements by public or private health insurance plans or collective entities.

Without the endorsement of healthcare professionals, the pace of widespread adoption of the Cellvizio could be more or less seriously slowed, which might have a material adverse effect on the Group, its business, financial situation, earnings, growth and prospects.

**The Group's development is also conditional on its capacity to commercialize its products in new indications in the medical and research fields.**

As of the registration date of this Registration Document, the Group is marketing the Cellvizio and its consumable miniproboscopes in two markets: the research laboratories market with a specific version of the product called the "Cellvizio LAB" and the healthcare facilities market (hospitals and clinics) where the Cellvizio is being marketed in the fields of gastroenterology, pulmonology and, more recently, urology.

The Group's development and its ability to generate revenue will depend in part on its ability to commercialize its products in new medical indications, which will itself be based on several factors such as:

- endorsement of the Cellvizio by the medical community concerned by these new applications;
- the ability to have the necessary sales forces;
- and/or the results from current and future clinical trials.

The Company intends to continue its research and development efforts in order to perfect its existing products and to develop new products to increase the outlets for the procedures performed with the Cellvizio, which the Company considers numerous.

**The Group's business development is conditional on its capacity to maintain the reimbursements already granted by some health authorities and to secure new reimbursements for certain indications in certain geographical areas.**

The success of the market deployment of the Group's products (Cellvizio and confocal miniprobes) depends in part on the conditions for coverage and reimbursement by the benefits agencies or private insurers in place in the countries where the Group wishes to market its products.

The governments and agencies in charge of public or private health insurance plans endeavor to control health expenses by limiting both the level of reimbursement and the coverage of certain products, particularly innovative products.

In spite of the clinical validation obtained, the Company cannot ensure that the Group will be able to obtain, in all the countries in which it wishes to market its products, firstly, these products' eligibility under the reimbursement conditions and, secondly, coverage and reimbursement levels that would encourage healthcare professionals to incorporate endomicroscopic procedures into their practices, nor can it ensure that it is or will be able to foresee potential changes over time in the coverage and reimbursement conditions that it could have obtained.

The absence of or insufficient reimbursement for or coverage of the Group's products or the adoption of more restrictive reimbursement or coverage measures might have a material adverse effect on the Group, its business, financial situation, earnings, growth and prospects.

In this field, however, the Company has completed an important first step. In March 2012, the American Medical Association created three new reimbursement codes for endomicroscopy, CPT Codes, of category I for the United States. Two of these codes concern gastroenterology and are intended to reimburse the procedures performed with the Cellvizio in the upper gastrointestinal tract. They were valued at \$1,013 as at January 1, 2014. The third code concerns histopathologists. In March 2015, the American Medical Association (AMA) assigned a new CPT code for use in endoscopic retrograde cholangiopancreatography (ERCP), allowing practitioners to diagnose biliary tract pathologies, notably strictures and cancers.

At the date of this Registration Document, the United States is the only country in which the Group has obtained reimbursement rates. In addition, the Group continues its efforts to secure reimbursement codes in new countries, as the first step before setting the corresponding rate.

**The Group might not be able to recruit and retain the direct and indirect sales forces within periods or under conditions compatible with its expansion.**

The marketing deployment of the Cellvizio with healthcare facilities (hospitals and clinics) is being carried out by a combination of two sales forces. A direct sales force is carrying out the commercialization in France, the United States and Canada. However, for the other geographic zones, particularly Asia, some countries in South America and European countries other than France and Germany, the Company intends to promote an indirect approach through a network of independent distributors to whom exclusive territories will be granted.

The successful marketing of its products in France, Germany and the United States depends in particular on the Group's ability to recruit and retain a sales force.

Furthermore, the successful international marketing of the Group's products in the other geographic zones depends on the financial resources, expertise and customers of its distributors. The Group cannot ensure that it will be able to retain its existing distributors or enter into new distribution agreements to reach all the countries with sales potential, or that these distributors will devote the resources necessary for the commercial success of its products. In order to limit this risk, part of the direct sales force has terms of reference to act as support for the distributors to help them to carry out in particular commercial actions such as maintaining a presence at trade shows and conducting demonstration workshops at hospitals and clinics. This point is all the more important as these are generally distributors of medical equipment and devices who have several products to promote and market, and consequently limited time to devote to each of them.

As of late December 2014, almost 50 exclusive distribution agreements had been signed not counting the one granted to the Company's United States subsidiary. For more information, refer to Section 6.4.1 "The marketing strategy" of this Registration Document.

The use of exclusivity clauses, as provided for by these agreements, might be challenged by French or European law. These clauses could also, in certain cases, be deemed unlawful, in particular if they result in abuse in the fixing of prices of the products by the Company or an obstacle to free competition. The exclusive distribution agreements entered into with some independent distributors

## SECTION 4 - RISK FACTORS

might therefore be the subject of termination and/or give rise to monetary penalties against the Group if some of the clauses they contain are held to be unlawful.

The business, financial situation, earnings, growth and prospects of the Group in the medium and long term might be materially affected by the materialization of one or more of these risks.

### **The marketing of the Cellvizio LAB now relies on a network of distributors and a limited direct sales force**

To date, the Company has entered into several distribution agreements in various countries and also performs direct sales in regions not covered by a distribution agreement.

The successful marketing of the products of the Group's Cellvizio LAB range depends in part on financial resources, expertise and customers of its distributors. The Group cannot ensure that it will be able to retain its existing distributors or enter into new distribution agreements to reach all the countries with sales potential, or that these distributors will devote the resources necessary for the commercial success of its products. In order to limit this risk, part of the direct sales force has terms of reference to act as support for the distributors to help them to carry out commercial actions among their targets.

### **The Group's ability to expand the outlets for its products will depend on the completion periods and results of future clinical studies, which are uncertain by nature.**

From 2005 to date, the clinical contribution of the Cellvizio has been the subject of more than 260 clinical publications throughout the world, including several multicenter clinical trials randomized and funded by the Group on key applications in gastroenterology. In spite of the compelling results already obtained, which have been the subject of communications, the Group is continuing its efforts in this respect and will continue to organize this kind of trial, in particular with a view to clinically validating the Cellvizio's contributions in new medical fields (urology, pulmonology, surgery, etc.).

The quality and interest of these multicenter studies depend on the Group's ability to select partner hospitals and clinics and to recruit the number of patients necessary within relatively limited periods in order to be able to publish the results quickly, as well as to choose the right service providers in charge of implementing the study protocol defined by the Group. The geographic remoteness or distribution of the clinical study centers may also cause operational and logistical difficulties, which could result in additional costs and time.

If the Group is unable to recruit the patients planned on, resulting in delay of the clinical studies and the publication of their results, there would be a delay in the endorsement both by specialty societies and by professionals from the relevant medical fields, and the Group's ability to market its equipment would be affected, which might have a material adverse effect on the Group, its business, financial situation, results, development or prospects.

Concerning fields other than gastroenterology, the number of clinical trials conducted is still limited. Other trials will be commenced. They concern medical uses falling within the fields of urology and pulmonology. If the results of these studies, whether comparative (randomized studies) or not, do not make it possible to prove the medical advantage of the equipment proposed by the Group, it would result in a setback in or absence of the scientific and medical community's recognition of the Cellvizio. If such a risk materializes, the Group's ability to win market share would be affected on a long-term basis, which might have a material adverse effect on the Group, its business, financial situation, earnings, development or prospects. The Company has not been able to move forward with the commercial expansion planned at the time of its IPO. Some of the reasons for this delay are presented in Section 6.4.3.

#### 4.2.2. Risks related to intellectual property

**The Company counts, to a great extent, on the exclusive nature of its intellectual property and know-how. However, the Company might not be able to maintain or obtain adequate protection and, in this way, to protect its technological and competitive advantage.**

The Company relies, for the protection of its products and technology, on the protection provided by intellectual property rights, such as patents and trademarks, but also on its commercial secrets and know-how, protected by confidentiality and other agreements. However, these means provide only limited protection and might not prevent unlawful use of the products or technology of the Group.

The products and technologies on which the Group's business is based are mainly protected firstly by several patents and patent applications which cover both the hardware and software aspects of its current products, but also a certain number of technologies or alternative processes currently being developed and, secondly, by the know-how of the Company, covering in particular manufacturing methods and the choice of certain critical components.

The Company could experience difficulties in obtaining some of its patent applications currently being examined. Furthermore, the issuance of a patent does not ensure its validity or applicability, both of which may be disputed 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 countries in Europe, Canada, Japan, Australia, and, for the most important patents, in China, India and Israel.

The Company cannot ensure with certainty that:

- the Company's patent applications that are in the process of being reviewed will actually result in the issuance of patents and accordingly in protection of the inventions that are the subject of the patent applications in question in all the countries where these patent applications were filed (refer to Section 11.2 "Patents and patent applications" showing the patents obtained and the patent applications currently pending);
- the patents issued to the Company will not be disputed, invalidated or circumvented;
- the extent of the protection provided by the patents will be sufficient to protect it against competition and the patents of third parties that cover similar products or devices;
- the competitors of the Group have not already developed a technology or products similar to those of the Group; and
- the Group's products do not infringe patents that belong to third parties.

The Group's competitors may thus successfully challenge the validity of its patents before a court or in the context of other proceedings, which, depending on the outcomes of said challenges, could reduce the scope of these patents, lead to their invalidity or enable competitors to circumvent them. Therefore, the Company's rights under its patents might not provide the expected protection against competition.

Nor can the Company ensure that its products and technology, which are closely linked to its know-how and commercial secrets, are adequately protected against competitors and cannot be usurped, or circumvented, by the latter. Indeed, in the collaboration and research and development agreements entered into by the Company, the latter must frequently provide its co-contractors, in

## SECTION 4 - RISK FACTORS

various forms, with certain items from its know-how, whether protected by patents or not, in particular information, data or knowledge concerning research, development, the manufacture and marketing of its products.

The Company seeks to limit the disclosure of key items from its know-how to third parties only to the information strictly necessary for the collaboration which it maintains with them and it ensures contractually that these third parties undertake not to misappropriate, use or disclose this information, in particular by means of confidentiality clauses. The Company cannot, however, ensure that these third parties comply with these agreements, that the Company will be informed of a breach of these clauses, or further that the damages it could possibly obtain would be sufficient in respect of the loss suffered.

Moreover, these collaboration and research and development agreements expose the Company to the risk of seeing its co-contractors claiming the benefit of intellectual property rights to the Group's inventions, knowledge or results. Lastly, these agreements could give rise to co-owned intellectual property rights or to the granting of exclusive licenses 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 and the United States in particular and in numerous countries, third parties could use or attempt to use this trademark or other trademarks of the Company, which would be of a nature to cause a commercial loss and harm the image of the Group.

The Company's protection of its intellectual property rights accounts for a considerable cost relating, in particular, to the expense of registering patents and keeping them in force and to managing its other intellectual property rights, which cost could increase, in particular if litigation were to be brought by the Company to assert its rights. In addition to these costs, if litigation were to prove necessary in order to enforce compliance with 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 have a negative influence on earnings and the financial situation of the Group, or fail to provide the protection sought.

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

The materialization of one or more of these risks could have a material adverse effect on the Group's business, financial situation, earnings, growth and prospects.

### **In the future, some of the Company's business could depend on technologies belonging to third parties.**

The Company benefits from two exclusive licenses for third-party technologies:

In the context of the exclusive license that was granted to it by the INSERM-APHP, the Company undertook to pay a fee calculated on the net sales of the products marketed by the Group. The calculation basis for this fee is 0.25% of the sales achieved through the sale of its systems. Furthermore, the Company undertook to cover the costs of filing INSERM-APHP patents and maintaining them in force.

In the context of the exclusive license that was granted to it by the Université Denis Diderot (Paris 7), the Company undertook to pay, on top of an initial lump-sum fee, a proportional fee calculated depending on the sale price of the products that are the subject of an order, to which is added the payment of a "minimum" amount. The Company is not currently using the technology covered by this license agreement, but it could be incorporated into future products, depending on the result of the research and development work currently underway.

The Company believes that neither the ongoing negotiations of these agreements nor the loss of exclusivity on these licenses will have a significant negative impact on its business.

Any violation by the Company of the conditions of these licenses may lead to loss of the right to use the technology in question.

For the success of its business, it is important that the Company be able to exploit its products and technology freely in regard to patents or intellectual property rights of third parties.

The Company cannot ensure that there are no patents or other intellectual property rights of third parties that may apply to certain of the Company's activities, products or technologies enabling

these third parties to bring a legal action for infringement, or for a similar ground, against the Group in order to obtain damages or the cessation of the use of the product or process called into question.

If these legal actions are carried out to conclusion and acknowledged, in full or in part, to have foundation, the Group could be forced to stop or delay the research, development, manufacture or sale of products or processes affected by these actions, which could significantly affect its activities.

In particular, the Group could be required, in addition to paying financial compensation, to:

- stop manufacturing, selling or using the products or technology called into question, in a given geographic zone, which could reduce its revenue;
- obtain, under conditions unfavorable to the Group, a license to the third-party intellectual property rights;
- find alternative solutions in order to avoid infringing the intellectual property rights of third parties, which could turn out, in some cases, to be impossible or costly in terms of time and financial resources, and could thus be an obstacle to its marketing efforts.

A lawsuit brought against the Group, regardless of the outcome thereof, could moreover result in substantial costs, disorganize its operation, and compromise all or part of its business, image and reputation.

The materialization of one or more of these risks could have a material adverse effect on the Group's business, its earnings, financial situation, growth and prospects.

#### 4.2.3. Risks relating to the manufacturing process

##### **The Company depends on a single partner for the supply of an important component.**

The components and raw materials incorporated in the manufacture of the Group's products vary in nature and include mechanical, electronic and optical elements (mirrors, lenses and laser fibers).

In order to secure its production process, the Company has strived to have at least two sources of supply for its primary components.

As an exception, in terms of optical components, the fiber optics purchased by the Company are only manufactured by a single supplier, namely Fujikura, a Japanese conglomerate active in multiple sectors of operations. This situation results from the Group's choice to develop its product using a certain type of fiber optics with very specific characteristics. This is why the Company has strived for several years to build a true long-term partnership with Fujikura. Accordingly, the latter became a shareholder of Mauna Kea Technologies in November 2006, at the time of an increase in capital, and held 1.5% of the capital as at March 31, 2015.

Since then, a collaborative cost reduction project has been carried out for almost five years, during which period both the Company and Fujikura carried out a joint comprehensive analysis of their mutual industrial constraints with two primary objectives:

- validating a type of fiber optics that would offer the potential of a substantial cost reduction for an increase in the volume produced, together with an increase in the technical performance of the Company's products;
- transferring to Fujikura the assembly of a miniprobe model in accordance with the processes validated by the Company.

These objectives were formalized by the two parties in December 2010 by entering into an agreement that set out the financial conditions of purchase (amount, currency and payment deadlines) between the Company and Fujikura for two years once each of the objectives has been achieved. This agreement also formally noted a joint undertaking to implement a new cost reduction program to be conducted jointly.

The first objective was achieved in March 2011 and the supplies under the agreement were provided in March 2013.

The second objective was achieved in June 2013 and enables the Company to expect growth in its production of miniprobes over the next two years, at a price and quantity determined by the terms of the agreement, which expires in May 2015.

After this first contract, a new framework agreement, effective from January 1, 2015 was entered into by the Company and Fujikura, for a term of three years and tacit renewal.

It sets a minimum purchase volume for the Company over three years. In exchange, Fujikura guarantees supply, as set out in the agreement, and commits to maintain, barring exceptional circumstances, the maximum price levels for the products and assemblies it supplies to the Company. The products and assemblies may have different definitions and specifications based on the parties' work.

The drafting and execution of this new contract strengthened the partnership between the Company and Fujikura.

The Company is confident of its ability to renegotiate its contracts with Fujikura under conditions that should not adversely affect its business. All of these reasons lead the Company to consider that the supply risk in respect of its partner is being managed correctly even though we cannot rule out a risk of contractual breach. The current contract contains clauses specific to this issue. More in particular, Fujikura has committed to manufacture, at the Company's request, sufficient volumes to guarantee appropriate stock levels and to propose the transfer of the fiber production to another company to guarantee the Company's operational continuity. When this stock runs out and under exceptional circumstances, provisioning of laser fibers - vital component of the probes - might be delayed to a certain extent or even halted.

Such a state of affairs could have a material adverse effect on the Company, its business, its earnings, financial situation, growth and prospects.

However, there are alternatives. The Company conducted technical evaluations of other sources in order to satisfy new developments or offset any breaking off of relations with Fujikura. However, such alternatives would require a period of adaptation of our product and the logistics chain, which could have a material adverse effect on the Company, its business, its earnings, financial situation, growth and prospects.

#### **The Company depends on third parties for the manufacture of its products**

The Company has decided to outsource some low value added assembly tasks involved in the manufacture of its equipment and consumables (confocal miniprobes).

Accordingly, the Company depends on third parties for the manufacture of all its products. Its commercial success therefore relies in part on its ability to obtain manufactured products from its sub-contractors that comply with regulatory provisions, in the quantities and periods requested and on a profitable basis. Problems could arise during their manufacture and distribution and could result in delays in the supply of products. This could result in increased costs, lower sales, damage to relations with clients and, in certain cases, product recalls that cause damage in terms of the image and risks of implication of the Company's liability if these problems are not discovered until the products are sold.

In addition, the manufacture of the Company's products is very complex and demanding, in particular because of the regulations applicable and the specifications imposed by the Company. All of the manufacturing process of the equipment and consumables of the Company, according to the designs patented by the latter, thus falls within the scope of application of the certificates obtained by the Company permitting CE marking and FDA approval, or any other regulatory approval.

Were the Company to change the critical suppliers or sub-contractors (fiber optics, optical lenses) of its equipment and consumables, it would be required to carry out revalidation of the manufacturing process and procedures in compliance with applicable standards. In this case, additional tests and validations could be necessary in order to maintain the CE marking and to obtain a new FDA approval, or other regulatory approvals, which apply to quality aspects but no longer to design aspects. This procedure could be costly, time-consuming and require the attention of the Group's most qualified personnel. Were these new authorizations to be denied, the Company could be forced to look for another supplier or sub-contractor, or to keep its current suppliers and sub-contractors, which might delay the production, development and marketing of its products and increase their manufacturing costs.

If, for various reasons, relations should have to be terminated with one of its suppliers or sub-contractors, the Company, moreover, might be unable to find a sub-contractor with the same skills within a satisfactory period of time or to obtain satisfactory sales terms.

Dependence on third-party manufacturers also gives rise to other risks the Company would not face if it produced its products itself, such as:

- non-compliance of the products manufactured by these third parties with regulatory and quality control standards;
- violation by these third parties of their agreements with the Company; and
- the breach or non-renewal of these agreements for reasons beyond the Company's control.

The Group is also unable to ensure that its sub-contractors or suppliers will always comply with applicable regulations, authorizations and standards. If products manufactured by some suppliers do not comply with applicable regulations or standards, the Company might be subject to penalties. These penalties could include fines, injunctions, damages, the refusal of permission to conduct clinical tests by regulatory authorities, the suspension or stoppage of clinical tests underway by regulatory authorities, the suspension or withdrawal of authorizations or certificates obtained, the withdrawal of licenses, the seizure or recall of its products, operating restrictions or restrictions on use, and criminal proceedings, all of which might have a significant negative impact on its business.

If more and more products are marketed, it cannot be ruled out that the Company will make greater use of sub-contracting.

Even if the Company looks for new suppliers or sub-contractors for its entire production and distribution chain, it cannot ensure that it will be able to enter into new agreements on acceptable commercial conditions, given the small number of specialized companies that have the infrastructure, experience and approvals and/or certifications permitting the production of this type

of medical device. In the event of a breach or deterioration in its relations with its subcontractors, or when its needs increase, the Company might be unable to establish relations with other suppliers or sub-contractors, which could be detrimental to its ability to produce, develop and market its products successfully.

The business, financial situation, earnings, growth and prospects of the Company in the medium and long term might be materially affected by the materialization of one or more of these risks.

#### **4.2.4. Risks relating to clients**

The Group's client portfolio comprises, on the one hand, healthcare facilities (hospitals and clinics) and research laboratories, and, on the other hand, distributors.

As healthcare facilities (hospitals and clinics) and research laboratories mainly function using budget headings, the Group has only been confronted with problems of insolvency in rare cases and for small amounts in this client range.

The extent of impairment of trade receivables is set out in Note 7.1 from the notes to the consolidated financial statements in Section 20.1 of this Registration Document.

As for the distributors, the Company is careful to monitor their financial standing, in particular with the support of Coface. The largest distributor in 2014 was Fujifilm, the distributor of the Cellvizio in China. This company generates sales of several billion euros and does not have a high-risk profile.

The payment deadlines granted to the Group's distributors are 60 days on average. They can be adapted depending on the circumstances (volume, etc.). In some cases and depending on the country risk analysis, down-payments or advance payments are received when the order is placed.

The largest client balance account comprises receivables from 2014 sales to an international distributor, of an amount €754K, still outstanding today.

The aggregate weight of the Group's three largest client balances accounts for 35% and 21% of trade receivables as of December 31, 2014 and 2013 respectively. This increase is due to delays in payment by some distributors.

In 2014, no client represented more than 10% of sales. In 2013, one client alone accounted for 11% of sales.

For these reasons, the Group considers that it is not faced with significant dependence on one client.

#### **4.2.5. Risks relating to potential product liability**

Aside from legal warranties, the Group could be exposed to risks from liability arising from the clinical development or commercial exploitation of its products, especially product liability. Criminal or civil proceedings might be brought or filed against the Group by users (patients, practitioners, researchers and other professionals in the fields of healthcare or research), the regulatory authorities, distributors or any other third party that uses or markets its products.

To date, the Group has not been the subject of any criminal or civil case in this area and has taken out product defect liability insurance that provides maximum coverage of €4 million per insurance year, increased by \$5 million per insurance year for the United States.

The Company cannot ensure that its current insurance coverage is sufficient to respond to liability actions that may be brought against it. If it was held liable, and it was unable to obtain and maintain appropriate insurance coverage at an acceptable cost, or to protect itself in any way against product liability suits, this would seriously affect the marketing of its products and, more generally, be detrimental to the business, results, financial situation, growth and prospects of the Group.

#### **4.2.6. Risks relating to the warranty granted on the products sold by the Company**

In parallel to the implementation and continuation of a Quality Management System (QMS) certified compliant with international standard ISO 13485:2003, seeking that its products meet strict quality criteria, the Company generally grants its clients a one-year product warranty from the delivery date of the products. This warranty covers material defects as well as compliance of the products

delivered with the technical descriptions and characteristics; it is limited to initial purchasers of the Company's products and cannot be transferred.

Although the financial consequences of the risk of this contractual warranty's being enforced were expected, the Company cannot ensure that these current provisions are sufficient to satisfy the enforcement of the contractual warranty by all its clients. If its liability were thus called into question, and if it were unable to obtain and maintain an adequate provision, or to protect itself in any way against the enforcement of this contractual warranty, this would seriously affect the marketing of products and, more generally, be detrimental to the business, results, financial situation, growth and prospects of the Company.

### 4.3. Risks related to the Company's organization

#### 4.3.1. Risk of dependence on key persons

**The Group could lose key associates and be unable to attract new qualified persons.**

The Group's success depends heavily on the involvement and expertise of its managers and of its qualified scientific personnel.

Even though the Company has taken out "key person" insurance for three persons (see Section 4.6 "Insurance and risk coverage"), the departure of one or more of these persons or other key associates of the Group could lead to:

- the loss of know-how and the undermining of certain activities, which would be exacerbated in the event of a move to the competition; or
- shortcomings in terms of technical abilities that could slow the business and could affect, going forward, the Group's ability to achieve its objectives.

Furthermore, the Group will need to recruit new managers, sales representatives and qualified scientists to develop its business. The Group competes with other companies, research entities and academic institutions to recruit and retain highly qualified scientific, technical and management personnel. If this competition is very intense, the Group might not be able to attract or retain these key persons on conditions that are economically acceptable.

The inability of the Group to attract and retain these key persons could prevent it from achieving its objectives overall, and thus have a material adverse effect on its business, earnings, financial situation, growth and prospects.

In view of this risk, the Company has implemented contractual provisions specific to its business and compliant with employment law legislation: non-compete clauses, non-entice ment clauses, transfer of intellectual property clauses and confidentiality clauses. It has also set up systems for motivating and creating loyalty in personnel, in the form of compensation that varies based on performance and the awarding of financial instruments giving access to the Company's capital (share warrants (BSA), founders' warrants (BSPCE) or stock options).

### 4.4. Financial risks

Refer also to note 24 to the consolidated financial statements closed on December 31, 2014, which appears in Section 20.1 of this Registration Document.

#### 4.4.1. History of operating losses – Specific risks related to projected losses

**The Group has a history of operating losses, losses which could continue.**

The Group has recorded operating losses every year since it began operations in 2000. The cumulative net losses (including carry-forwards) came to €(70,069) thousand, including a net loss of €(13,991) thousand for the financial year ended December 31, 2014. These losses are due mainly to research expenses, costs of development and sales and marketing expenses incurred.

The Group could experience additional operating losses in the coming years, as it pursues its research and development and marketing activities, especially in view of:

- the expansion of its portfolio of products intended for new medical sectors of application;

- the need to conduct new clinical trials to accompany the marketing of the Cellvizio on new medical sectors;
- the development of its research and development activities and, perhaps, the purchase of new technologies, products or licenses;
- commercial deployment that stretches beyond the gastroenterology market; and
- increased regulatory requirements regarding the manufacture of its products.

An increase in these expenses could have a material adverse effect on the Group, its business, financial situation, earnings, growth or prospects.

### 4.4.2. Liquidity risk – Future capital needs and additional financing

**The Company could need to strengthen its shareholders' equity or resort to additional financing in order to ensure its development.**

Historically, the Company has financed its growth by increasing its shareholders' equity through capital increases or by issuing bonds convertible into shares (fully converted in late 2007) but has never made use of bank loans. Therefore, the Company is not exposed to liquidity risk resulting from the potential enforcement of prepayment clauses in bank loans, taking into account that it no longer has any convertible bonds.

At December 31, 2014, the Group's cash and cash equivalents came to €15 million. The Group plans to put in place appropriate solutions to cover its future cash requirements. An equity financing facility was granted by Société Générale on March 11, 2015, under which Société Générale will be allocated 1,390,000 share warrants enabling it to subscribe Company shares at its request, subject to certain conditions (subscription floor price and minimum average daily volumes) and resell them on the market over a period of 10 months. At the date of this Registration Document, 210,000 share warrants have been subscribed, for an amount of €1,024,100.

On May 7, 2015, the Company carried out a capital increase through a private placement, leading to the issuance of 1,189,251 new shares, i.e. 8.49% of outstanding shares, and raising a gross amount of €4.7 million.

The Company has made significant research and development efforts since the start of its business as well as in terms of sales and marketing with, in particular, the completion of clinical trials, which has generated negative consolidated operating cash flows to date. The Group's consolidated cash flows relating to operating activities amounted respectively to €(12,731) thousand and €(9,612) thousand for the financial years closed on December 31, 2014 and 2013.

In the future, the Group will continue to have significant financing needs to develop its technologies and market its products. The Group may be unable to generate funds internally for its growth, which would cause it to seek other sources of financing, particularly through new capital increases.

The level of the Group's financing needs and their scheduling over time depend on elements that are largely beyond the Group's control, such as:

- higher marketing and sales development costs than expected, and slower progress than expected in terms of the technology's adoption by health professionals;
- higher costs and slower progress than expected in its research and development programs and in clinical studies;
- the costs of preparing, filing, defending and maintaining its patents and other intellectual property rights;
- the costs of responding to technological developments and to the market, and to ensure the manufacture and marketing of its products;

- higher costs and longer time periods than expected to obtain regulatory authorizations, including the time needed to prepare applications for the regulatory authorities; and
- new opportunities for the development of new products or the purchase of technologies, products or companies.

The Company may be unable to raise additional capital when it needs it, and this capital may not be available on financial conditions that are acceptable to the Group. If the necessary funds are not available, the Company could have to:

- reduce its sales and marketing expenses or stop marketing in unprofitable geographic zones;
- delay, reduce or end research programs;
- obtain funds through partnership agreements that could require it to waive rights to some of its technologies or products;
- grant licenses to its technologies to partners or third parties;
- enter into new collaboration agreements that could be less favorable for it than those it might have obtained in a different context.

Furthermore, if the Company raises capital by issuing new shares, the stakes of its shareholders could be diluted. Debt financing, if available, could also include restrictive conditions for the Company.

The materialization of one or more of these risks could have a material adverse effect on the Group, its business, financial situation, earnings, growth or prospects.

Given its resources used to date as well as those that can be used and in respect of its projected cash-flows, the Group deems that it does not face a liquidity risk and will be able to honor its obligations and its cash resource requirements. Note 1.1 from the notes to the consolidated financial statements, which appears in Section 20.1 of this Registration Document, specifies the information regarding the absence of liquidity risk.

#### 4.4.3. Risks related to the research tax credit

The Company has also opted for the Research Tax Credit (“CIR” [*Crédit d’Impôt Recherche*]) to finance its business. This credit is a tax credit offered by the French Government to companies that make significant investments in research and development. The research costs eligible for the CIR include, among others, salaries and wages, depreciation of research equipment, provision of sub-contracted services to approved research entities (public or private), and intellectual property costs. When preparing the information to be declared under the CIR, the Company is assisted by a specialized consulting firm. The Company was subject to a tax audit for all taxes of 2009 and 2010, including the CIR. No tax adjustments were necessary.

As regards 2011 and the following years, it cannot be ruled out that the tax authorities may challenge the methods used to calculate the Company’s research and development costs, or that the CIR may be challenged due to a change in regulations or may be challenged by the tax authorities even if the Company complies with the documentation and eligibility requirements regarding costs. If such a situation were to occur, it could have an adverse effect on the Group’s earnings, financial situation and prospects.

Every year, an amount was repaid by the tax authorities on account of the CIR within six-nine months following the filing of the tax return.

The following table describes the changes in the Research Tax Credit during the 2012-2014 financial years:

(in €K)	12/31/2014	12/31/2013	12/31/2012
Research Tax Credit	1,251	984	1,100

**4.4.4. Risks relating to access to public advances**

At December 31, 2014, the Company enjoyed the following aid:

At Dec. 31, 2014 (in €K)	Amount granted	Amount received	Amount repaid
OSEO sub-total	4,436	3,297	720
Total COFACE advances	1,704	1,704	986
<b>Total aid</b>	<b>6,140</b>	<b>5,001</b>	<b>1,706</b>

If the Group does not comply with the contractual conditions of the repayable advance agreements entered into, it could be forced to repay the sums advanced ahead of schedule (refer to Note 11 of the notes to the consolidated financial statements closed on December 31, 2014 presented in Section 20.1 "Consolidated financial statements prepared according to IFRS for the financial year ended December 31, 2014" of this Registration Document). Such a situation could deprive the Company of some of the financial resources needed to successfully carry out its research and development projects. Indeed, the Company cannot ensure that the Group will then have the additional financial means needed, the time, or the ability to replace these financial resources with others.

**4.4.5. Exchange rate risk**

The main currencies for which the Group is exposed to a significant exchange rate risk are the US dollar and the yen.

The purpose of the Mauna Kea Technologies Inc. subsidiary established in the State of Georgia is to distribute and market the Group's products in the United States. To this end, it is fully financed by the parent company, with which it has established three agreements:

- a cash management agreement for a current account in USD;
- a distribution agreement;
- a service agreement (Management fees).

The Group's major exchange rate risk is linked to the Euro/USD parity fluctuation. In fact, the Group markets the product and services in the USA through its subsidiary Mauna Kea Technologies Inc. Its revenues and expenses - including the purchases of Cellvizio and probes to Mauna Kea Technologies SA - are expressed in US dollars the operational currency of the subsidiary. As a result, the Group is exposed to changes in the EUR/USD exchange rate through that subsidiary.

A change in exchange rates has an impact on Group earnings and shareholders' equity in the same manner, as follows:

- A variation in the EUR/USD exchange rate of +10% would have generated an improvement in earnings of €527K as of December 31, 2014;
- A variation in the EUR/USD exchange rate of -10% would have generated a drop in earnings of €(644)K as of December 31, 2014.

In 2013, the Company entered into a yen forward contract to reduce its exposure to exchange rate risk on future purchases. It expired in 2014. There are no other contracts on this risk.

Sales in foreign currencies are broken down as follows:

Foreign currency	Weight of currencies in sales
USD	27%
EUR	70%
Other	3%
<b>Total</b>	<b>100%</b>

#### 4.4.6. Interest rate, credit and cash management risks

##### ***Interest Rate Risk***

The Company's exposure to interest rate risk primarily involves cash equivalents and investment securities. These are comprised of money market funds and term deposit accounts. Changes in interest rates have a direct impact on the rate of return for these investments and the cash flows generated.

As of December 31, 2014, the Company's financial debt was not subject to interest rate risk because it primarily involved interest-free repayable advances in a total non-discounted amount of €3,296K as described in Note 11: Borrowings and financial debt. Borrowings and financial debt in the consolidated notes presented in Section 20.1 of this Registration Document.

As of this date, the Company has not taken out any loans with credit institutions and therefore has only a very low exposure to interest rate risk.

##### ***Credit and cash management risk***

In the Company's experience, the payment of certain public financing of research expenditures is subject to credit risk.

The Company manages its available cash in a prudent manner. Cash and cash equivalents include available cash and current financial instruments owned by the Company (mostly money market funds). As of December 31, 2014, the available cash and investment securities owned by the Company were for the most part invested in products with a maturity of less than 12 months.

Credit risk related to cash, cash equivalents, and current financial instruments is insignificant in light of the quality of the co-contracting financial institutions.

With regard to its customers, the Company has no significant concentration of credit risk. The Group has established policies that insure it that its customers have an appropriate credit risk history.

#### 4.4.7. Risk of dilution

The Company could proceed in the future with issuing or awarding shares or new financial instruments giving access to the capital of the Company in the context of its policy to motivate its managers and employees.

As part of a policy to motivate its managers and employees, the Company has, since its founding, regularly issued or allocated stock options, share warrants (BSA) and founders' warrants (BSPCE). In the context of this policy, the Company may, in the future, issue or award new financial instruments that give access to the Company's capital.

The full exercise of all the instruments that give access to capital, awarded and in circulation to date, would enable the subscription of 1,599,289 new shares, thus generating a dilution equal to 10.35% on the basis of the capital existing to date and 9.38% on the basis of the diluted capital. The dilution in voting rights would come to 8.92% on the basis of the voting rights existing to date and 8.19% on the basis of the diluted voting rights.

Any additional award or issuance will result in a potentially significant additional dilution for the Company's shareholders.

The Company could also issue shares as part of an external growth transaction. Any additional share or issuance will result in a potentially significant additional dilution for the Company's shareholders.

## 4.5. Legal risks

The Company manages internally the legal aspects and compliance of its operations with its regulatory framework (marketing authorizations, registration and performance of clinical trials, insurance, intellectual property, registration of trademarks and domain names, etc.). In this respect, the Company may call upon specialized intermediaries, service providers or advisors to complement its expertise, or sub-contract certain tasks to them. For example, the Company resorts in particular to consultants, distributors or local regulatory representatives for the submission of registration applications with some local regulatory authorities, to firms specializing in intellectual property for the registration and review of files, or further to insurance brokers, etc.

### 4.5.1. Risks relating to regulations applicable to the medical devices developed by the Group and possible changes in regulations

The control, manufacture and sale of the Company's products are subject to obtaining and maintaining legal and regulatory authorizations and certifications necessary for the marketing of medical devices. In fact, the Company's products are subject to strict regulation that is constantly evolving.

Compliance with this regulatory process can be long and costly, and there is no guarantee that authorizations will be obtained or of how long it may take to obtain or renew them. If certification or authorization to market the Company's products were refused, their marketing could be delayed or prohibited in the countries involved.

If such a situation were to occur, it would have a material adverse effect on the Company, its business, financial situation, earnings, growth and prospects.

Although the Company takes into consideration, as part of its business, the potential evolution of legislation or changes in standards or regulations applicable in the countries in which the Company markets and plans to market its products, new regulatory restrictions could prevent the sale of the Company's products in the event of withdrawal or suspension of marketing authorizations, or could delay sales, by making their production more costly, among other things.

If such a situation were to occur, it would have a material adverse effect on the Company, its business, financial situation, earnings, growth or prospects.

### 4.5.2. Risks relating to authorizations already obtained or ongoing processes

#### 1. Risks relating to the regulatory environment in Europe - CE marking

The Group's products fall under the category of medical devices and are governed by, among others, by the provisions of European directive 93/42/EEC, which standardizes the conditions for the sale and free circulation of the Group's products within the European Economic Area.

These products cannot be offered in the market unless the certificates are obtained that allow CE marking; these certificates are valid for three years. CE marking is proof that the medical device in question complies with essential health and safety requirements, established by the applicable European directive, and certifies that it has undergone adequate evaluation procedures as to that compliance.

If the wrong medical device is chosen or it is misclassified, this could result in increased costs or longer delays in obtaining the certifications required for CE marking, or could even make it impossible to obtain the certificates required for marketing the medical device in question.

Although existing products have already obtained CE marking, products being developed will be subject to this same regulation and their marketing could be delayed if the certificates allowing CE marking were not obtained within the time periods established.

If such a situation were to occur, it would have a material adverse effect on the Company, its business, financial situation, earnings, growth and prospects.

Renewal applications of the certificates relating to CE marking also involve a long and complex process with the main points reviewed being: the consideration of regulatory changes, the updating

of the management of risks and compliance with the essential requirements of the applicable European directive.

If the Company were unable to obtain the renewal of the certificates necessary for CE marking of its existing products within the required time periods, the sale of its products would be interrupted until these authorizations were obtained.

If such a situation were to occur, it would have a material adverse effect on the Company, its business, financial situation, earnings, growth and prospects.

#### **Risks related to the regulatory environment in the United States**

The U.S. market is governed by the regulations established by the Food and Drug Administration (FDA), which regulates pre-clinical and clinical tests, and the manufacture, labeling, distribution and promotion of medical equipment.

The marketing of products, such as those manufactured by the Company, in the U.S. market is subject to a PMN, or Pre-Market Notification, before they are put on the market. These products are medical devices with a medium risk potential (class II for the FDA), and for which it is possible to establish substantial equivalence to a medical device already approved on the U.S. market. The Company may thus use a "510k" procedure in order to submit the application for FDA review. After the application is approved, the medical device is registered in a register maintained by the FDA.

The Company has already obtained FDA approvals for the applications of its existing products in the gastrointestinal, pulmonary and urological fields (approvals K051585, K061666, K111047, K120208, K122042, K123676, K132389, K133466 and K141358).

If the FDA approvals relating to the existing products of the Group were to be called into question, or if the approval applications relating to the new products of the Group were to be denied by the FDA, the Company would be unable to market its products on the U.S. market or would have to implement other, longer and more costly, procedures to obtain or update its approvals. If such a situation were to occur, it would have a material adverse effect on the Company, its business, financial situation, earnings, growth and prospects.

#### **Risks related to the regulatory environment in other countries**

The offer of medical products on markets in other countries requires that specific steps be taken in order to obtain the necessary authorizations.

However, transfer and recognition of certifications do exist in certain countries. These transfers or recognitions are important elements in the process of deciding to market the Group's products in a new country.

The Company has already obtained marketing authorization for its existing products in some countries outside of the European Union and the United States, in particular in Singapore, Korea, Canada, China, Brazil, Russia, Turkey, Canada, Israel, Saudi Arabia, Colombia, and more recently in Japan (April 2014).

The Company's inability to obtain or maintain the necessary authorizations for its products could have a material adverse effect on the Company, its business, financial situation, earnings, growth and prospects.

At the date of this Registration Document, the United States is the only country in which the Company has obtained reimbursement rates. In addition, the Group continues its efforts to secure reimbursement codes in new countries, as the first step before setting the corresponding rate. In this regard, in October 2014 the French Health Authority authorized the use of endomicroscopy in patients with Barrett's esophagus, a medical condition that requires monitoring in light of the risk of esophageal cancer.

**4.5.3. Risks related to failures in industrial processes (such as failure to comply with product traceability or other failures)**

The Company's products are categorized as medical devices and, as such, are subject to specific regulations in all the countries in which they are manufactured, tested or marketed. These regulations and standards impose obligations, in particular with regard to:

- design;
- pre-clinical tests and clinical tests of products;
- manufacture, quality control and quality assurance of the products;
- labeling of the products, including instructions;
- storage of the products;
- identification and traceability of the products;
- procedures for data preservation;
- oversight subsequent to market introduction and reporting of incidents related to the use of the products.

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

The principle of complete traceability of all the product's components, as well as the implementation and continuation by the Company of a Quality Management System (QMS) certified compliant with international standard ISO 13485:2003 and a lean manufacturing system seeking to guarantee full compliance of each product with regulations applicable as well as its quality.

The Company cannot, however, ensure that its suppliers or sub-contractors comply or will comply with applicable regulations at all times. The body notified, in the event of a certification or follow-up audit, or the regulatory authorities, during an inspection or at the time of any other regulatory process, might identify breaches of the regulations or standards applicable and require that the breach be remedied by corrective actions that might interrupt the manufacture and supply of the Company's products. The suspension, total stoppage, or total or partial prohibition of the activities of the Company's suppliers might materially affect the business, financial situation, earnings and reputation of the Group.

**4.5.4. Environmental risks**

The nature of the Group's activity does not give rise to significant environmental risks at the date of filing this Registration Document.

#### 4.6. Insurance and risk coverage

The Company has purchased a policy that covers the principal insurable risks and has the coverage amounts it deems compatible with the nature of its business. The policies the Group benefits from today are the following:

Insurance policy/risks covered	Insurer	Amount of the coverage
<b>Comprehensive corporate insurance</b>	AXA	
Fire and secondary risks		Ceiling €8.8 million
Broken glass		€15,000
Operating losses		€5,241,000
<b>Broken machinery</b>	AXA	
Cellvizio loaned or leased to a healthcare facility		€350,000
Investment guarantee		€100,000
		Equipment shown at trade shows (one per month)
<b>Civil operating liability</b>	CHUBB	Per year
All bodily harm, property and non-material damage taken together without being able to exceed for the damages below:		€8,500,000
- Inexcusable fault/occupational illness		€2,000,000
- Property and non-material damage		€4,000,000
- Non-consequential and non-material damage		€300,000
- Damage resulting from accidental harm to the environment (excluding sites subject to authorization)		€750,000
<b>Criminal defense - Appeal</b>		€30,000
<b>Civil liability / products</b>		
All damage taken together resulting from Product Civil Liability		€4,000,000
		(\$5,000,000 for the United States)
- Including non-consecutive non-material damage (coverage not acquired in US and Canada)		€500,000
- Including recall expenses incurred by third parties or the Insured outside of the US and/or Canada		€500,000
- Including recall expenses incurred by third parties or the Insured in the US and/or Canada		€500,000
<b>Assistance to persons travelling</b>	AXA	
All travelers (Company and Subsidiary)		
Personal accident insurance		€50,000
Civil liability insurance		€4,500,000
<b>Key persons accident</b>	CHUBB	€150,000/person
Risks covered:		€450,000/event
- accidental death		
- total irreversible loss of autonomy		
3 persons concerned: Chief Executive Officer, VP Finance and Scientific Director		
<b>Employer's liability</b>	Chartis Insurance	€500,000
Civil liability on account of a social breach		Per year
Defense		
Legal advice		
<b>Liability of corporate officers</b>	AIG	€5,000,000
All de jure and de facto senior managers (Company and Subsidiary)		
<b>Transported merchandise</b>	AGCS	Sales price
		Max: €1.5 million/claim

#### 4.7. Legal and arbitration proceedings

The Group was subpoenaed by a customer in the United States over a trade dispute. The dispute was settled amicably in January 2015. The provision recognized in the financial statements to December 31, 2014 covered the amount paid by the Group. (see Note 12.3 to the consolidated financial statements presented in Section 20.1 of this Registration Document).

In the course of the 12-month period preceding the registration date of this Registration Document, the Group has been involved in no other administrative, criminal, civil or arbitration proceedings that could have a material adverse effect on the Group, its business, financial situation, earnings or growth, nor, to the Company's knowledge, is the Group threatened with such proceedings at the date of filing this Registration Document.

## SECTION 5 INFORMATION ABOUT THE COMPANY

### 5.1. History and growth of the Company

#### 5.1.1. Corporate name of the Company

The corporate name of the Company is: Mauna Kea Technologies SA.

#### 5.1.2. Registration place and number of the Company

Mauna Kea Technologies was registered in the RCS [*Registre de Commerce et des Sociétés*, Trade and Companies register] of Paris on May 3, 2000 under number 431 268 028.

#### 5.1.3. Date and term of incorporation

The Company was incorporated for a term of 99 years ending May 3, 2099, except in the case of early winding up or extension.

#### 5.1.4. Registered office of the Company, legal form, legislation governing business activities

The Company was first incorporated as a Simplified Joint Stock Company [*Société par Actions Simplifiée*] and was transformed into a corporation [*société anonyme*] by a decision of the general meeting of partners on May 25, 2011.

The Company is subject to French law for its operations, primarily Articles L. 225-1 et seq. of the French Commercial Code.

The registered office of the Company is located at: 9 rue d'Enghien, 75010 Paris. The contact information for the Company is as follows:

Telephone: +33 (0)1 48 24 09 77

Fax: +33 (0)1 48 24 12 18

E-mail: [investor@maunakeatech.com](mailto:investor@maunakeatech.com)

Website: [www.maunakeatech.com](http://www.maunakeatech.com)

### 5.1.5. Significant events in company history

#### May 2000

The Company is created after the project wins the first competition for assistance in creating innovative enterprises (“*concours d'aide à la création d'entreprises innovantes*”) in the “emerging” category in July 1999 and wins the Aventis Foundation award in January 2000.

#### July 2000

The Company wins at the national level of the second competition for assistance in creating innovative enterprises in the “creation-development” category.

#### September 2000

Investment of €1.6 million by a group of French entrepreneurs including: Marc Vasseur (Genset), Jérôme Chailloux (Ilog), Jean-Luc Nahon (Isdnet), Christophe Bach (Isdnet), Patrice Giami (Isdnet), Philip Maes (Gemplus) and Daniel Legal (Gemplus) – through their fund Finadvance Ventures – as well as Jacques Attali.

#### 2002

The first OSEO innovation aid is obtained.

#### 2004

Delivery of the first two Cellvizio LABs to the laboratory of Alan Koretsky at the NIH (National Institutes of Health) and to the laboratory of Chris Contag in Stanford.

Creadev, Mulliez family, acquires a stake in the capital of Mauna Kea Technologies as a reference shareholder in July.

#### 2005

Creation of the U.S. subsidiary Mauna Kea Technologies, Inc.

Obtained CE marking for the Cellvizio's applications falling within the fields of

gastroenterology and pulmonology.

Obtained FDA (Food & Drug Administration) approval for the marketing of the Cellvizio in the United States for the applications falling within the fields of gastroenterology and pulmonology.

First images of patients made with the Cellvizio.

#### 2007

Signing of a distribution agreement for the Cellvizio LAB with Leica Microsystems in order to cover the research laboratories market.

Launch of the Cellvizio for the applications in gastroenterology. The Mayo Clinic of Rochester is the first U.S. hospital to become equipped, followed shortly thereafter by the Mayo Clinic of Jacksonville.

In December, a €20.3 million private placement is made with Psilos Group, Health Evolution Partners, Seventure and Creadev.

#### 2008

Mauna Kea Technologies is the only French company to obtain the Wall Street Journal Innovation award.

Launch of two multicenter clinical trials in the field of cancer of the esophagus and cancers of the biliary ducts.

Obtained the “OSEO-Innovative Enterprise” label.

#### 2009

First annual ICCU (International Conference of Cellvizio Users), a conference bringing together the Cellvizio user community; 45 physicians attended in Miami Beach (United States).

Launch of Cellvizio.net, the first educational site on endomicroscopy for the Cellvizio user community.

Signing of a worldwide distribution agreement with VisualSonics for its range of Cellvizio LAB instruments, as the agreement with Leica Microsystems did not enable reaching the anticipated objectives.

Launch of the NeuroPak, the first instrument in the world making deep brain imaging of live animals possible at microscopic level.

#### 2010

Second annual ICCU conference with 67 physicians meeting in Paris, France.

Obtained a €7.6 million award from OSEO, €4.9 million of which going to the Company (grant for €1.5 million and repayable advances of €3.4 million), for an industrial research and development project led by Mauna Kea Technologies (PERSEE project).

More than 20 studies on the Cellvizio in gastroenterology are presented exclusively at the DDW international conference on digestive disease.

#### 2011

IPO on the regulated market of NYSE Euronext in Paris (compartment B) with €56.5 million in funds raised (July).

Launch of the Cellvizio Series 100 version at the third annual ICCU conference with 96 physicians attending in Nice.

Launch of version 2 of Cellvizio.net, which boasts 600 active members.

Partner of the UHI project, named the winner of the “*Investissements d'Avenir IHU* [UHI Future Investments]” call for projects with an allocation of €67.5 million. This project will enable a world center for excellence in

the field of mini-invasive image-guided surgery to emerge.

Major participation at the world conference on digestive disease (Digestive Disease Week - DDW) in Chicago where 36 presentations on the Cellvizio were given, including two during presidential plenary sessions and two in plenary sessions on the major results of the significant clinical trials sponsored by the Group.

Obtained 510(k) approval from the American FDA (Food and Drug Administration) to market the new-generation Cellvizio® in the United States, named Cellvizio® 100.

Obtained CE marking for Cellvizio® 100 in April 2011.

## 2012

Fourth annual ICCU conference with 123 physicians attending in Rome.

Obtaining three Category I CPT® reimbursement codes to use the Cellvizio in the upper digestive tract, awarded by the American Medical Association (AMA) selection committee.

Obtaining a reimbursement rate of \$927 from Medicare/Medicaid (United States) for these codes, for each use of the Cellvizio in the upper digestive tract.

## 2013

Fifth annual ICCU conference with more than 200 participants, including 25 experts, in Versailles.

Entry into force of these reimbursement codes

(Category I CPT Codes) on January 1.

Clearance to sell the AQ-Flex™ 19 miniprobe in the United States for use in fine needle aspiration procedures.

Assignment of an OPS code in Germany for the reimbursement of endomicroscopy by Cellvizio.

## 2014

Sixth annual ICCU conference with more than 260 participants, including 85 experts, in Opio.

Enactment by US health authorities of practitioner compensation for practitioners performing Cellvizio procedures in the upper digestive tract. Reassessment of the CPT codes' reimbursement rate from \$927 to \$1,013 in early 2014.

Obtaining 510(k) regulatory approval from the FDA in urology for the use of the Cellvizio via Uroflex™ B and CystoFlex™ F confocal miniprobes.

Installing the first Cellvizio system in India at the Apollo Gleneagles Hospital in Kolkata, the flagship hospital for gastroenterology in India and a member of the Apollo Hospitals Group.

Obtaining Class 1 regulatory authorization from the Japanese Ministry of Health, Labor and Social Protection (MHLW) to use the Cellvizio technology and Class 2 regulatory authorization (NINSHO) for the endoscopic use of Cellvizio miniprobes.

510(k) regulatory approval obtained for a new Cellvizio using an infrared wavelength

French Health Authority authorizes the use of endomicroscopy in patients with Barrett's esophagus

Mauna Kea Technologies receives regulatory approval in Brazil

Partnership agreement signed with Siemens to evaluate the use of endomicroscopy with Cellvizio in interventional radiology procedures.

## 2015

Publication of the FOCUS pivotal trial in Gastrointestinal Endoscopy, confirming the high accuracy of pCLE in the diagnosis of bile duct cancer during endoscopic retrograde cholangiopancreatography (ERCP)

Publication in the United European Gastroenterology Journal of a clinical consensus report endorsed by 26 international experts on the use of endomicroscopy in gastroenterology;

CPT reimbursement code obtained in the United States for the use of Cellvizio in the biliary tract

Marketing authorization for Cellvizio received from the Mexican Health Authority.

Capital increase through a private placement, leading to the issuance of 1,189,251 new shares and raising a gross amount of €4.7 million.

CE marking obtained for interventional radiology.

## 5.2. Investments

### 5.2.1. Principal investments made since 2012

Gross investments	FY 2014	FY 2013	FY 2012
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(IFRS, in €K)	12 months Consolidated	12 months Consolidated	12 months Consolidated
Intangible assets	403	973	968
Property, plant, and equipment	253	208	289
Non-current financial assets	28	13	15
<b>TOTAL</b>	<b>684</b>	<b>1,194</b>	<b>1,272</b>

***Intangible investments***

The intangible investments are primarily made up of development expenses and expenses for registering patents. Details thereof by nature of expense are presented in Note 3 of the consolidated notes inserted in Section 20.1 of this Registration Document.

The research expenses are consistently recognized as expenses. Only development costs that meet the criteria of IAS 38 are recognized as intangible assets (see Note 1.4 to the consolidated financial statements in Section 20.1 of this Registration Document).

In 2014, research and development expenses were mainly attributed to research, hence the lower capitalization.

***Tangible fixed investments***

Tangible fixed investments primarily consist of industrial equipment and office and computer equipment. A breakdown by type of expense is given in Note 4 of the consolidated notes in Section 20.1 of this Registration Document.

***Non-current financial assets***

The non-current financial assets include only the security deposits paid according to ordinary rental agreements.

**5.2.2. Principal investments in progress**

Since December 31, 2014, the investments made have been of the same kind and order of magnitude as those mentioned above during the 2011-2014 period.

**5.2.3. Principal investments projected**

At this time, the Group is not planning to make any significant investments for the years to come for which the executive bodies of the Company have made any firm commitments.

## SECTION 6 OVERVIEW OF ACTIVITIES

### 6.1. Executive summary

Mauna Kea Technologies is a worldwide business specialized in medical devices, devoted to the emergence of optical biopsy and leader in endomicroscopy.

The Company designs, develops and markets innovative tools for real-time visualization and characterization of cellular anomalies during standard gastrointestinal and pulmonary endoscopy procedures.

Its flagship product, Cellvizio<sup>®</sup>, is a confocal miniprobe endomicroscopy system which provides physicians and researchers high-resolution images of tissues at the cellular level.

International multicenter, randomized clinical trials have shown that Cellvizio can help physicians to detect early-stage pathologies more precisely and make immediate therapeutic decisions.

Cellvizio has obtained 510(k) regulatory authorization from the United States Food and Drug Administration and the CE mark in Europe, for its use in digestive, pulmonary and urological tracts as well as via a cytopuncture needle. Today it is marketed in more than 40 countries.

The Company has been awarded 167 patents.

#### ➤ **Cellvizio, a breakthrough technological innovation**

Cellvizio is the smallest microscope capable of obtaining microscopic images inside the human body with high image quality and frequency (12 images per second) and exceptional stability. The images are magnified up to 1000 times. They are obtained simply by pressure of the Cellvizio miniprobe on the wall of the mucosa or target organ. The process is therefore minimally invasive and perfectly repeatable.

#### ➤ **Cellvizio, a benefit for patients, physicians and health systems**

Cellvizio is designed to help physicians with their diagnosis, provide better treatment for patients and reduce hospital costs.

Cellvizio provides physicians with cellular information, in vivo, in real time and during procedures. This information is obtained in a minimally invasive way and therefore does not damage the patient's tissues. Cellvizio is compatible with almost all the endoscopes on the market and is used like an endoscopy tool, so it does not change medical endoscopy practice but significantly improves it. Medical benefit has been proven by many clinical trials concerning each of the indications in which it is used.

For patients, the benefit is significant at several levels. Apart from not having to wait for the results of a physical biopsy, which can sometimes take several weeks, the process is non-invasive and can be replicated because it does not destroy the areas it inspects, and is painless. Above all, it can be used for faster characterization of precancerous and cancerous lesions.

For the health system, an optical biopsy is used to reduce the number of useless physical biopsies, since the great majority of physical biopsies are found to be negative (prostate: 75%<sup>1</sup>, Barrett's esophagus: 58%<sup>2</sup> for example), and reduce the number of endoscopic procedures by providing better characterization of precancerous or cancerous lesions. Cellvizio also avoids useless surgery, notably of the pancreas. (See Section 6.2.2 Products and clinical validation)

#### ➤ **Cellvizio, a multiple-indication platform**

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

<sup>2</sup> Bertani H. et al. Improved Detection of Incident Dysplasia by pCLE in a BE Surveillance Program. Dig Dis Sci, 2013.

Cellvizio is designed to be a platform potentially capable of application in all medical sectors in which endoscopic procedures are routinely performed. These include gastroenterology, urology, pulmonology as well as gynecology and surgery. With the recent development of its new miniaturized miniprobe (diameter < 1 mm), capable of penetrating a surgical needle, the Cellvizio can now access organs in the human body internally, thus paving the way for new routes of access to patients with potential not yet evaluated.

Cellvizio can be used in gastroenterology, pulmonology or urology, where only miniprobes are specific to each indication. There is a miniprobe for each indication, which is reusable 10 or 20 times, depending on the model. (See Section 6.2.2 Products and clinical validation)

➤ **A protected ownership innovation**

In early April 2015, the Mauna Kea Technologies patents portfolio included 167 national and international patents. This policy of innovation and of protecting its intellectual property constitutes a significant barrier to entry for possible competitors. The Company continues to invest in R&D and will continue to maintain a dynamic patent filing policy. (See Section 11 "Innovation, Patents, Licenses, Trademarks and Domain Names")

➤ **Very rich and statistically significant clinical validation**

Establishing a breakthrough technology in the medical world today first requires having scientific and medical proof of the proposed innovation's contribution. A vast program of international multicenter clinical trials has been undertaken since 2005 on applications relating to the digestive tract, pulmonology and urology. All the studies finalized to date have provided conclusive results as to the Cellvizio's contribution in relation to traditional endoscopies, in particular as to the quality of the diagnosis it procures.

More than 260 clinical trials had been completed by the end of December 2014 on Endomicroscopy by miniprobe.

For example, in October 2014, Dr. Bertand Napoléon published the results of the study "A novel approach to the diagnosis of pancreatic serous cystadenoma: needle-based confocal laser endomicroscopy" in the journal "Endoscopy". The study, involving 31 patients in four French centers, showed that needle-based endomicroscopy successfully confirmed the benign nature of undetermined pancreatic cysts with 100% specificity by identifying a superficial vascular network found only in this type of cyst and invisible to traditional imaging. This characteristic had never before been observed using other medical imaging techniques and represents a real advance in the diagnosis of benign pancreatic cysts (serous cystadenomas), thus potentially eliminating useless operations and examinations for many patients.

➤ **Marketing authorization obtained**

The Group has obtained nine 510(k) regulatory authorizations from the United States Food & Drug Administration (FDA) as well as CE marking for its use in digestive and pulmonary tracts. Mauna Kea Technologies has also obtained CE marking for a complete range of Urology probes and, more recently, in March 2014, an FDA regulatory authorization in urology.

On the basis of these two internationally recognized labels, Mauna Kea Technologies has obtained marketing authorizations in more than 40 countries on various continents (North America, Europe, Asia). The most recent authorizations have been obtained in China, Brazil, Russia and Japan. The Company has obtained a double authorization in Japan: a Class 1 to use Cellvizio technology and a Class 2 (NINSHO), for endoscopic use of the Cellvizio miniprobe. They both cover all Cellvizio's current clinical indications: gastroenterology, urology and pulmonology, except AQ Flex miniprobes for pancreatic cysts.

➤ **Repayment**

In the United States, in March 2012, the Group obtained the creation of three new category 1 CPT<sup>®</sup> codes for the upper digestive tract. Two of these codes are available to gastroenterologists, the third code was created for use by histopathologists following a request from the College of American

Pathologists. This latter code applies to the entire human body. Since January 1, 2014, the Medicare/Medicaid payment linked to these first two codes is \$1,013 per procedure, this amount being reassessed every year. In March 2015, the American Medical Association (AMA) assigned a new CPT code for use in endoscopic retrograde cholangio-pancreatography (ERCP), allowing practitioners to diagnose biliary tract pathologies, notably strictures and cancers.

In Germany, the German Institute for Medical Documentation and Information (DIMDI) has awarded an OPS code to endomicroscopy in the final 2014 list of OPS codes. The allocation and implementation of an OPS code allows the German health authorities to measure volumes of endomicroscopy procedures as well as the related costs of treatment, in order to propose a repayment.

## Summary Table of Repayments

Country	Indication	Competent authority	Date of issue	Title	Pricing
United States	Upper digestive tract	American Medical Association/ Centers for Medicare & Medicaid Services, CMS	201 2	Reimbursement Code CPT 43206. Upper digestive tract. Esophagoscopy with endomicroscopy. Effective from January 1, 201 3	\$1 ,064 for hospitals and \$1 43 for physicians
		American Medical Association/ Centers for Medicare & Medicaid Services, CMS	201 2	Reimbursement Code CPT 43252. Upper digestive tract. Endobrachyoesophagus with Endomicroscopy. Effective from January 1, 201 3.	\$1 ,064 for hospitals and \$1 78 for physicians
		American Medical Association/ Centers for Medicare & Medicaid Services, CMS	201 2	Reimbursement Code CPT 88375. To interpret the images obtained with endomicroscopy. Effective from January 1, 201 3.	According to published rates
	Biliary tracts (CPRE)	American Medical Association/ Centers for Medicare & Medicaid Services, CMS	201 5	Reimbursement Code CPT 039X7T. Attribution of a CPT code for endomicroscopic technique in the biliary tracts. It will become effective on January 1, 201 6.	To be obtained
France	Endo-brachyoesophagus	French National Authority for Health (HAS)/UNCAM	201 4	The HAS has rendered a favorable decision for registration of optical endomicroscopy used to observe endobrachyoesophagus on the list of reimbursable procedures	Has been submitted to the UNCAM
	Follow-up of polyp resection scars in the colon	French National Authority for Health (HAS)/UNCAM	Q4 201 5	Registration in the HAS work program for the period Q4 201 4- Q4 201 5	NA
	Characterization of biliary strictures	French National Authority for Health (HAS)/UNCAM	Q4 201 5	Registration in the HAS work program for the period Q4 201 4- Q4 201 5	NA
Germany	Endomicroscopy	German Institute for Medical Documentation and Information (DIMDI)	201 3	Endomicroscopy with Cellvizio has been recorded in the final 201 4 list of OPS codes for the reimbursement of medical and associated surgical procedures	To be obtained

### ➤ Installed base of more than 440 systems

The Company chose rapid internationalization at the start of the marketing phase. The installed base of more than 440 systems is thus well distributed over several continents with more than 140 systems installed in the American zone, more than 190 systems installed in the EMEA zone and more than 90 systems in the Asia Pacific zone (APAC), 15 systems in the Latin American zone, including fewer than 10 in the process of being made available.

### ➤ Size of market

The number of facilities with endoscopy rooms is estimated at around 60,000 throughout the world, including 5,000 in the United States, 15,000 in Europe and more than 40,000 in Asia (see Section 6.3.1 below relating to the market).

In the United States, the Group is initially targeting a market of 1,000 hospitals, particularly including Academic Medical Centers, Veterans Affairs hospitals and Community hospitals..

The total number of procedures so far which could benefit from the Cellvizio, in clinically validated indications, is estimated at between one and two million for the United States per year.

The potential market in the United States is estimated at \$500 million to \$2 billion.

### ➤ Commercial structure in position

The Company has chosen to sell directly on some of its biggest markets, United States, France and Germany, and has set up a distribution network in the other markets where it has obtained marketing agreements. The main countries in which distribution agreements have been signed are Italy, the United Kingdom, China, Japan, Russia and Brazil. In all, the Group has signed nearly 50 distribution agreements.

Sales are made directly in France, Germany and the United States, and through distributors in the rest of Europe and in Asia.

Concerning the commercial organization, in the EMEA zone at the end of 2014, the team comprised 5 people: three "Systems" sales managers and two "Probe" sales managers.

In the United States, at the end of December 2014, the team was comprised of 18 people. The team is composed of eight regional "Systems" sales managers and seven "Probes" sales managers. These sales teams are led by three Sales Directors.

Finally, in Asia, the Asian General Manager leads the Group's activity in the region. For development in Asia he is assisted by a consultant in Japan and a country manager in China.

Overall, at the end of 2014, the Group had a sales force of 26 people.

➤ **Conclusion: establish ourselves as the leader in vivo microscopic imaging**

We are convinced that the ability to use a microscope inside the human body marks the start of a new era in medical imaging and Mauna Kea Technologies intends to pursue an ambitious strategy to push optical biopsy as a treatment standard.

The proposed utility of Cellvizio can be applied to all medical sectors which include endoscopy, so the Group will continue its clinical validations of Cellvizio in pulmonology and urology, thereby accelerating sales in these new markets.

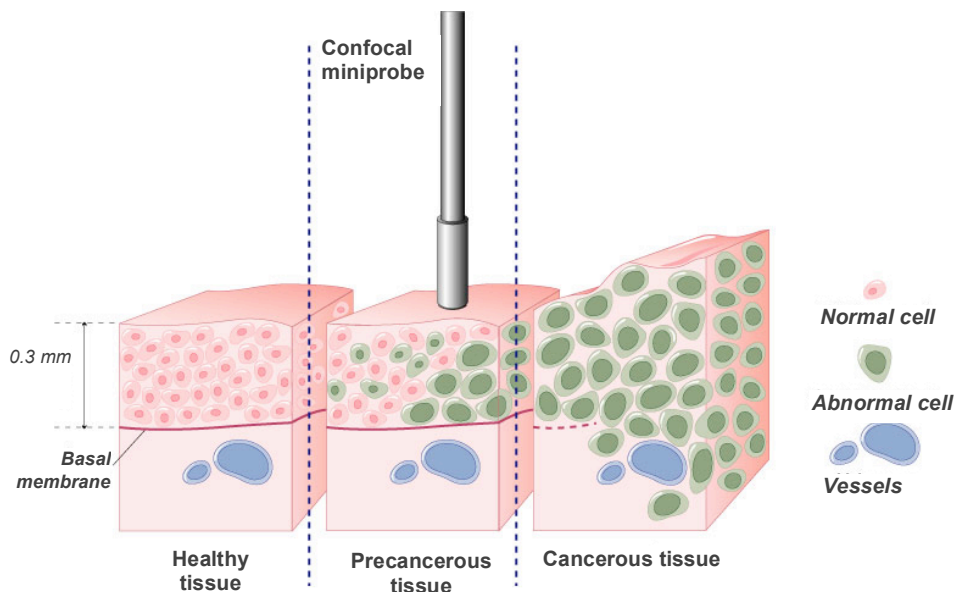
At the same time, the Research and Development team will continue its work to propose a specific range of Cellvizio adapted to each other medical field, for example abdominal and thoracic surgery, gynecology or ENT.

## 6.2. Optical biopsy and its current applications

### 6.2.1. Functions and benefits of the technology

#### The principles of optical biopsy

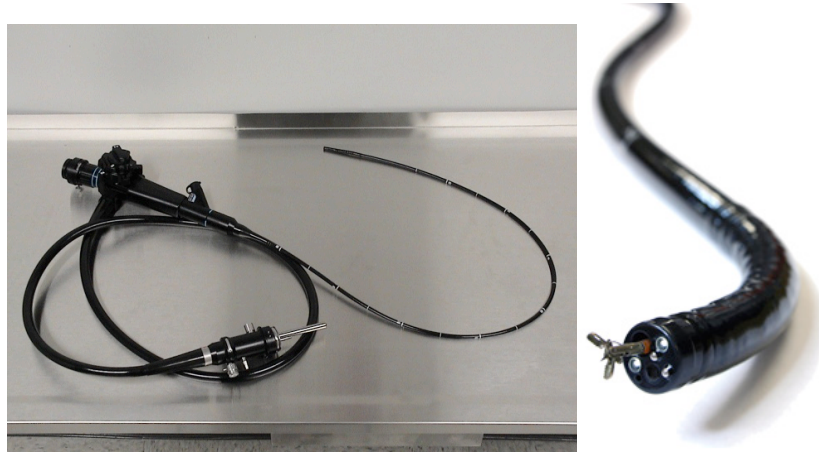
Endoscopy, based on visual, minimally invasive entry into the body's natural passages, is a well-known screening and treatment method. Since nearly 90% of cancers develop in the mucosa (Source: *Year 2000 Surveillance Research from the American Cancer Society*), endoscopic access to these membranes, located in hollow organs like the esophagus or colon, provides a major improvement in patient comfort and diagnosis generally. If everyone aged 50 and over followed screening recommendations, particularly for colonoscopy, 60% of colorectal cancer deaths could be avoided. (Source: *Centers for Disease Control*: [http://www.cdc.gov/cancer/colorectal/pdf/SFL\\_brochure.pdf](http://www.cdc.gov/cancer/colorectal/pdf/SFL_brochure.pdf)).



*Diagram of cancer cell progression from the mucosa to the surface (progression invisible with endoscopy) and ability of Cellvizio miniprobe to image a precancerous zone.*

Using a camera located at the end of a flexible, articulated tube – an endoscope – the physician can identify lesions from which samples (biopsies) can be taken for histological confirmation of the macroscopic diagnostic impression.

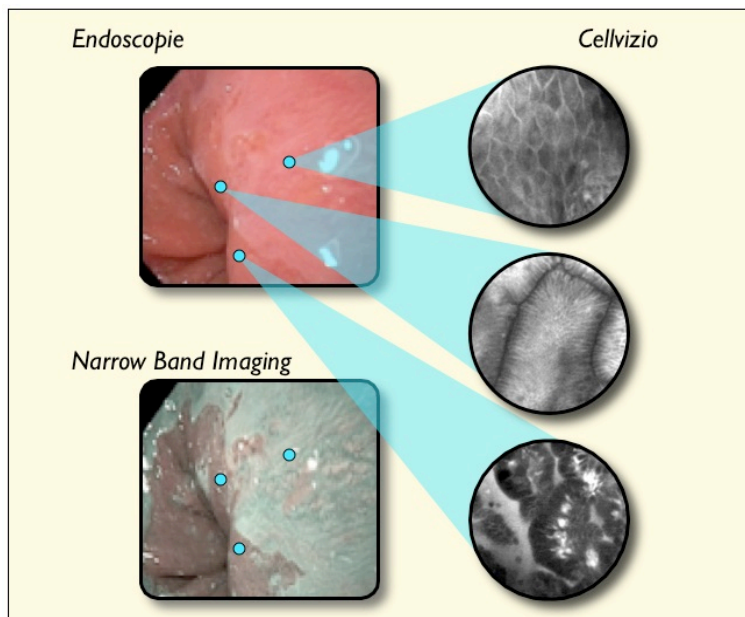
Microscopic analysis of the cellular architecture of the samples is then entrusted to the histopathology department, which differentiates and characterizes any alterations found. This sampling and testing procedure is always conducted on dead cells over a period of time that may take weeks, so the physician is unable to intervene in real time during the endoscopic procedure. Moreover, for the biopsy itself, the physician must rely on the images received from the endoscope, so the selection of sampling zones is limited by the microscopic size of the cells and their location under the surface of tissues (esophageal, gastric, etc. mucosa), i.e. areas that cannot be accessed with a biopsy forceps. When they can be done, biopsies are therefore conducted “blind” in areas where the physician can only estimate that suspect lesions are probable. The quality of the sample is thus not always usable for diagnostic purposes, often requiring one or more additional endoscopic procedures, delaying diagnosis and therapy for diseases for which early intervention is a determining factor in recovery rates.



*General view of a standard flexible endoscope (left) and view of the distal end with the camera, illumination fiber optics and operating channel, in which a biopsy forceps is inserted*

In view of this, for the past twenty years, players on the endoscopy market have developed their equipment with the aim of improving macroscopic vision. However, this progress only marginally improved the ability to locate suspicious lesions and did not enable microscopic-level access, which remained for the tissue pathologist alone.

The diagram below shows the essential difference between a standard or improved endoscope and the Cellvizio. The slide on the left shows the macroscopic vision of esophageal mucosa with standard endoscopy, corresponding to actual size x4, and on the lower left with contrast enhancement (narrow band imaging, NBI), with no change in image size. The images on the right show a real-time in situ microscopic image obtained with the Cellvizio, which allows for immediate characterization. The scale is normal x1000, corresponding to visualization at the cellular level.



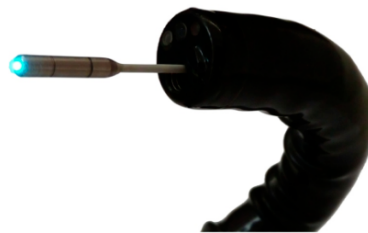
### Benefits of the technology

By bringing the microscope to the patient rather than taking a sample (biopsy) from the patient and putting it under a microscope, the Cellvizio combines all the key diagnostic steps into the endoscopy procedure. Indeed, for the first time, the clinician has the pertinent cellular information in real time:

- For optimized diagnosis and better diagnostic yield than traditional biopsies;
- For places which are difficult to access, where performing a biopsy is compromised, the Cellvizio can provide key microscopic information for diagnosis;
- To decide, if necessary, to perform an immediate therapeutic endoscopic procedure, to send a patient to surgery or not, or to confirm the absence of disease and limit useless operations.



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



*Confocal miniprobe exiting the end of the operating channel of a standard endoscope. All endoscopes have such a channel for instrument passage.*



*Cellvizio procedure in an endoscopy room: the physician has the endoscopic image (macroscopic, on the left of the image) and the Cellvizio image (microscopic, in the center of the image)*

Mauna Kea Technologies offers a major value proposition because it benefits all actors in the healthcare chain.

#### ➤ **Benefits for Patients**

- Faster, more reliable diagnosis;

- Real-time diagnostic information;
- A procedure that is less invasive than biopsy;
- The possibility of immediate intervention;
- Reduction of unjustified endoscopic and surgical procedures.

➤ **Benefits for Physicians**

- In situ and in vivo cellular-level visualization of the mucosa at suspicious sites, enabling microscopic visual characterization of tissues in real time, which increases diagnostic accuracy;
- Improved patient management that reinforces the physician's role during both diagnosis and therapy selection: the ability to both avoid useless treatments and anticipate those that are necessary;
- Being at the cutting edge of technology compared to their peers;
- Increased visibility for their department or healthcare facility, thus an increased number of patients treated by their department or facility.

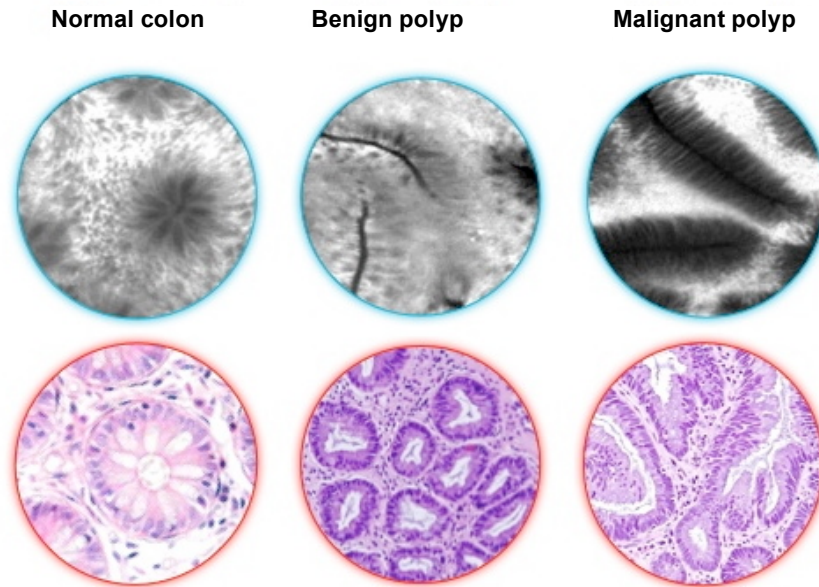
➤ **Benefits for Healthcare Facilities**

- Presenting themselves as an expert center equipped with cutting edge technology;
- Offering advanced endoscopy for the digestive, pulmonary and urinary systems;
- Improved financial balance from the return-on-investment proposed by the Cellvizio due to its effectiveness (increased number of cancers detected and treated) and/or possible reimbursements;
- Attracting clients seeking the best medical practices;
- Limits the risk of legal repercussions that can result from uncertain diagnoses.

➤ **Benefits for Healthcare Systems (social security, insurance, etc.)**

- Yield optimization for diagnostic procedures;
- Better therapeutic decisions;
- Fewer unnecessary endoscopic and surgical procedures.

Each of these points helps significantly reduce healthcare costs for public or private actors.



*Images obtained in vivo with the Cellvizio during a colonoscopy (above) compared with images obtained ex vivo in the analysis laboratory. Note the similarity between the images.*

### Current applications

The Cellvizio potentially targets all the medical fields in which physicians need to evaluate the type of tissues to make decisions regarding their patients' treatments. These include gastroenterology, urology, pulmonology and surgery.

As the Company does not have the resources necessary to pursue all of these outlets head-on, in 2005 the Company chose gastroenterology as the priority market in respect of the Cellvizio's contributions to various pathologies which are particularly difficult to diagnose: Endo-brachy-esophagus, precancerous lesions in the stomach, biliary strictures, colorectal polyps, chronic inflammatory intestinal diseases, and more recently, pancreatic cysts. The first sale in this field was made in 2007. The same year, the first sale of a Cellvizio dedicated to pulmonology was made.

To date, digestive pathologies accessible by endoscopy are still the indications in which Cellvizio is the most used and the most sold. Pulmonary applications (bronchoscopy procedure) are in the minority. Finally, a range of miniprobes for urological applications has been developed, and the range has obtained a marketing authorization in Europe and the United States, opening the door for bladder indications, which could eventually account for a growing share of commercial activities.

## 6.2.2. Products and clinical validation

### Product description

The Group offers two product ranges: the first range is designed for healthcare facilities (hospitals and clinics) and the second is for small animal research laboratories and is known as Cellvizio LAB.

No matter what its application, the Cellvizio system comprises four main components:

- A central base comprising the display screen, optoelectronic Laser Scanning Unit or LSU;
- The computer processor;
- The Confocal Miniprobes, specific to each indication, which are therefore the consumable components;
- The real-time image processing and display software. The extremely high quality of the images delivered by the miniprobes is one of the group's primary areas of expertise, image processing; without this, the images captured by the tens of thousands of miniprobe fibers would simply be illegible for the physician.

Given technical and software developments, the Cellvizio's obsolescence is reached after five to seven years. The most recent version of the Cellvizio, called Cellvizio 100, is the second generation platform and is currently marketed in most countries, in particular in Europe and the United States. The Cellvizio 100 is an easier to use system, through an improvement in the user interface, its general ergonomics and the time needed to start up the device. Progress has also been made in the quality of images obtained. In several countries, including China, the Group is waiting for a marketing authorization for the Cellvizio 100 which will replace the previous generation.

The miniprobes can be reused between 10 and 20 times and are removed with standard equipment, in the same way as endoscopic accessories. They constitute a source of recurrent revenue for the Group.

To date, the Cellvizio\* is offered with various probes designed to meet the specific needs of each medical specialty:

#### ➤ **For digestive endoscopy applications**

- GastroFlex UHD probe for eso-gastro-duodenoscopy (EGD),
- CholangioFlex probe for endoscopic retrograde cholangio-pancreatography (biliary strictures),
- ColoFlex UHD probe for colonoscopy (colorectal polyps),
- AQ-Flex probe for cytopuncture using echoendoscopy to access pancreatic cysts;

#### ➤ **For bronchoscopic applications**

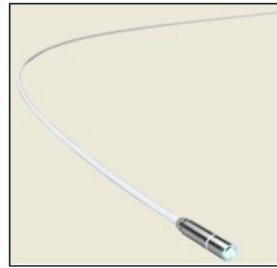
- AlveoFlex probe to access the pulmonary bronchi and alveoli (peripheral nodules);

#### ➤ **For urological applications**

- UroFlex probe for ureteroscopy (upper urinary tract),
- CystoFlex for flexible cystoscopy (bladder),
- CystoFlex UHD probe for rigid cystoscopy (bladder).



**Central unit**



**Confocal miniprobe to be connected to the scanning unit**



**Example of miniprobe packaging**

Confocal miniprobes are made up of a bundle of several tens of thousands of optical fibers sequentially scanned by a laser beam emitted by the scanning unit. They transport the Laser beam to the area to be observed, inside human anatomic tracts. Fluorescence (exogenous or endogenous) emitted by the tissue under laser excitation is collected by the miniprobe and analyzed to compose the image of the tissue.

During use, the miniprobes must be connected to the Laser Scanning Unit and then inserted into the operating channel of the endoscope like a biopsy forceps would be, for example, to provide the in vivo fluorescence microscopic imaging during the endoscopy procedure. They are fully compatible with all the standard equipment being used in endoscopy rooms, and unlike traditional endoscopy, provide deep observation of the mucosa (up to 150  $\mu\text{m}$ ), the preferred layer for locating cancerous tumors.

Apart from the hardware platform and miniprobes, Mauna Kea Technologies is also developing successive versions of its image processing software. In 2013, the Group announced the launch of EVA, "Endomicroscopy Virtual Assistant" based on version 2.2 of its software, which improves the ease of using the Cellvizio and reduces the learning curve by using new functions such as the on-board atlas of reference images, the tool for automatically selecting the most stable videos, or its connectivity with hospital patient data archiving systems. EVA is part of the service offer linked to Cellvizio, allowing users to add different services to their equipment: preventive maintenance, curative maintenance, loan or replacement service in the event of failure, software updates, remote support, etc.

The main benefit of the Cellvizio design, apart from being particularly adapted for easy manufacture, lies in the fact that it consists in a unique microscopy technological platform, providing guaranteed stability over several years and the fact that only the probes provide the specific link between this standard platform and the application concerned (digestive, pulmonary tracts, etc.), thus enabling the platform to be used by several hospital departments or physicians.

The catalog price of a Cellvizio 100 is €137,000 in Europe and \$190,000 in the United States, that of a miniprobe varies between €4,000 and €7,000, depending on the application, remembering that the miniprobes can be reused between 10 and 20 times depending on the type of procedure, after retreatment.

The Cellvizio LAB is a version of Cellvizio adapted for the needs of laboratories and research centers that conduct testing on small animals. The miniprobes used with Cellvizio LAB are specific and lead to broader applications than the clinical version, such as neuroscience and immunology applications.

## Clinical validation

Mauna Kea Technologies has launched an ambitious clinical trial program. Although these studies are not part of a regulatory process for marketing authorization, they are every bit as critical. Imposing a new technology within the terms of perfectly known medical procedures mastered by health professionals (physicians and nursing staff) first means obtaining the support of opinion leaders in the field concerned. This means scientifically demonstrating the benefits of “optical biopsy” as compared to existing alternatives and distributing these results to opinion leaders and specialty societies so that they could use them to recommend this new procedure and request that it be included in their respective countries' reimbursement programs.

The key mission of the Group's Clinical Affairs Department is to enter into collaborative studies with expert centers to establish the clinical validity of the Cellvizio. With years of experience in international multicenter studies and randomized studies, the clinical teams move through a sequential process for each trial using the following steps:

- Selection of the therapeutic intervention with senior management;
- Expected value proposition;
- Once the clinical roadmap has been decided, Mauna Kea Technologies goes through a rigorous selection process to determine which hospital centers would be best positioned to collaborate with the projected study;
- Definition and monitoring of study protocols;
- Patient recruitment management;
- Definition and monitoring of study protocols;
- Data analysis;
- Scientific communications and medical articles.

Numerous international multicenter clinical trials to date have shown that with the Cellvizio, physicians are able to more precisely and rapidly detect or characterize early forms of diseases, thus enabling them to decide which treatments to prescribe in real time. This clinical validation is decisive. It conditions the support of many opinion leaders throughout the world and American and French scientific societies. It consists in more than 260 clinical publications about Cellvizio in reference scientific journals and constitutes one of the Group's most important elements prior to the widespread marketing of Cellvizio for growing indications.

The majority of studies of digestive tract disease indications were part of the business strategy started by the Group in 2007 to make gastroenterology its priority market. Today, “Optical Biopsy” has a significant amount of clinical evidence for digestive indications, demonstrating the unrivaled accuracy of real-time tissue imaging by Cellvizio. This level of evidence provides access to the medical-economic demonstration stage which is key for access to reimbursement. The results detailed below include the main published clinical results for the most solicited indications.

The results of a meta-analysis combining the conclusions of 11 major studies of three separate indications in gastroenterology, show that the unrivaled accuracy of real-time tissue imaging by Cellvizio definitely leads to changes in practitioners' diagnostic conclusions and patient treatment. Optical Biopsy can be used to significantly improve the detection of precancerous and cancerous lesions compared with conventional endoscopy and biopsy procedures for patients concerned, as well as confirming the absence of suspect lesions in healthy patients. This leads to faster and more justified intervention for patients, thus enabling them to avoid certain complex and useless procedures.

### EBO (Endo-brachy-esophagus)

Pathology characterized by the development of a metaplasia in the lower esophagus, following reflux. Normal esophageal tissue is gradually replaced by abnormal, intestinal type tissue in the lower esophagus, which may develop into a form of cancer in the absence of treatment.

According to four trials concerning 242 patients, Optical Biopsy using Cellvizio detected 97% of patients suffering from EBO-type dysplasias compared with traditional endoscopy techniques, which detect 10% fewer. Moreover, the diagnostic results of this imaging technique provide the possibility of reducing the number of physical biopsies, eliminating negative samples while enabling immediate endoscopic treatment through the ability to exclude the dysplasia, with a high confidence level and a negative predictive value of 98%

Optical Biopsy therefore provides a valid option for monitoring patients suffering from an EBO, providing a diagnostic tool with reliable and immediate results, enabling an appropriate treatment to be provided for their needs.

### **Biliary duct strictures**

This involves shrinkage of the biliary tracts preventing the bile from circulating from where it is produced, in the liver, to the gallbladder and intestines. Biliary strictures may be benign in origin or caused by a form of cancer, cholangiocarcinoma, with a pejorative prognosis and very fast evolution in the absence of early treatment.

Four trials concerning 252 patients revealed that Optical Biopsy detected 88% of biliary strictures of cancerous origin against 59% for traditional tissue sampling methods. This excellent result in favor of Cellvizio can be used to envisage a significant modification of treatment of patients suffering from this very aggressive form of cancer, by considerably reducing the number of **repeated diagnostic** procedures and offering a more adequate and earlier treatment. On the other hand, a negative Cellvizio result will reassure patients with a high level of confidence and avoid repeated procedures which generate anxiety and are costly, thanks to a 78% negative predictive value versus 57% for tissue samples.

### **Colorectal polyps**

Colorectal polyps are tumors which develop in the colonic and rectal mucosa. Some polyps are precancerous lesions which can lead to colorectal cancer. Early diagnosis is vital for this form of cancer, the second most deadly cancer and the third most frequent in France.

The three trials concerning 378 patients revealed that Optical Biopsy provided an accurate diagnosis for 90% of colorectal lesions against 68% using standard endoscopic procedures. Cellvizio therefore provided better characterization of precancerous polyps and for immediate treatment of the lesions if necessary. After resection of such a polyp, Cellvizio also facilitates characterization of the resection site to enable retreatment in real time if necessary, a recent study having shown that this technique could be used to correctly identify 100% of residual lesions (Shahid et al, Diagnostic accuracy of probe-based confocal laser endomicroscopy in detecting residual colorectal neoplasia after EMR: a prospective study.) *Gastrointest Endosc.* March 2012)

Moreover, Mauna Kea Technologies promotes a strong policy of innovation, and for that, has launched a number of clinical projects to prove the utility of its new products concerning new indications. These include the characterization of pancreatic lesions, in real time, as well as pulmonary nodules. The miniprobes used in these two indications have been approved by regulatory authorities for the main markets.

### **Cystic tumors of the pancreas: a new application with high potential**

Cavity full of pancreatic liquid developing on the pancreas, often some time after an episode of acute pancreatitis. These cysts are usually detected by accident during a scan or MRI, and some of them are potentially degenerative which can lead to pancreatic cancer.

The CONTACT 1 study, carried out on 31 patients, the results of which were published in the journal "Endoscopy" helped to refine comprehension of the images obtained by Cellvizio in pancreatic cyst lesions and determine that the presence of a superficial vascular network is 100% specific to a particular sub-type of pancreatic cysts (serous cystadenoma), which is always considered to be benign. This advance will help counter the limitations inherent to taking conventional cytological samples, such as the absence of analyzable fluid.

These results represent a major advance in terms of patient treatment, avoiding useless surgery for patients with benign lesions.

The study also revealed how easy it is to interpret the images obtained with Cellvizio so that any endoscopist, even a novice, can achieve a reliable diagnosis.

A second trial, CONTACT 2, with the objective of prospectively validating the results of the first trial and evaluating the impact of the technique on patient treatment, is currently in progress. This prospective trial concerns a total of 200 patients, with the end of inclusion scheduled for mid-2015.

### **Pulmonary nodules**

Pulmonary nodules (round or oval lesion less than three cm in diameter, surrounded by healthy pulmonary tissue) are usually detected accidentally, and benign, but they can also be forms of lung cancer, the most common cause of death from cancer in men and women, after breast cancer, with 1.3 million deaths per year throughout the world. In 2013, Mauna Kea Technologies initiated a major trial in ten reference centers in the United States, to measure the impact of Optical Biopsy on the diagnosis of pulmonary nodules. The objective of this two-phase trial, concerning 200 patients, consists of demonstrating that the Cellvizio improves the accuracy of bronchoscopies, while avoiding the need for costly and invasive clinical examinations. The Optical Biopsy will provide pulmonologists with a new diagnostic solution to improve the diagnostic yield of bronchoscopies, while providing the possibility of real-time differentiation between healthy tissue and nodular tissue.

Moreover, this same trial aims to assess optical biopsy's role in detecting rejection following a lung transplant. Indeed, these fragile patients must undergo a large number of bronchoscopies with tissue samples, during the weeks following the transplant, in order to detect any signs of rejection. The risk of bleeding linked to physical biopsies subjects these patients to a non-negligible risk of morbidity. The first results, presented at the conference held by "The International Society for Heart & Lung Transplantation" by Dr. Keller of the Mayo Clinic, Jacksonville, Florida, showed that the Cellvizio helped visually identify certain criteria associated with early rejection. Clinical validation of these first results should help demonstrate the potential impact on treatment for these patients. Several clinical trials are currently in progress. in world-renowned centers such as the Cleveland Clinic (USA).

## 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 rate of recurrence (75%) which means life-long monitoring, very difficult for patients and costly for health systems.

Within the context of application to detect and treat bladder lesions, the confocal endomicroscopic technique using miniprobes provides a dynamic view of the cellular organization of the bladder wall, non-invasively, using miniprobes inserted into the cystoscope operating channel.

ECM is thus the only technique which supplies a reliable real-time diagnosis based on microscopic images, compared with simple morphological analysis based on cystoscope macroscopic images of tissue pathology obtained several days later.

To date, more than ten clinical publications concerning the use of ECM in the bladder have been published. The technical feasibility of the ECM procedure has been reported in work done by Liao et al. since 2009.

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

The first clinical trials held ex vivo demonstrated the technical feasibility of ECM in the bladder and its ability to obtain interpretable images in this indication.

A study carried out in 2011 by the same team refined the optical specifications of the miniprobe used during rigid cystoscopic procedures.

More recently, several prospective studies have led to the compilation of an atlas of ECM images in the bladder and adjacent organs and the assessment of diagnostic performance. More precisely, the atlas of ECM images obtained for a cohort of 66 patients led to the establishment of a preliminary classification of lesions observed in the bladder, kidney, prostate, urethra and ureter, including differentiation of normal tissue from inflammatory or malignant lesions.

In a study by Liu et al published in 2012, the diagnostic accuracy of ECM was compared with that of white light on 57 patients during TURB procedures. For low-grade lesions, the combination of white light and ECM achieved a diagnostic accuracy level of 100%, and 100% sensitivity for high-grade lesions also. (Source: *Interobserver Agreement of Confocal Laser Endomicroscopy for Bladder Cancer, The Journal of Urology, DOI: 10.1089/end.2012.0549, May 2012*)

Moreover, Prof. Traxer (Tenon hospital, Paris) recently presented the first clinical results obtained in the upper urinary tract with the Cellvizio (EAU, 2014). Upper urinary tract tumors represent 5% of urothelial tumors. Considering the difficulties in access, these lesions are extremely difficult to diagnose using current techniques.

The preliminary data in favor of Cellvizio is used to envisage a potential role for this technique, in both diagnosis and treatment of these lesions. Bigger trials are currently in progress to validate this preliminary data.

## Surgery

Mauna Kea Technologies is now working to extend the scope of application of the technique, assessing its potential role in surgery, particularly minimally invasive surgery. Indeed, image-guided surgery, particularly using fluorescence imaging, has become the norm over the past few years. Feasibility and clinical validation in this field for the Cellvizio began in 2014, with the start of several clinical trials in digestive surgery, gynecology and neurosurgery.

### 6.2.3. Marketing and reimbursement authorization

#### Marketing authorization

The Company is subject to regulatory obligations specific to its activity concerning:

- product marketing;
- relations with health professionals;
- the environment;
- reimbursement.

The regulatory aspects relating to the Company's operations are managed by the Regulatory Affairs team, which comes under the Operations department.

Marketing the Cellvizio<sup>®</sup> and Confocal Miniprob<sup>™</sup>, as medical devices, requires specific authorizations certifying product compliance with local regulations, which are more or less restrictive. Although there are exceptions like China, an effort is noted towards global convergence for the harmonization of requirements and mutual recognitions between states/organizations which facilitates access to the different markets.

The Group's products present a moderate level of risk and thus benefit from regulatory pathways for access to different global markets which are not the most restrictive. However, the time needed to market a new product or for substantial modification of existing products may be extended in certain countries.

### **European context**

CE Marking is a legal authorization which allows the manufacturer to market devices in the European Union. It guarantees safety for users and patients and proves that all measures have been taken by the manufacturer to ensure compliance with the essential requirements of European directives. The Cellvizio<sup>®</sup> and Confocal Miniprobes<sup>™</sup> products are subject to the European Directive relating to Medical Devices (Directive 93/42/EEC of June 14, 1993). However, a manufacturer must also take any particularities of national transpositions into account.

As a Medical Device (MD) carrying a potential moderate risk (active medical device invasive in the short term), the Cellvizio<sup>®</sup> is a Class IIa device.

To obtain the CE marking, the Company has chosen the method of evaluation of compliance according to appendix II of Directive 93/42 based on the compliance of its global quality system to harmonized standard ISO 13485:2003 (Medical devices - Quality management systems - Requirements for regulatory purposes).

CE marking of its products is based on ISO 13485:2003 certification, and French standard (NF) EN ISO 13485:2012, completed by a technical file including product descriptions and proofs of its compliance with the essential health and safety requirements of the directives applicable for its projected use. Demonstration of compliance with the essential requirements is based on compliance with applicable harmonized technical standards. The Company applies all the applicable harmonized standards to its products.

The Cellvizio<sup>®</sup> and Confocal Miniprobes<sup>™</sup> as a “fibered confocal microscopic imaging system” obtained CE marking on December 13, 2005. The CE marking certification (No. 7816) is renewed every three years.

The CE marking obtained means that the Group can market the Cellvizio<sup>®</sup> in all European Union Member States.

Moreover, the Group obtained the certification according to the CB scheme of its Cellvizio 100 Series in March 2013 (certificate OC FR 637203). This certification was then used to prove this compliance outside Europe for access to other markets.

### **American regulations**

Marketing the Cellvizio<sup>®</sup> in the United States is conditional on obtaining an approval issued by the FDA (Food & Drug Administration).

In the United States, medical devices (“MD”) are classified in 3 categories: Class I carries the least risk and class III MDs carry maximum risks. The various classifications and associated requirements are specified in the Code of Federal Regulations (21 CFR 820).

As the Cellvizio<sup>®</sup> is an MD with a medium risk potential, it falls into class II of the U.S. system. Class II MDs are subject to a premarket notification procedure. The authorizations for Cellvizio<sup>®</sup> and the Confocal Miniprobes were obtained through a “510(k)” procedure, establishing a file submitted to the FDA for examination. This file includes the same type of items as the CE marking file and must demonstrate substantial equivalence to a medical device already approved for the U.S. market. After approval of the file, the FDA registers the medical device in the Medical Device listing it keeps up to date.

Since the Cellvizio<sup>®</sup> emits laser radiation, it is also subject to a specific American regulatory requirement (21 CFR part 1040) which involves submitting an annual report to the FDA, which issues an annual “accession number” needed for access to the American market.

Finally, independent of product classification, the Quality Management System must comply with the requirements of the 21 CFR 820.

The first 510(k) authorizations were obtained for gastrointestinal applications in September 2005 (K051585) and for pulmonary applications in August 2006 (K061666). Since then, seven new authorizations have been added, either for product and miniprobe upgrades (K111047, K120208, K133466 and K141358), or to cover more specific indications (K122042, K123676 and K132389).

New applications for authorization are being drawn up and the files will be submitted to the FDA in 510(k) format in 2015.

The Company also has “accession numbers” used for customs release for systems sent to the United States. An FDA inspection of the Group’s production site, intended to check that the quality system complies with 21 CFR 820 requirements, also took place in January 2014.

### **Primary other regulations**

The regulations required in other countries can be split into two categories: those based on "mutual recognition" of the CE marking and/or the FDA agreement, and those requiring implementation of a specific procedure.

The Group has chosen an authorized organization with recognition agreements with several competent authorities and a technical certifying organization belonging to the IECEE CB scheme (IEC system for Conformity testing and Certification of Electrotechnical Equipment and Components) which 54 countries belong to, and this allowed them to obtain authorizations in the following countries: Canada (2006), Taiwan (2010), Australia (2013), Mexico (in progress).

In some countries, a marketing authorization for a medical device is obtained through a process similar to the CE marking process. The Cellvizio<sup>®</sup> benefits from this procedure in the following countries: Russia; (2009), Turkey (2009), Thailand (2009), Israel (2011), Singapore (2011), Indonesia (2011), Malaysia (2011), Saudi Arabia (2013), Ecuador (2014) and Venezuela (in progress).

In other countries, the procedures for obtaining marketing authorizations are more complex and require, as for the United States, a file to be submitted to the competent local authorities to demonstrate compliance with the regulations applicable in the country. Further technical tests to be carried out in the country in question or a specific audit may also be required.

### **China**

The competent authority is the CFDA (Chinese Food and Drug Administration). In addition to reviewing the file, electrical compliance, laser and safety tests, as well as a demonstration of biocompatibility must be conducted by local technical testing centers.

The marketing authorization for Cellvizio<sup>®</sup> in China was obtained in December 2012. A new procedure is in progress for the Cellvizio<sup>®</sup> 100 Series and the new models of Confocal Miniproboscopes, and the authorization is expected to be awarded during the first half of 2015.

### **South Korea**

The competent authority is the KFDA (Korean Food and Drug Administration). The marketing authorization for Cellvizio<sup>®</sup> in Korea was obtained in March 2011, then renewed in June 2013 for the Cellvizio<sup>®</sup> 100 Series.

### **Brazil**

In Brazil, the relevant authority is the ANVISA (Agência Nacional de Vigilância Sanitária). In addition to the file, the product is inspected to prove its compliance with international standards and local Brazilian regulations on the manufacturer's site by a body recognized by Brazil.

The marketing authorization for Brazil for the Cellvizio<sup>®</sup> 100 Series was obtained in November 2011.

### **Japan**

The Cellvizio<sup>®</sup> is considered to be a class I device, and benefits from a simplified self-declaration procedure (Todokede).

The Confocal Miniproboscopes are classified as class II, for medical devices under special control, and benefit from a regulatory pathway for marketing, requiring an RCB (Registered Certification Body) approved by the Ministry of Health (Ninsho). The manufacturer must name the holder of the authorization (MAH or D-MAH) who will manage the records, submit a request for accreditation of a foreign manufacturer and submit the premarketing request to the RCB. The RCB issues the certificate on the basis of evaluation of the technical file provided and auditing of the manufacturer's quality system according to the requirements of Japanese law concerning pharmaceutical affairs (PAL) and order No. 169 which details the requirements relative to the quality management system similar to those of standard ISO 13485.

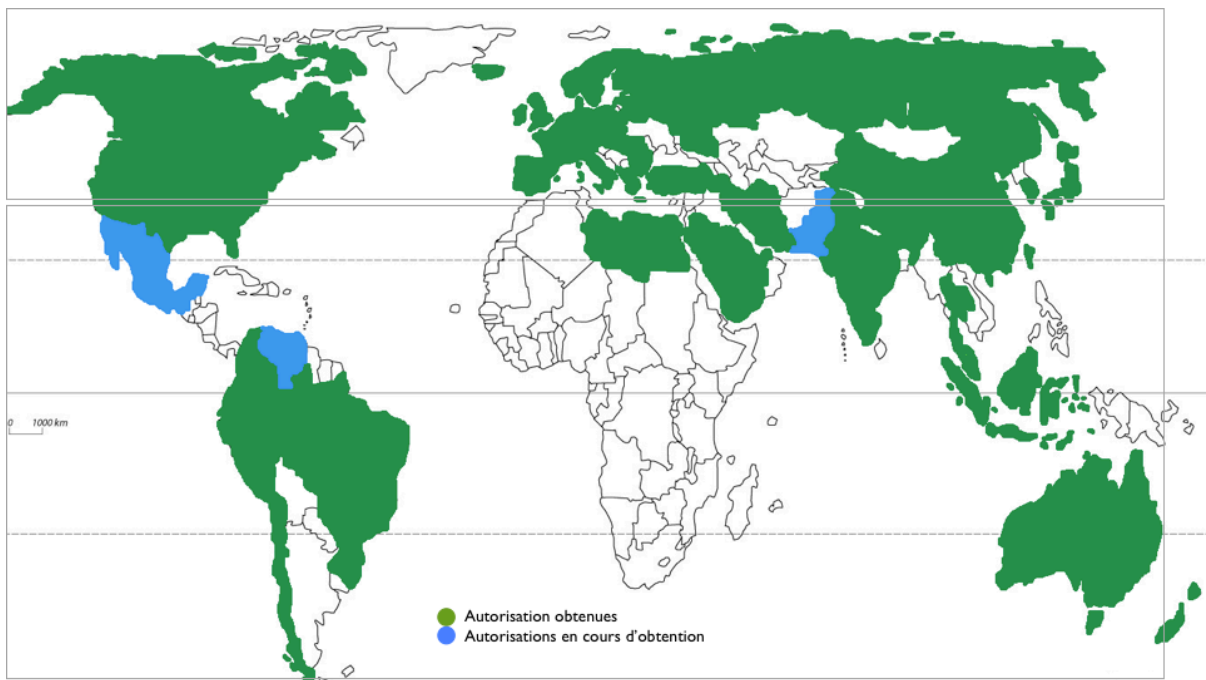
In April 2014, the Company obtained double authorization in Japan for class I and class II for all the Cellvizio's current applications: gastroenterology, urology, and pulmonology.

Summary of authorizations obtained or in the process of being obtained

	Cellvizio Systems	Probes							
		Pulmonology	Digestive endoscopy				Urology		
Country	Cellvizio	AlveoFlex	GastroFlex	ColoFlex	Cholangio-Flex	AQ-Flex	UroFlex	CystoFlex	CystoFlex UHD
Europe CE	✓	✓	✓	✓	✓	✓	✓	✓	✓
Israel	✓	✓	✓	✓	✓	✓	✓	In progress	In progress
Russia	✓	✓	✓	✓	✓	✓	✓	✓	✓
Belorussia	✓	✓	✓	✓	✓	✓	✓	✓	✓
Saudi Arabica	✓	✓	✓	✓	✓	✓	Not started	Not started	Not started
Turkey	✓	✓	✓	✓	✓	✓	✓	✓	✓
Australia	✓	✓	✓	✓	✓	✓	✓	✓	✓
China	✓	✓	✓	✓	✓	In progress	In progress	In progress	In progress
Hong-Kong	No regulation								
India	No regulation								
Japan	✓	✓	✓	✓	✓	In progress	✓	✓	✓
South Korea	✓	✓	✓	✓	✓	Not started	✓	✓	In progress
Singapore	✓	✓	✓	✓	✓	✓	In progress	In progress	In progress
Taiwan	✓	✓	✓	✓	✓	In progress	In progress	In progress	In progress
Thailand	✓	✓	✓	✓	✓	✓	✓	✓	✓
Canada	✓	✓	✓	✓	✓	✓	✓	✓	✓
United States	✓	✓	✓	✓	✓	✓	✓	✓	✓
Brazil	✓	✓	✓	✓	✓	✓	✓	In progress	In progress
Mexico, Venezuela	In progress	In progress	In progress	In progress	In progress	In progress	In progress	In progress	In progress
Colombia	✓	✓	✓	✓	✓	✓	✓	✓	In progress
Ecuador, Peru	✓	✓	✓	✓	✓	✓	✓	✓	✓

The United States is the only country in which the Group currently has reimbursement rates (see the next paragraph on the reimbursement process)

The following map summarizes the marketing authorizations obtained or in progress for Cellvizio medical devices.



## Relations with health professionals

In France, relations with health professionals are governed by the provisions of Article L. 4113-6 of the public health code concerning the advantages consented to health professionals (so-called "anti-gift" law). In this respect, the Company has implemented ethics rules which meet these provisions. Moreover, since 2013, the Group has declared established agreements and advantages consented to health professionals in accordance with transparency requirements in France and the United States (Sunshine Act).

## Environment

The Company has taken European environmental regulations into account; (e.g. REACH, ROHS, DEEE, etc.) which are intended to:

- limit waste and its hazards;
- promote reuse and recycling;
- improve conditions for disposal and control;
- limit or prohibit the use of certain materials.

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

## Reimbursement processes

Processing of the medical procedure representing use of the Cellvizio is a critical part of the widespread use of the technique. In each country, or each region, public and/or private insurers cover the reimbursement of medical procedures for their patients. Mauna Kea Technologies aims to obtain access to reimbursement for the Cellvizio for the most common indications. For this purpose, the Clinical Affairs team is working in close collaboration with management, Operational Marketing resources (and, if necessary, local distributors), as well as internal resources dedicated to the United States, in order to draw up and implement the plan for access to reimbursement in the different countries and indications concerned.

Access to reimbursement generally involves creating a procedure (recognition of a new procedure and registration in the nomenclature), by obtaining cover for this procedure, and generating a tariff for it; three stages which can be carried out in parallel or sequentially depending on the countries and insurers in question.

### - In the United States

A new procedure was created for using Cellvizio in the upper digestive tract (esophagus, stomach, duodenum, pancreas). This procedure was priced and is generally covered (except in Florida at this time) in each State, by the public insurers, so that both hospitals and the physician carrying out the Cellvizio procedure can receive a relevant payment. Mauna Kea Technologies is currently implementing actions to extend this cover to private insurers. To date, procedures using the Cellvizio in other indications can be reimbursed in the United States thanks to an all-purpose, exceptional mechanism. Most Cellvizio users in the U.S. can thus be reimbursed for their Cellvizio procedures, under entirely satisfactory conditions. However, establishing long-lasting reimbursement is desirable and should take place via a request for the creation of new procedures.

In January 2013, endomicroscopy procedures using Cellvizio in the upper gastrointestinal tract were added to the list of investigations that can be carried out at ambulatory surgery centers in the United States. These centers, which specialize in outpatient care and less-invasive investigations, are equipped with the latest medical technologies and offer patients a quick and efficient same-day service. A reimbursement rate of \$520 was applied by the U.S. health authorities (Medicare and Medicaid) to procedures with a category I CPT code that were previously created for the use of Cellvizio in hospitals and clinics, and a reimbursement rate of \$927 has been effective since January 1, 2013. The latest rate was reassessed to \$1,013 on January 1, 2014.

In January 2014, the U.S. Centers for Medicare & Medicaid Services (CMS) released the amounts of the 2014 Medicare fees for doctors who carry out Cellvizio procedures in the upper digestive tract. Practitioners will be now paid for these procedures according to the published rate.

During the first quarter of 2015, the Company obtained a 4th CPT code for the endomicroscopic technique used in the biliary tracts, an application identified as key and for which the clinical trial results were very positive. This code will go into effect in January 2016 at the latest.

#### - In France

A request for a procedure concerning the main digestive indications was submitted in September 2010 to the French National Authority for Health (HAS) in France. The file's admissibility was notified in January 2011. The evaluation program for the procedure finally began at the end of 2013 and was finalized for the first indication evaluated, follow-up of endo-brachy-esophagus at the end of 2014, with a favorable HAS decision for registration of a new procedure on the list of reimbursable procedures. Since then, the *Syndicat des Médecins de l'Appareil Digestif* (SYNMAD) (Digestive Tract Physicians' Union) has applied to the *Union Nationale des Caisses d'Assurance Maladie* (UNCAM) (National Union of Health Insurance Funds), an authority in charge of studying the scope of applications accepted for reimbursement and the treatment rates. The UNCAM timetable is not yet known, but the Law on Social Security Financing 2014 (and 2015) normally plans for a maximum period of 6 months after notification of a favorable HAS decision.

Moreover, the HAS is currently evaluating other indications for endomicroscopy, including the characterization of biliary tract strictures, an indication for which the company recently announced a positive publication of results of its pivotal clinical trial.

#### - In Germany

A code for endomicroscopy in the digestive tracts (OPS code) was created in 2013 to document the procedures carried out with the Cellvizio. Evaluation of rates will focus on 2014 and 2015, with an inventory of Cellvizio procedures as well as extra costs in Germany during these two years, which will enable the authorities to establish and publish the payment linked to the recently created code.

Endomicroscopy with Cellvizio has been included in the final 2014 list of OPS codes for reimbursement of associated medical and surgical procedures by the German institute for medical documentation and information (DIMDI).

In other countries in which Mauna Kea Technologies markets the Cellvizio, procedures are in progress for familiarization with the health system and procedures for obtaining reimbursement, and preparing the requests for cover, notably in the United Kingdom, where the Company is currently working with NICE (National Institute for Health and Care Excellence) on evaluating the use of endomicroscopy in pancreatic cysts and biliary tracts.

It is interesting to note that in China and Ecuador, there are regional reimbursements for using the Cellvizio.

Summary table of progress in repayment procedures:

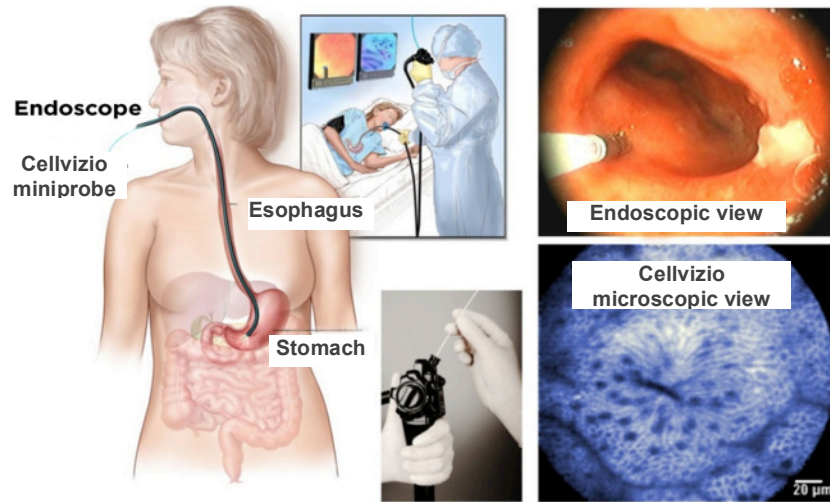
Country	Indication	Competent authority	Date of issue	Title	Pricing
United States	Upper digestive tract	American Medical Association / Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement Code CPT 43206. Upper digestive tract. Esophagoscopy with endomicroscopy. Effective from January 1, 2013	\$1,064 for hospitals and \$143 for physicians
		American Medical Association / Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement Code CPT 43252. Upper digestive tract Endobrachyoesophagus with Endomicroscopy. Effective from January 1, 2013.	\$1,064 for hospitals and \$178 for physicians
		American Medical Association / Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement Code CPT 88375. To interpret the images obtained with endomicroscopy. Effective from January 1, 2013.	According to published rates
	Biliary tracts (CPRE)	American Medical Association / Centers for Medicare & Medicaid Services, CMS	2015	Reimbursement Code CPT 039X7T. Attribution of a CPT code for endomicroscopic technique in the biliary tracts. It will become effective on January 1, 2016.	To be obtained
France	Endo-brachy-esophagus	French National Authority for Health (HAS) / UNCAM	2014	The HAS has rendered a favorable decision for registration of optical endomicroscopy used to observe endobrachyoesophagus on the list of reimbursable procedures	Has been submitted to the UNCAM
	Follow-up of polyp resection scars in the colon	French National Authority for Health (HAS) / UNCAM	Q4 2015	Registration in the HAS work program for the period Q4 2014- Q4 2015	NA
	Characterization of biliary strictures	French National Authority for Health (HAS) / UNCAM	Q4 2015	Registration in the HAS work program for the period Q4 2014- Q4 2015	NA
Germany	Endomicroscopy	German Institute for Medical Documentation and Information (DIMDI)	2013	Endomicroscopy with Cellvizio has been recorded in the final 2014 list of OPS codes for the reimbursement of medical and associated surgical procedures	To be obtained

### 6.3. Market and competition

The Group's business model is based on sales of medical equipment, the Cellvizio, and various types of limited-life miniprobes needed for Cellvizio use.

The Cellvizio sales market is therefore based on the number of healthcare facilities that can use the technology, and the market for miniprobes is based on the number of procedures in which the Cellvizio will be used.

The Cellvizio is used via the operating channel of most flexible endoscopes available on the market. However, the Cellvizio does not compete directly with existing product lines in the flexible endoscopy market. Rather than eating into shares of the flexible endoscope market, the Cellvizio is used in complement to them.



*Illustration showing the complementarity between standard endoscopy and endomicroscopy by miniprobe (ECM) with the Cellvizio: the Cellvizio provides the desired microscopic views during the procedure.*

Optical biopsy or endomicroscopy is, in itself, a new segment of the endoscopy market, like the previously emerging segment of the endoscopic capsule (for which the world leader is Given Imaging Ltd recently bought out by Covidien.)

(Source: <http://www.givenimaging.com/en-int/AboutGivenImaging/Pages/pageAbout.aspx>).

It is therefore difficult to estimate the potential market for the Cellvizio in the sense that having developed a piece of equipment which meets a need not yet fulfilled, Mauna Kea Technologies has created its own market.

Precise global evaluation of the number of biopsies is also difficult to carry out. In France in 2008, 1.3 million biopsies were carried out following endoscopic procedures of the gastrointestinal tracts (Source: *SFED 2008*). Given the relative uniformity of gastroenterology practices in France and the main countries in Europe, North America and Japan, we can estimate that the overall number of biopsy procedures numbers in the tens of millions, with France representing approximately 5% of the endoscopy device market.

#### 6.3.1. The hospitals and clinics market

In its current configuration, the Cellvizio is intended only for use by private hospitals and clinics that have an endoscopy room and physicians trained in the technique.

Of the three geographic zones formed by the United States, Europe and Asia, the total number of hospitals and private clinics is around 50 000 (Source: *HOPE/DEXIA, American Hospital Association, Japanese Ministry of Health*).

#### United States

Mauna Kea Technologies' main target in the United States during the next few years includes "Community Hospitals" as well as academic hospitals.

The American Hospital Association identified 5,008 hospitals in this category. Community Hospitals are non-governmental hospitals that offer short-term patient management. There are also 211 governmental hospitals.

(Source: *American Hospitals Association - Fast facts on US hospitals*

<http://www.aha.org/aha/resource-center/Statistics-and-suites/fast-facts.html>)

The segment of Academic Medical Centers includes 400 establishments according to the AAMC (Association of American Medical Colleges - <https://www.aamc.org/members/coth>), bringing the total number of targets for Mauna Kea Technologies in the United States to between 3,000 and 5,000, if we consider that not all Community hospitals have medical innovations.

For the moment, the Group is targeting the 1,000 community hospitals specializing in interventional endoscopy, i.e. exploration of the biliary and pancreatic tracts as well as pancreatic cysts.

## Europe

In 2004, the European Union had a total of more than 14,000 hospitals providing leading-edge treatment (medicine, surgery, obstetrics) or another activity (psychiatry, medium- or long-term stay) (Source: *"Les Hôpitaux" study by Dexia, in partnership with Hope, the European federation of hospitals and health services - July 2008*). In terms of population, Germany and France are the two European countries with the most hospitals, close to 3,500 and 3,000 respectively.

Country	No. of Hospitals
Germany	3,460
France	2,890
United Kingdom	1,300
Italy	1,295
Spain	740
Russia; <sup>3</sup>	9,000
Others	4,615
<b>Total</b>	<b>23,300</b>

## Asia

Japan and China are the biggest markets for Cellvizio in Asia.

The number of target hospitals by country breaks down as follows:

Country	No. of Hospitals
Japan	7,474
China	23,170
<b>Total</b>	<b>30,644</b>

<http://www.mhlw.go.jp/toukei/saikin/hw/iryosd/13/dl/1-1.pdf>

<http://www.statista.com/statistics/279322/number-of-hospitals-in-china/>

## South America

Brazil is the biggest South American market with about 7,500 hospitals (70% of which are private and 30% public) and a highly developed endoscopic activity (Source: *International Journal for Quality in Health Care 1999; Volume 11, Number 5: p. 437-441*).

Finally, the Group has studied the healthcare facilities which are priority targets, based on a multi-criteria analysis. For example, in the United States, the first market segment target includes 1,000 hospitals, each with more than 325 beds, located in densely populated geographic areas and focusing strongly on endoscopy, particularly interventional procedures. These establishments have, for example, chosen to purchase equipment specifically for treating Barrett's esophagus or bile duct and pancreatic exploration by echopuncture procedures.

<sup>3</sup> Source <http://dcc2.bumc.bu.edu/RussianLegalHealthReform/ProjectDocuments/n970.IIIE1.Analysis.pdf>

**6.3.2. The potential market for probes: The number of optical biopsy procedures**

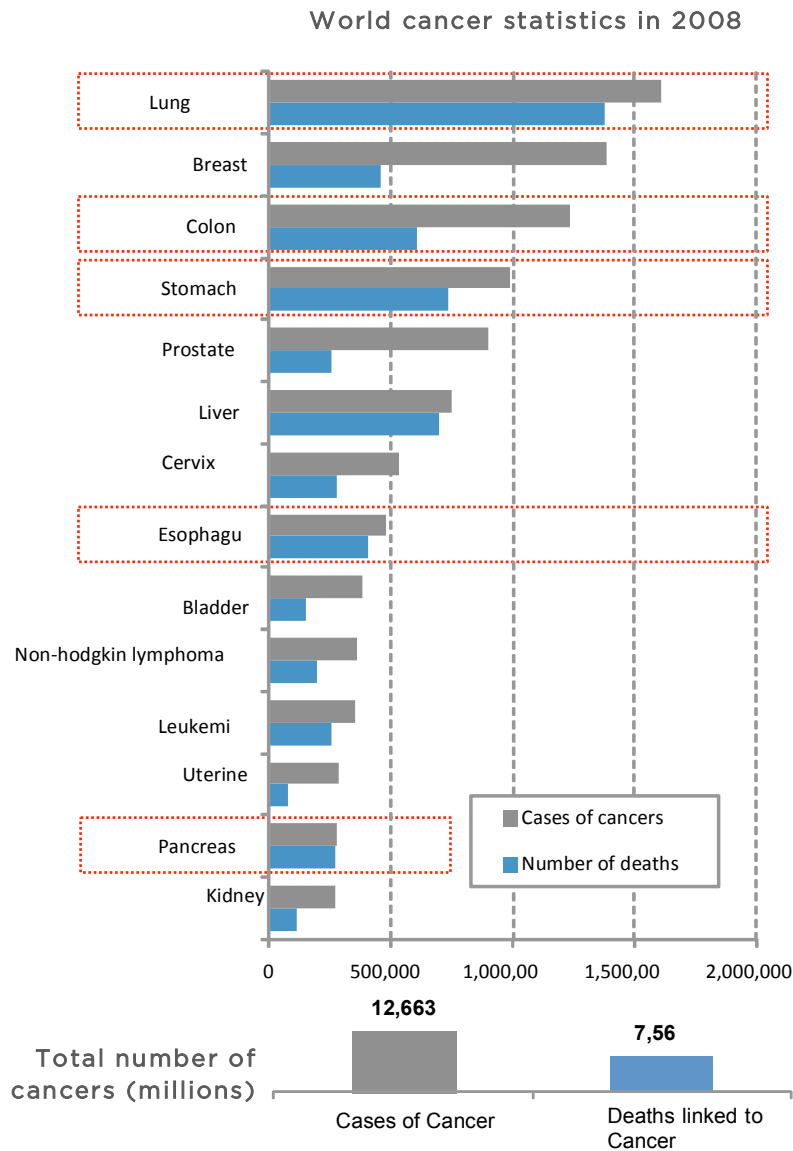
Here, we concentrate mainly on digestive endoscopy indications, in which the Cellvizio is most used.

The number of endoscopies carried out in the United States is estimated at 55 million procedures per year, according to IdataResearch Inc. (2010). Considering that the United States represents at most 50% of the world market (i.e. the United States share of the market in value of endoscopic medical devices (Source: *GBI Research –December 2010*), it can be estimated that the world market for endoscopic procedures is close to 100 million procedures per year.

Public authorities have set up cancer screening programs in the major industrialized countries. In the United States, for example, (Source: *The Patient Protection and Affordable Care Act of 2010*) the Government’s effort to promote better availability of medical treatment and consequently make the rules for reimbursement of colorectal cancer diagnosis more flexible means a new patient population in the United States should have access to this procedure.

The European health authorities have also set up public health policies to promote colorectal cancer screening, which should result in a significant increase of the total number of endoscopic procedures in years to come.

According to the International Agency for Research on Cancer, worldwide cancer statistics broke down as follows in 2008:



Endomicroscopy is a medical procedure separate from the endoscopy procedure during which it takes place. The Cellvizio's compatibility with the endoscopes and endoscopic tools on the market enables the miniprobe endomicroscopy (with the Cellvizio) to be performed during an endoscopy procedure in order to improve its diagnostic reliability, for example.

It is therefore possible to estimate the endomicroscopy market in number of procedures, by considering for example the indications for which the greatest number of validation works has been carried out.

### **Barrett's esophagus**

In the United States, it is estimated that 1.6% of the adult population has at least one symptom of Barrett's esophagus<sup>4</sup>, i.e. 3.6 million people.

The ability to monitor these patients endoscopically is directly linked to the detection of precancerous zones and their potential treatment. The very positive results of these treatments (see paper in New England Journal of Medicine on BarrX technology) confirm the benefits of this screening and lead one to think that increasing numbers of patients will be included in Barrett's esophagus monitoring programs, which consist in carrying out an upper GI endoscopy at least once a year. A hypothesis of 15% of patients suffering from **Barrett's** esophagus joining a screening program during the years to come is not unreasonable. This could represent a potential of about 500,000 upper endoscopy procedures per year for the Cellvizio, the value of which in monitoring Barrett's esophagus has been demonstrated by numerous large clinical trials.

### **Indeterminate biliary strictures**

Concerning the biliary tracts, an estimated 500,000 ERCP procedures are carried out per year in the United States with an estimated 10% of these on patients with a stricture for which endomicroscopy may be prescribed, giving 50,000 procedures per year.

### **Monitoring colorectal mucosectomy**

The number of colonoscopies carried out per year in the United States is growing constantly and is currently around 14.2 million<sup>5</sup> 60% of colonoscopies are carried out in hospitals rather than "ambulatory surgical centers" which represent 40% of colonoscopies<sup>6</sup>. One or more polyps are found in 40% of colonoscopies and 90% of these polyps are benign. Considering only the use of the Cellvizio to detect recurrent cancers (Source: *multicenter trial accepted for publication*), the market potential is therefore around 340,000 procedures (60%x40%x10%x14.2) which would benefit from the Cellvizio.

### **Pancreatic cysts**

3 to 10% of the American population has one pancreatic cyst, representing several million patients<sup>7</sup>. Today, an estimated 120,000 new cysts are identified each year<sup>8</sup>. With a conservative estimate of 40% of patients with these cysts receiving an endoscopic diagnostic procedure justifying use of the Cellvizio (because some cysts can be characterized as benign or malignant on the basis of endoscopic ultrasound imaging), we reach a figure of 50,000 procedures per year for which the Cellvizio could be indicated to diagnose a pancreatic cyst.

Market potential can therefore be estimated at one million procedures for the Cellvizio in the United States, based on indications which have already been clinically validated.

By taking a standard ratio of 40% for the U.S. market, the world potential in terms of procedures would therefore be of the order of 2.5 million procedures per year worldwide, for the indications evaluated above alone. The total market potential including procedures currently being validated could be significantly greater.

## **Biomedical Research and Biomolecular Imaging Markets**

Biomedical research is the primary market for the Cellvizio, with a specific product - the Cellvizio LAB - intended for endomicroscopy in small animals. The Cellvizio LAB is the premier instrument for non-invasive observation at the cellular level in laboratory animals. It is particularly adapted for

<sup>4</sup> Source: *Gastroenterology* - Dec 2005 - Ronkainen et al

<sup>5</sup> Source: *Gastroenterology*, Dec 2004, Seef LC et al 127(6): 1670-7

<sup>6</sup> Source: <http://advancingsurgicalcare.com/index.cfm/news/ambulatory-surgery-center-industry-applauds-new-measure-improving-patient-access-to-colorectal-cancer-screenings/>

<sup>7</sup> <http://www.ncbi.nlm.nih.gov/pubmed/24091499>

<sup>8</sup> <http://gi.org/guideline/diagnosis-and-management-of-neoplastic-pancreatic-cysts/> and <http://www.cdc.gov/nchs/fastats/hospital.htm>

observing changes in their vascular architecture or cellular morphology, and interactions between proteins or specific molecules with biological components. Alternatives to the Cellvizio LAB are instruments that cannot provide microscopic imaging, or that can offer it but in a completely invasive manner, i.e. post *mortem* or *ex vivo*. Thanks to the Cellvizio LAB, longitudinal studies, so crucial for biological research, can be conducted on laboratory animals. The Cellvizio LAB is perfectly suited for the *in vivo* imaging trend in small animals that appeared at the end of the 1990s. To date, the Cellvizio LAB is still the only instrument capable of providing this type of information *in vivo in situ* in a minimally invasive way for oncology, neuroscience or stem cell researchers. Other microscopy instruments (called intravital microscopy or rigid endomicroscopy) cannot access internal organs without a considerable, and often terminal, procedure.

More than 100 articles in major scientific journals have been published by Cellvizio LAB users since 2005, attesting to its benefit for this booming market segment.

There are nearly 20,000 research laboratories around the world and numerous research centers associated with large pharmaceutical companies. The *in vivo* small animal imaging (preclinical imaging) market has resisted consolidation in the pharmaceutical and biotechnology worlds, and the limitations in government budgets for life sciences. This market was estimated at 530 million dollars in 2012 worldwide, and should grow to 1,005 million dollars in 2017 (Source: *Markets & Markets Preclinical In Vivo Imaging Market*).

This niche market is particularly interesting in that it is attached to the clinical market and can notably be used as a research platform for future surgical indications and future products. Additionally, “translational” research, which is research that goes “from bench to bedside”, thus adding value to basic research in human health, is a national priority in the U.S. and in all developed countries. It is in fact well known that the biggest advances in human health are made through translational research. The Cellvizio LAB is one of the only purely translational instruments, as it exists in versions that are adapted for both research and clinical work. Many highly visible articles – e.g., Hsiung et al., *Nature Medicine* 2008 – have demonstrated the utility of the Cellvizio in such translational research. The research laboratory market is quite fragmented, with primarily public sources of funding, with the exception of pharmaceutical companies and private research foundations. Mauna Kea Technologies has undertaken actions directly linked to the market, which have led to significant growth in the results of this division and help anticipate the maturation of this market.

### 6.3.3. Competition

#### Optiscan / Pentax

The Australian company Optiscan has developed a technical solution for endomicroscopy which is not based on the same technological choices as the Cellvizio, and has licensed their system to the Pentax group (since purchased by Hoya).

Owing to a lack of adequate performance (image cadence too slow, diameter too large and rigidity too great), the clinical and commercial development of this system has not met Optiscan's expectations; the company has not been able to finance it themselves and in fact suffered heavy losses (accumulated losses of 47.5 million Australian dollars, i.e. nearly 44.6 million American dollars) (Source: *Optiscan Annual Report 2013*). Today, Optiscan has fewer than five employees and no longer has an agreement with Pentax (since July 2009), which stopped marketing the product based on Optiscan technology.

In small animal imaging, Optiscan markets a system called FIVE 1, which is a rigid endomicroscope 6 mm in diameter (Source: *Optiscan*). This system does not enable the non-invasive exploration of small animals, and also suffers from the same image rate limitations.

In rigid endoscopy, Optiscan is pursuing a partnership with the Zeiss company, probably in the area of neurosurgery. The details of this development are not yet known.

#### Olympus

Olympus, Japanese global leader in flexible endoscopy with 71% of market share (Source: *Endoscopy Devices Market to 2016, GBI Research, December 2010*), does not have a commercial solution for endomicroscopy, in any form whatsoever. A prototype called "endocytoscope" was shown at several symposia and conferences with very preliminary and mixed clinical results (Source: *American Gastroenterology Association* [http://www.asge.org/uploadedFiles/Publications\\_and\\_Products/Practice\\_Guidelines/endocytocopy.pdf](http://www.asge.org/uploadedFiles/Publications_and_Products/Practice_Guidelines/endocytocopy.pdf). Citation: "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 only be used in a single center in the world (in Japan), requires the use of several stains (ibid.) and does not appear to be adapted to any routine clinical practices. Moreover, the few rare publications about this experimental device note major difficulties for physicians in managing image interpretation to make it reproducible (ibid.).

#### Fujifilm

Fujifilm is one of the main actors in flexible endoscopy, under the Fujinon trademark. Fujifilm offers advanced imaging systems on its high-end flexible endoscopes under the name FICE (Fuji Intelligent Color Enhancement). This is a system of electronic filters that enhance some of the colors in the image. Developed to help characterize tissues, this system has shown itself to be inferior to Cellvizio in an independent study performed 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*)

Furthermore, the Company concluded a distribution partnership with Fujifilm at the end of 2012 for the Chinese market.

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

#### SpectraScience

The American company SpectraScience has developed a system for spectroscopic interrogation of colorectal polyps called Wavstat. This device does not produce images but rather analyzes the light backscattered by the tissues that make up the polyps and uses a proprietary algorithm to provide biochemical data. Today, this device is distributed by Pentax in some regions.

**Oncoscope**

The American company Oncoscope has developed a tissue interrogation system called SCOB-E intended to detect precancerous lesions in the esophagus. This system does not provide any images, but instead a mathematical analysis of tissues. It has only been tested clinically on 34 patients and has not yet been awarded FDA approval or CE marking for marketing (Source: *Oncoscope Document*).

**Nine Point Medical**

Nine Point Medical, a company based in Cambridge, Massachusetts, signed a licensing agreement in December 2010 for Massachusetts General Hospital patents concerning *in vivo* optical tomography technologies. The company, now provided with major financial resources (\$33 million in a first round of financing, then \$34 million in a second round in 2014) (Source: <http://www.octnews.org/articles/2369751/ninepoint-medical-completes-33-million-series-a-fi/>), is still in its research and development phase. Several clinical trials are currently in progress. It has obtained an FDA 510k approval for its first device, mainly dedicated to esophageal endoscopy.

**LLTech**

The French company LLTech markets microscopic tomography technologies developed by researchers at ESPCI (industrial chemistry and physics college). Today, the company is focusing on the research and histopathology markets (Source: *LLTech*). It also communicates regularly on upstream technical developments relating to rigid endomicroscopy.

**Caliber ID (formerly Lucid Inc.)**

The American company Caliber ID has developed a system of *in vivo* microscopy for exclusive use in dermatology. No endoscopic application appears to be planned at this time.

**6.3.4. The platform's growth relays**

Although the Group began selling in the gastroenterology, then pulmonology sectors, in 2013, it obtained marketing agreements for a range of miniproboscopes dedicated to urological applications. Indeed, Mauna Kea Technologies intends to extend its commercial offer to other endoscopic and surgical fields. In fact, microscopic vision is key for many cancers as well as many other diseases, and the Cellvizio could provide a minimally invasive instant response to many diagnostic problems. The Group is already positioned to rapidly implement this development plan.

**Interventional pulmonology Market**

Lung cancer is still the leading cancer in men, although its incidence has stabilized (Source: *American Cancer Society 2008 - stats*). The incidence in women continues to increase slightly. Lung cancer is the most common cause of death in the western world for both women and men. The prognosis for lung cancer depends on several factors, one of the most important being the stage of development when the cancer is diagnosed. Patients who present with peripheral lesions less than three centimeters in diameter (T1) are the best candidates for surgical resection and have the best chance of survival, with a five-year survival rate of 60% to 80%. Fewer than 1% of patients suffering from an advanced stage of cancer are still alive five years after diagnosis. (Source: *World Health Organization*)

Once the patient exhibits symptoms, the disease is generally quite advanced at the time it is diagnosed and the vital prognosis is quite critical. Most often, however, a peripheral nodule (a small mass, either benign or malignant) is found in the lungs during a routine exam, like a CT scan. The problem is characterizing such a nodule in order to direct therapy in the most appropriate way. With the improvement in wide field imaging techniques such as scans, and the introduction of lung cancer screening programs, the number of nodules identified during these imaging examinations is multiplied, as is the need for characterization. American scientific societies have recently recommended screening for these pulmonary nodules, because it has been shown that screening improves the prognosis for patients while reducing the cost of treatment (Source: *Powell et al., Ann Surg. September 2004; 240(3): 481-489, and CHEST / 142 / 2 / 385-393 August 2012*)

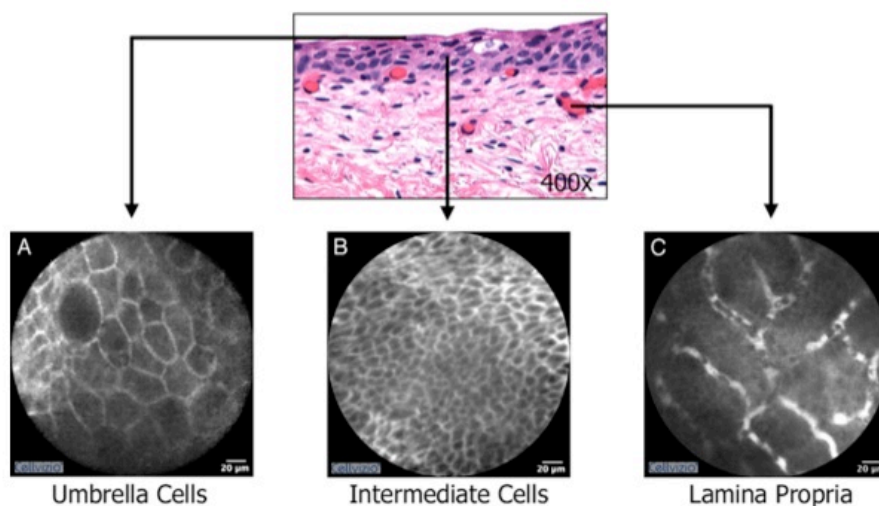
Several techniques can be used to characterize a pulmonary mass. The most effective, when possible, consists in physically sampling a piece of tissue from the nodule, either via a biopsy through a bronchoscope, sometimes equipped with an electromagnetic navigation device in the pulmonary tract, or by taking a transpleural biopsy with external access. In both cases, the procedure is risky and complex for the patient, because it is very invasive and the current diagnostic yield of these procedures is low because of sampling errors. The Cellvizio could be used to guide the procedure to take biopsies including the right diagnostic information, thereby improving the result of the procedure and giving the patient faster access to treatment, where necessary. The Lung Registry study, currently in progress in several American (centers (<https://clinicaltrials.gov/ct2/show/NCT01793246?term=lung+registry&rank=23>) is precisely concerned with demonstrating this proposed added value provided by the Cellvizio.



*Insertion of an Alveoflex confocal miniprobe into a bronchoscope*

The bronchoscopy market is very similar to that of digestive endoscopy relative to medical equipment: all healthcare facilities that have an endoscopy unit have at least one bronchoscopy room that could be outfitted with the Cellvizio. This represents more than 60,000 hospitals and clinics in Europe, the United States and Asia. The number of bronchoscopy procedures was estimated at approximately 500,000 per year in the U.S. in 1996, and continues to grow. This volume, although less than that of digestive endoscopy, is reflected in a potential of several hundred thousand Cellvizio procedures in the pulmonology field, and associated renewal with several tens of thousands of confocal miniprobes per year. Source: *Centers for Disease Control and Prevention, [www.cdc.gov](http://www.cdc.gov)*

### Endo-Urology Market



*Example of Cellvizio images of the bladder and correlated to standard histology.*

Endo-urology is an area of urology that consists of examining the urinary tract endoscopically to look for obstructions or cancers, and when necessary performing endoscopic treatment procedures. The most common exploration performed in endo-urology is cystoscopy, an examination of the

bladder. There were approximately 71,000 new cases of bladder cancer in the U.S. in 2010, and 15,000 deaths from this disease. One in 27 men will develop this disease in his life, as will one in 85 women. Nearly 90% of patients with this cancer are over the age of 55. (Source: *American Cancer Society*, [www.cancer.org](http://www.cancer.org)).

The management of bladder cancer requires several cystoscopy procedures. The first one is usually performed in the physician's office with a flexible cystoscope to find evidence of a lesion. The second procedure, performed in the operating room with a rigid cystoscope, is to obtain biopsies of the lesion. When possible, the third will be to perform an endoscopic resection of the tumor, although this is not always possible as too many cancers are diagnosed at an advanced stage. One-quarter of patients present with a cancer that has invaded the muscle and/or metastatic barrier, while over 20% of patients have a cancer that is less advanced but already high grade. The bladder cancer recurrence rate is quite high, between 50% and 90%, which requires continual life-long surveillance for patients who survive this disease. This surveillance is conducted via repeated cystoscopy procedures at regular intervals. These multiple diagnostic and follow-up endoscopic procedures make the management of bladder cancer the most costly of all cancers, representing approximately \$3.7 billion in the U.S. 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 to be 37,000 per year, and the number of therapeutic cystoscopy procedures is estimated to be 52,000 per year. On this basis we can estimate that there are approximately 470,000 diagnostic cystoscopy and 670,000 therapeutic cystoscopy procedures in Europe every year.
- in the United States (Source: *NHSR, Number 11, 2009, "Number of ambulatory surgery procedures, US, 2006*) there are 750,000 diagnostic cystoscopy procedures and around one million therapeutic cystoscopy procedures each year.

As for bronchoscopy, all healthcare facilities that have an endoscopy unit have at least one cystoscopy room that could be outfitted with the Cellvizio.

The Cellvizio can be used during diagnostic and therapeutic cystoscopy procedures, as shown by several studies by Prof. Liao of the VA Hospital, 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 in progress to confirm this American data with European results, which will help support the diffusion of Cellvizio in urology in territories covered by CE marking, obtained for the range of miniprbes in endourology in 2013. Using the Cellvizio in endourology seems to provide a critical benefit in optimizing the transurethral resection procedure for precancerous and cancerous lesions, in identifying further lesions not identified during the primary diagnostic examination (flexible cystoscopy), as well as post-resection follow-up, which could eventually lead to a reduction in recurrences.

The volume of procedures represented by endourological applications is significant. Finally urology is a specialty at the frontier between endoscopy and surgery, so urological indications may provide Mauna Kea Technologies with an entry onto the surgical applications market, which is a major challenge for the company.

### **The surgical market**

Very open to innovation and naturally including endoscopy-related devices as part of the treatment for certain types of cancer (digestive, pulmonary and urological), surgeons are naturally interested in the Cellvizio, seeing it as a tool which can help them refine their procedures, for better preservation of function in resected organs, while ensuring complete eradication of cancerous cells.

In 2010, Mauna Kea Technologies and its PERSEE project partners (a collaborative project supported by the OSEO/ICI program; see Section 6.6.1.2) began developing a robotic-assisted, minimally-invasive endomicroscopic exploration solution for the abdominal cavity to improve the management of cancer patients, with the goal of reducing the number of unneeded and/or incomplete surgeries (up to 25% of pancreatectomies, for example). The prototype resulting from this project will shortly be tested during a clinical feasibility study on patients, and will then naturally take up position on the market of medical devices for surgery.

Moreover, Mauna Kea Technologies is devoting ever more time and effort to developing endomicroscopy systems for surgical specialties, through:

- identification of this development as a central company project;
- the recruitment of dedicated resources;
- the integration of operating theater restrictions in designing its next generation Cellvizio systems;
- launching clinical trials specifically concerning surgical applications, whether at the Group's initiative or directly by surgeons who have used the Cellvizio.

These clinical trials are currently in progress or being set up in the fields of laparoscopic abdominal surgery, neurosurgery, robotized surgery for urological and gynecological cancers, and colorectal surgery.

## 6.4. Company strategy

### 6.4.1. Marketing strategy

#### The economic model

The Company's economic model is based on the sale of equipment (or systems), consumables (called miniprobes) which can be used a limited number of times, and services.

The latest generation of Cellvizio currently sold in most countries, to hospitals and clinics, is the Cellvizio 100\*. The Group has developed a range of miniprobes suitable for the Cellvizio 100. There is a miniprobe for each of the medical indications for which Cellvizio is marketed.

In 2014, earnings through sales of equipment represented 65% of the sales total, with consumables representing 27% and services 8%. In the medium-term, the percentage of sales of consumables is likely to progress as the installed base increases.

The average sale price of the systems was €82K in 2014 and €94K in 2013. The average sale price of the probes was €3.3K in 2014 and €3.8K in 2013.

In units, the group sold 88 systems in 2014 against 73 in 2013, and 896 probes in 2014 against 688 in 2013.

The gross margin recorded for equipment and probes fell slightly. It can vary strongly from one region to another. Overall, for all regions and equipment, it was 67% in 2014, against 70% in 2013 and 69% in 2012.

In 2014, the Group adjusted its sale price in the United States relative to its global price policy, thereby reducing its average sale price and gross margin.

At the time this reference document was drafted, the Group has an installed base of more than 450 units, mainly resulting from the sale of equipment and, to an accessory extent, from making equipment available (fewer than ten items of equipment).

Annual maintenance contracts or warranty extensions, software upgrades and offers of training are also proposed, generating a recurrent share in earnings which should gradually increase as the installed base increases.

### **Dual commercial organization**

For sales to hospitals and clinics, the Group has applied a dual commercial strategy, with the deployment of a direct sales force in the United States, France and Germany, linked to a distribution network for all other countries in which it has obtained marketing authorization.

For sales to research laboratories, the group recruited a sales team based in Paris, consisting in four people who use a network of distributors in a certain number of countries and provide direct marketing in others.

#### ***A direct approach in the United States, France and Germany***

In these three countries, where the direct approach had priority, the group recruited a sales force of two teams with different skills and responsibilities. The first team comprises equipment sales representatives (Area Sales Manager - ASM) and the second team of consumables sales representatives (Clinical Account Manager - CAM), particularly in charge of procedures and thus acceptance of the Cellvizio and training hospital personnel as well as correct use of the equipment and probes during procedures.

Each sale of equipment includes clinical training in how to use the Cellvizio, notably interpretation of the images obtained. The training covers all stages of use from plugging the equipment in to disinfecting the probe after the procedure.

The hospital medical teams responsible for the procedures receive long-term support to ensure that the Cellvizio is used under the best conditions. For this reason, during the first months of use, CAMs regularly meet hospital management for planning intervention, to work together to identify the patients whose pathologies are particularly suitable for the Cellvizio. The CAMs are also present in the endoscopy rooms during the procedure, to train the medical teams. This commercial presence in the field is the determining factor in encouraging professionals to endorse this new tool, so that they include it in their clinical routine.

Concerning the commercial organization, in the EMEA zone at the end of 2014, the team comprised 5 people: three "Systems" sales managers and two "Probe" sales managers.

At the end of December 2014, the US team comprised 18 people. The team is composed of eight regional "Systems" sales managers and seven "Probes" sales managers. These sales teams are led by three Sales Directors.

Finally, in Asia, the Asian General Manager leads the Group's activity in the region. For development in Asia he is assisted by a consultant in Japan and a country manager in China.

Overall, at the end of 2014, the Group had a sales force of 26 people.

#### ***An exclusive distributor network for the other countries***

The "export" sales strategy (excluding France, United States and Germany) for the Group is based on a distribution network, used to ensure a presence in many areas. The Group has particularly chosen to be very actively present in the main countries of the European Union, Middle East and Asia, as well as in Russia and Latin America. The distributors have been selected according to the following criteria:

- comprehensive knowledge and mastery of the sector;
- a "product" synergy, helping to accelerate the sales process;
- a proven ability to get across sometimes complex sales pitches quickly; and
- an ability to maintain a field presence, indispensable to promoting technology effectively.

For two years, this network has filled out and now includes almost 50 distributors, who have exclusivity in their commercial area. This network is under the responsibility of Export Managers, based at the head office in Paris, or in Asia.

These Export Managers intervene for operational support for local sales forces deployed by the distributors, helping them in their training and setting both strategic and operational objectives. They travel through their zones weekly and ensure that objectives are met. In China and Japan, the Group has set up local support for distributors.

To date, the Group is present mainly in the following geographic zones:

- Europe (United Kingdom, Spain, Italy, Belgium, the Netherlands, Scandinavia, etc.);
- Middle East (United Arab Emirates, Saudi Arabia, Turkey, Israel, etc.);
- Russia;
- Asia (Japan, China, India, Malaysia, Singapore, Thailand, etc.), where the Group is present with a sales office based in Singapore. This office provides support for local distributors;
- Latin America (Brazil).

As well as providing support for distributors, the Export Managers provide good "visibility" for the group and its products in each zone:

- participating in professional conventions and "industrial" and "commercial" shows;
- organizing workshops intended to train prospects and clients;
- implementing in situ demonstrations at "target" medical centers;
- training distributors regularly on the technical aspects of the product as well as on the continually evolving purely clinical aspect of the system's applications; and
- defining and approving communications that must be both coherent and homogenous, but also adapted to the cultural specificities and commercial expectations of the various markets.

These actions are indispensable in an awareness-building phase, and in winning markets.

In this respect, note that most of the Group's distribution contracts include minimum annual sales objectives, which, if not respected, leave the group free to renegotiate the contract and exclusivity accorded.

Some local actors sometimes move in very early to accompany the Group in its procedures to obtain regulatory marketing authorization whenever a specific procedure is necessary in the countries. This was the case in Brazil (marketing agreement obtained in 2012) and China (agreement obtained in December 2012).

## Section 6 - OVERVIEW OF ACTIVITIES

The current list of the Group's commercial partners is given here:

Country	Name of distributor
Algeria	SARL Medicalex
Saudi Arabia	Stars Horizon Medical Services Co.
Australia and New Zealand	Medical Technologies Australia P/L
Austria	Reinhard Di Lena GmbH
Bangladesh	Medimen Healthcare Ltd/Biogene Pharma Ltd.
Belgium, Luxembourg	Neo Medical Systems
Belarus	Tradintek
Brazil	Labor-Med Aparelhagem de Precisão Ltda
Bulgaria	Trimed Medical Bulgaria
Chile	Zepeda
China, Hong Kong, Macao	Fujifilm Medical Systems (Shanghai) Co. Ltd.
Colombia	Hospimedics S.A.
South Korea	BR Holdings
Croatia, Slovenia, Serbia, Bosnia	Civog AG
Denmark, Sweden, Finland	Kebomed A.S.
Egypt	Scope Medical Co.
United Arab Emirates	Smart Medical Supplies
Ecuador	Bio-Electronica Blanco S.A.
Greece and Cyprus	Endoscopiki S.A.
India	InVive Healthcare Pvt. Ltd
Indonesia	PT Global Jaya Medika
Iran	Mavarae Fonoon Asr Group
Ireland	SRA Medical
Israel	MDHWT
Italy	AB Medica
Japan	AMCO Inc.
Kuwait	Tareq Company
Lebanon	Allied Medical Group
Libya	Alshamesse Almoshreka
Malaysia	Chemopharm Sdn Bhd
Mexico	Medical Scope
Norway	DIDR. Mehn-Andersen
Pakistan	Allmed Solutions
Baltic Countries	Oliver Medical
Peru	Tecnasa
Poland	Trimed Sp. z.o.o.
Portugal	Alves & Ca (Irmãos), Lda
Qatar	Al Danah Medical Company
Czech Republic and Slovakia	Imedex sro
Romania	Temco
Russia	JSC Intermedservice
Singapore	Somnotec(s) Pte. Ltd.
Thailand	Science Engineer International Co. Ltd

Tunisia	Biocare
Turkey	Penta Elektronik Medikal Sistemler San.Tic.As.
UK	Elemental Healthcare Ltd.
Uruguay	Labimed
Yemen	Yemen Equipment & Supply Ltd

#### ***A specific indirect approach for the research laboratory market***

The market for small animal imaging systems dedicated to research having reached a new stage of maturity, in 2011 Mauna Kea Technologies decided to reorient its strategy and modify its distribution channels. Therefore, a new distribution network has been developed for a certain number of countries and direct commercial action instigated in others. This new approach has led to significant results and better anticipation of future needs on this market.

### **6.4.2. Marketing strategy and actions**

#### **The marketing department**

With ten employees, including two based in the United States and one in Asia, the marketing department drafts and ensures implementation of the Group's marketing strategy.

The marketing department is based on three central themes:

- event communication and digital marketing;
- marketing applications and Medical Education;
- Product management.

#### ***Event communication and digital marketing***

The event communication / digital marketing team has a strategic goal of increasing the visibility of the Group's product and trademarks. More specifically, communication is in charge of circulating marketing messages drawn up by the clinical and product teams, and implementing them in the form of marketing and communication media. It organizes events for prospects and customers and participation in international conferences. Its competence also extends to the digital communication platform (particularly websites) and public relations.

Media are divided into five categories:

- websites;
- printed material;
- events including ICCU, the conference for Cellvizio users;
- public relations and institutional communication;
- local communication actions for hospitals and clinics.

#### ***Marketing applications and Medical Education***

The marketing applications / medical education department is in charge of marketing specific to Cellvizio indications, mainly in digestive endoscopy but also in the other fields being studied.

This department acts as a relay between the marketing department's other functions and the sales forces, direct or indirect, deployed in the field. In particular, marketing applications and medical education teams are in charge of ongoing training for their sales force, deployment of new products or new offers, local communications campaigns and taking part in local events.

### **Product management**

New product development or improvement projects are mainly initiated by product leaders in the marketing department, who act as pilots for these projects. This arm is in charge of listening to the market and clients in order firstly to select the most promising projects in terms of market and return on investment and secondly to draft the corresponding functional specifications, then take care of monitoring technical development efforts.

Once the products have been developed, the product management team is in charge of their global launch and providing the relevant sales support.

#### **6.4.3. The brakes in sales acceleration**

The Group's sales plan has generally been slower than was envisaged at the time of its IPO in July 2011.

The brakes slowing down fast sales development are described in this paragraph.

- 1) The lack of social security reimbursement in Europe and Asia

The lack of social security reimbursement in Europe and Asia and the lack of automatic cover by American private insurers are certainly responsible for this slowing of diffusion of the Cellvizio. This is because it is harder to persuade a hospital or clinic to purchase technology when the procedures are not reimbursed, in France of course, but also in the rest of Europe and the United States.

- 2) The lack of official recommendation by a learned society

The incorporation of endomicroscopy into an official recommendation from a European or American learned society would be a powerful commercial lever.

- 3) Reorganization of the sales team in the United States in 2013

At the beginning of 2013, the Group's American subsidiary lost a major part of its sales force. The poor growth during the second half of 2013 and probably the first quarter of 2014 was partly due to the necessary stage of rebuilding the team and time needed to train the sales representatives.

- 4) The impact of Obama Care (Accountable Care Act and Affordable Care Act)

The in-depth reform of the American health system orchestrated by Obama Care had a double negative consequence for the medical equipment market in the United States.

On the one hand, healthcare establishments have been forced to invest massively in Computer Management Systems (IT) to modernize their information systems and this has meant using part of their investment budget for medical equipment on their IT infrastructure instead.

On the other hand, this led to serious disturbances in their medical equipment purchase practices and their methods of evaluating this equipment. The introduction of new practices, new decision circuits and new models for Return on Investment led to a prolongation in sale cycles.

- 5) Acceptance curve: the slowness of gastroenterology in accepting new technologies.

Finally, and this may be the biggest brake of all, gastroenterologists, who normally form our leading market segment in the hospital market, have been slower to accept the Cellvizio than the company had envisaged. This slowness is characterized by a certain rigidity in issuing new, clear and powerful recommendations, and a strong need for support in their practices by reference clinical publications which justify their procedures.

#### **6.4.4. Clinical affairs**

The team's main mission is to define and implement the Company's clinical plan. More particularly, clinical resources are dedicated to setting up and carrying out clinical trial campaigns on existing products or new products, on clinical training operations (developing programs and educational materials, clinical training for sales teams) as well as developing medical economic evidence based on using the Cellvizio, a decisive element in applications for Optical Biopsy cover by health authorities (public and private insurers).

#### 6.4.5. Innovation strategy

##### A High Capacity For Innovation

- **Technological expertise oriented towards excellence and feasibility**

The origin of any innovative medical device, i.e. the starting point for the innovation process, is a clinical need and ideas to meet that need. Mauna Kea Technologies' strength has always been to consider that the most effective solution for designing new equipment is to start from a blank slate and to rethink the concept entirely before modeling it. In this spirit, a multidisciplinary team (see below) was created in order to integrate, far upstream, all the constraints linked to the solutions' industrialization and not to developing a prototype that is certainly on the cutting edge of technology but cannot find an economic model.

Building on this approach, in late 2003, the first Cellvizio came to be after a team of experts was able, in the context of an iterative process, to meet challenges as varied as:

- the design of a "plug and play" high-resolution confocal microscope, i.e. requiring no adjustment at its installation or during use;
- extreme miniaturization of the miniproboscopes;
- optimized image processing to make up for the physical limits of the optical components;
- the ability to be integrated into standard equipment;
- the definition of a design of each component able to make future manufacture as easy as possible.

The quality of the study carried out upstream of the Cellvizio's design today enables Mauna Kea Technologies to have a technical platform adaptable for multiple applications with a marginal additional research and development investment.

In 2008, the industrial direction of innovation at Mauna Kea was strengthened by uniting the Research and Development, Production and Supply teams into one Operations department. This simple and structured organization came together with the implementation of a "lean" approach, started at the production level and quickly spreading to product development.

- **A High-Level Multidisciplinary Team**

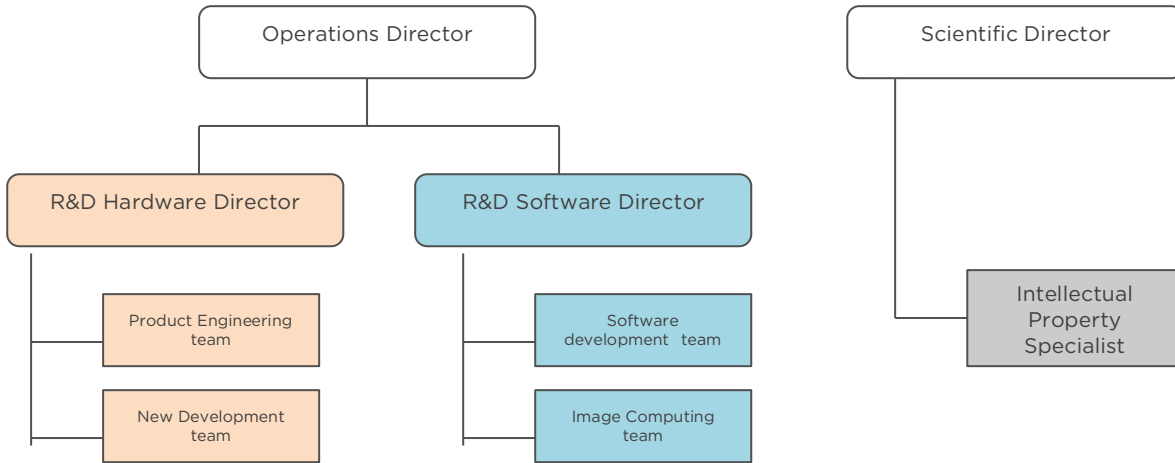
At the end of December 2014, the Research and Development team had 29 employees (doctors, engineers or technicians) covering the fields of expertise necessary for the development of the Group's products and technologies, namely:

- optics and optoelectronics;
- mathematics applied to image processing;
- digital and analog electronics;
- software development;
- micro-mechanical engineering, materials and processes for precision assembly.

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

- **A structured Research & Development Division**

The Research and Development Division consists of two departments under the responsibility of the Director of Operations Manager and Scientific Department, as in the diagram below.



Each R&D department is the interface in the Company for the management of any issue related to its expertise and it oversees the technical work throughout during the entire life cycle of the product, from initial design to production support.

- **Upstream R&D**

The Company is organized to develop the resources to directly inspire technological innovations that will enable it to expand in its market and win new markets by studying solutions likely to encourage the development of innovative new products in order to continue to improve the care given to patients.

Scientific and technological oversight occurs continuously under the Scientific Department to identify and verify the interest of emerging components or technologies. This oversight makes it possible to be at the forefront of technology as well as limit any risks associated with components that contribute to manufacturing by identifying technical alternatives upstream.

The upstream studies arising from this monitoring are conducted by R&D department teams, either internally or through external collaborative efforts.

They may constitute the preliminary phase of feasibility assessment that helps to decide whether to begin a product development project.

At the clinical level, the Company conducts efforts in collaboration with various hospitals to assess the potential interest and technical feasibility of using Cellvizio technology in new indications.

The upstream studies carried out in collaboration with academic laboratories are often co-funded to optimize the costs of research through grants or doctoral thesis scholarships. For example, the Company is currently engaged in the following collaborative efforts:

- a "Smart Atlas" project which is a completely innovative software tool that searches for similarities using content in images. This "Smart Atlas" would integrate an observation sequence history under Cellvizio and conduct an immediate comparison of reference images with images in an ongoing procedure. This study was the subject of a thesis started in 2008 in close collaboration and under the direction of Nicholas Ayache, head of the INRIA Asclepios laboratory in Sophia Antipolis. Since 2012, it has existed in the form of an i-Lab contract between INRIA and the Company, in which two INRIA engineers who are experts in image processing are involved, in addition to the Group's engineers;

- a partnership with the team headed by Professor Guang-Zhong Yang, Director of the Hamlyn Centre at the British university, Imperial College London, started in late 2013. The objective is to develop new imaging opportunities for improving optical biopsy procedures and make them completely intuitive for practitioners, regardless of their specialty. The Company and the Hamlyn Centre will combine their resources to develop innovative vision technologies by computer for the

Cellvizio platform and its EVA operating system. These efforts will help facilitate the use of optical biopsies during invasive endoscopic and surgical procedures.

- **R&D Applied To Improving Current Products And Optimizing Their Manufacture (Product Support)**

The mission of the Research and Development teams is to cause existing solutions to develop in a continual improvement approach, while listening to their internal and external clients, and more precisely with the missions:

- ensuring and improving product manufacturing as part of a "lean" approach. To this end, monthly meetings between each R&D department, the production team and the support team are organized;
- developing new functions or improving the performance of existing products. The improvements are implemented after analysis of the improvement needs expressed by clients and their technical feasibility by product marketing managers.

A particular effort is being made relative to the approval of new methods for disinfecting or sterilizing Confocal Miniprobes so that the system can be used in accordance with current hygiene regulations in the different countries in which it is marketed.

- **Product technical development**

In this mission, the Research and Development teams, and more broadly all members of the Operations department, work with the product leaders and clinical affairs managers to develop new products within the framework of company project management.

Among the major projects being developed, we can cite:

**The "PERSEE" project**

A real technological showcase for the group, this project was awarded 7.6 million euros in aid in April 2010 by OSEO over a period of four years. "PERSEE" is an industrial research and development project to develop a robotized, miniature, flexible endomicroscope, destined for minimally invasive exploration of the abdominal cavity. Its ambition is to provide cancer patients with the possibility of opting for the best therapeutic strategy, between surgery, chemotherapy or radiotherapy. The partners of the "PERSEE" project are therefore working on combining the Cellvizio with robotic resources, which will enable exploring the abdominal cavity through a simple incision, to search for information essential to decision-making by surgeons. The Company is the leader of this collaborative project along with EndoControl, a developer of robotic solutions to assist surgeons and physicians, the *Institut des Systèmes Intelligents et de Robotique* (ISIR) at the *Université Pierre et Marie Curie*, the digestive diseases department of the *Institut Mutualiste Montsouris* (IMM) and the departments of Cellular Imaging, Gastroenterology and Pathobiology of the *Institut de Cancérologie Gustave Roussy* (IGR).

In 2013, the consortium successfully completed a major step in the program, allowing it to benefit from the third installment of funds granted by OSEO.

In parallel with this project, the Company is working on the development of a complete offer in the surgical field.

Development of the new generation of Cellvizio Systems based on better user ergonomics and equipment miniaturization. For this purpose, the R&D teams are evaluating the incorporation of new technology stacks, such as for lighting or laser scanning, and have concluded partnerships with major European laboratories such as the Fraunhofer Institute in Germany.

### Effective project management

The product design, modification and development activities are formalized and monitored using rigorous procedures, while preserving the agility needed for development and innovation. These activities are managed through a key quality management system within the company.

In an extremely practical approach to project management, and depending on the nature of the project, in addition to the Research and Development, marketing and applications associates, representatives from production, the supply chain and the Regulatory Affairs teams come together far upstream in order to quickly work through technical feasibility or approval problems of the products developed.

A technological and scientific "roadmap" is established and monitored regularly to ensure overall project coherence and phasing. Project advancement is reviewed regularly at meetings during which the project manager reports to a reporting committee on the different project milestones and progress of the expected deliverables.

These projects often provide an opportunity for implementing collaborative processes with industrial concerns, laboratories or academic institutions in order to optimize resources and also to add additional fields of competence.

Similarly, product developments intended for new applications in the clinical field give rise to close collaborations with physicians and/or partner laboratories.

#### 6.4.6. Production strategy

##### Internalization of the high value-added stages

The Company externalizes part of its production line, only retaining the high added-value stages which include the Company's core expertise.

In this context, as well as identifying and selecting raw material suppliers (lasers, mobile mirrors, mechanical control components, electronic components, etc.), the Company has developed a network of subcontractors to fulfill certain stages in the manufacture of the laser scanning unit (pre-assembly of mechanical components for the unit's optical base, incorporation and wiring of electronic cards and power supplies). As for the production of Miniprobos, the Company decided to subcontract the manufacture of certain models of miniprobos or part of their assembly so as to optimize its capacity and production costs, while retaining internal control and expertise for high added-value operations.

Because of the quality of the design which was defined and validated during the product design stage, whether specially made parts (e.g. optical lenses) or shelf parts, manufacturing procedures are optimized. The result is a cost price largely composed of material costs.

##### Lean Manufacturing

As part of its quality assurance and continual improvement effort, the Company has also been working since 2008 on Lean Manufacturing projects, bringing together the R&D, quality, production and supply chain teams.

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

- cost reduction by eliminating waste;
- just-in-time production;
- quality.

Having these three elements function interdependently and optimally provides sustainable and efficient results, and enables the enterprise to be more competitive and to adapt to any market development.

This production organization enables the Group to maintain a high level of reactivity in view of the uncertainty concerning the speed of deployment of the equipment in order to meet customer requirements as quickly as possible.

The implementation of a "lean" procedure has also helped to more than double production capacity since 2008, with constant resources and to reduce the cycle time by a factor of three.

In 2010, the Company also decided to subcontract the optomechanical assembly of a first model of Confocal Miniprobes from a supplier who is an expert in optical fiber and precision optical assembly. Complete validation of this subcontracting was finalized early in 2013 so that the Group can now pass part of its Miniprobe production to this partner, thus ensuring a growth in productivity without further investment. In 2014, this procedure was extended to other stages in Miniprobe manufacture and will be continued in the years to come.

After all the work done in Lean Manufacturing to improve productivity, and considering the structure of the current production team and the subcontracts carried out, the Company can now guarantee production of Cellvizio systems and Miniprobes for the next two years, in accordance with its business plan and without significant investment.

## Quality Assurance

The Company has included quality in its management system since its creation in 2000 and the first ISO 9001 certification was obtained in 2002. It was extended to ISO 13485 for medical devices in 2005.

The production line is thus certified during certification renewal audits (every three years) or annual monitoring, certification covering activities linked to procurement, product manufacture and packaging.

In this context, all major changes in the production line (subcontracting, offshoring, etc.) must be reported to the third-party organization and may be audited to ensure continued certification.

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

## Selection and monitoring of suppliers and subcontractors

The Company identifies and selects suppliers with the industrial capacity necessary to support its commercial ambitions. The choice of partners meets product and regulatory constraints, production capacity meeting the Group's ambitions, and economic and profitability considerations.

Raw materials are the biggest part of production cost, the purchasing process being a key company process, split into several areas:

- Partners are selected jointly by the Research and Development division and the Purchasing department. Once the selection has been made, the R&D department works upstream with subcontractors to produce the first prototypes, and with suppliers to validate critical or sensitive components and assemblies (i.e. meeting critical technical specifications or having strong impact on product quality and safety). Once the partner has been validated, the service is contractualized by the Purchasing department on the basis of the specifications validated during production engineering. Critical suppliers and subcontractors must therefore report any changes to their own production line (raw materials, manufacturing methods and processes, offshoring or subcontracting, etc.) and submit them to the Company for approval;
- Suppliers and subcontractors are monitored and evaluated by the Purchasing department, based on multiple criteria covering, for example, respect of deadlines, delivery noncompliance, organization, financial declarations, etc.;
- Supplier audits are carried out by the Company, based on an annual schedule drawn up by the Purchasing and Quality Assurance teams. Thus, the 2015 schedule includes at least nine supplier audits, of which six are overseas.

## Selection of main partner sub-contractors

Of the Company's current industrial partners, the optical fiber supplier Fujikura is particularly important in so far as the Cellvizio has been completely designed (imaging system, image processing) on the basis of this component. Based in Japan, this company, a reference global actor in the manufacture of optical fibers (Source: *Fujikura, 2013 annual report*), has, nevertheless, entered into a real long-term partnership with the Company and became a shareholder in 2006.

An initial collaborative project to improve performance and reduce the cost of optical fibers took place over three years in close partnership with Fujikura industrial teams and the Company's Research and Development teams. This project has led to the cost price of optical fibers being halved and still has the potential to lower it further when volumes are big enough.

At the same time, the Company wants to externalize all or part of the assembly stages of some of these models of Confocal Miniprobes to Fujikura, to benefit from this supplier's industrial expertise.

The imaging system uses a high-speed optical scanning system coupled to an optical system designed by the Group's R&D division. Cambridge Technology Inc., world leader in industrial optics (Source: *Cambridge Technology Inc. website, "About" section, <http://www.camtech.com/about/index.html>*) and inventor of the optical scanner with galvanometric

motor, is the supplier of the system chosen for Cellvizio. The Company is evaluating alternatives to this technology as part of its Research and Development projects.

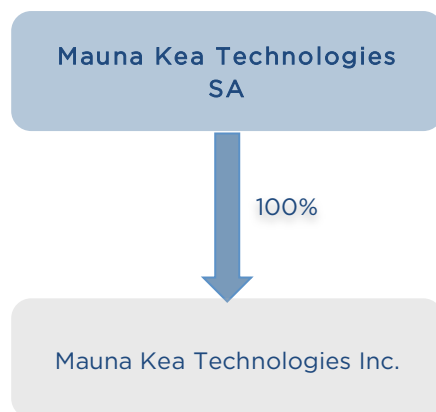
A new type of camera, used for fast, high-sensitivity optimized detection has been designed in partnership with the world leader Hamamatsu (Source: *2013 Annual Report on the Group's website: <http://sales.hamamatsu.com>*) which develops innovative electronic systems for all industrial markets.

Finally, concerning the logistics department, the Company has called for all types of service providers according to local constraints (country). Manufacturing times are taken into account in order to minimize inventories, while ensuring a level of delivery time to clients comparable with market standards.

## SECTION 7 ORGANIZATIONAL CHART

### 7.1. Legal entity organizational chart

As of the registration date of this Registration Document, the legal entity organizational chart of the Mauna Kea Technologies Group is as follows:



### 7.2. Group companies

**Mauna Kea Technologies SA:** Based in Paris, Mauna Kea Technologies S.A. is the Group's parent company.

**Mauna Kea Technologies, Inc.:** Based in Suwanee in Georgia, United States, Mauna Kea Technologies Inc. was founded in 2005. This entity markets the Group's products on U.S. territory and provides an interface with the regulatory authorities (FDA). As of December 31, 2014, it had 28 employees and posted sales of \$3,516K (i.e. €2,646K with a conversion rate of 1.3288) and a net loss of \$7,738K (i.e. -€5,823K with a conversion rate of 1.3288).

### 7.3. Principal intra-group flows

There are primarily three kinds of intra-group flows.

a) **Commercial flows:** As all the equipment sold throughout the world is manufactured in France, the Company signed an exclusive distribution agreement with its U.S. subsidiary granting the latter territorial exclusivity for the distribution of Group products (equipment and consumables) in the United States and Canada.

b) **Charging of services:** A service agreement was entered into on January 1, 2010 between the Company and its U.S. subsidiary for an initial term of five years, thereafter renewable annually. Therein it is provided that the Company contributes its assistance to Mauna Kea Technologies Inc. in five areas:

- ✓ Management of the subsidiary;

## Section 7 - ORGANIZATIONAL CHART

- ✓ Accounting and financial assistance (drawing up budgets and their follow-up, implementing control tools, advising on relations with banks, tax assistance, etc.);
- ✓ Commercial assistance (defining strategic plans, marketing plans, organizing commercial events, sales administration, assistance in terms of product regulation management, etc.);
- ✓ Technical assistance (sales support, maintenance and improvement in quality control);
- ✓ Assistance in terms of human resource management (recruiting key associates, training, employment regulations, dedicated IT tools, HR policy, etc.).

The agreement provides that the inherent costs of the assistance services actually provided will be invoiced by the Company to its subsidiary at real cost, plus a 3% margin. The cost of services that the subsidiary could, as the case may be, have provided to the Company in these same areas will be deducted from the amounts owed.

For the 2014 financial year, the Company invoiced its subsidiary for the amount of €397K.

c) **Financial flows:** A Group cash flow agreement was entered into on October 11, 2005. Advances made by either of the two entities of the Group are remunerated on the basis of the legal interest rate in France.

For the 2014 financial year, the Company invoiced its subsidiary for interest totaling €9.8K.

## SECTION 8 PROPERTY, PLANT AND EQUIPEMENT

### 8.1. Property and equipment

#### 8.1.1. Leased property

The following are the only premises used by the Group:

**Registered office in Paris:** Located at 9 rue d'Enghien in Paris (75010), France, the head office of the Company is set up on five floors of the property with a total surface area of about 1,133 sq.m. (including the basement). The Company became the lessee of the premises as and when it expanded and has five separate leases contracted with SCI Enghien 9, which is the owner thereof and which has no capital link with any of the managers and/or shareholders of the Company. The various commercial leases entered into by the Company within the property are summarized as follows:

Location	Surface Area	Start Date	Term	Expiry of the lease	Initial rent provided for in lease
1st floor	115 sq.m.	June 1, 2005	9 years	N/A	21,915
1st floor + underground parking	223 sq.m.	Oct. 1, 2000	9 years	N/A	42,495
2nd floor (left-hand side)	115 sq.m.	Jan. 1, 2005	9 years	N/A	21,915
2nd floor (right-hand side)	223 sq.m.	Feb. 1, 2004	9 years	N/A	42,495
3rd floor + basement	157 sq.m. + 60 sq.m. in the basement	Nov. 1, 2008	9 years	Oct. 31, 2017	40,820
4th floor	140 sq.m.	Nov. 1, 2009	9 years	Oct. 31, 2018	32,240
5th floor	100 sq.m. + 20 sq.m. of terrace	Nov. 15, 2013	9 years	Nov. 15, 2022	30,000

By applying the price adjustment conditions provided for in the leases, the Company recorded a rental expense (excluding rental charges) of €328K for the year ended December 31, 2014.

**Premises in the United States:** Formerly based in Newton, followed by San José, Mauna Kea Technologies Inc. currently has offices at 1325 Satellite Boulevard Unit 108, Suwanee in Georgia. The lease was originally signed on January 15, 2013 and was subsequently renewed until February 28, 2017. The rental charges recorded in the United States for the 2014 financial year total \$32K.

#### 8.1.2. Other tangible assets

The principal tangible assets held by the Company are described in Note 4 to the 2014 consolidated financial statements, appearing in Section 20.1 of this Registration Document.

### 8.2. Environmental issue

The nature of the Group's activity does not give rise to significant environmental risks at the registration date of this Registration Document.

## SECTION 9 EXAMINATION OF EARNINGS AND FINANCIAL POSITION

The reader is invited to read the following information on the Group's financial position and earnings with the Group's consolidated financial reports prepared in accordance with IFRS for the year ended December 31, 2014, and to refer to the notes to the 2014 consolidated financial statements contained in Section 20 of this Registration Document. The 2012 and 2013 financial statements can be viewed on the Group's website: [www.maunakeatech.com](http://www.maunakeatech.com).

### 9.1. Overview

#### 9.1.1. Consolidated financial statements

In accordance with European Regulation No. 1606/2002 of July 19, 2002, the 2014 consolidated financial statements of Mauna Kea Technologies, approved by the Board of Directors on April 13, 2015, were prepared in accordance with IFRS as adopted by the European Union.

#### 9.1.2. Operations of the Group

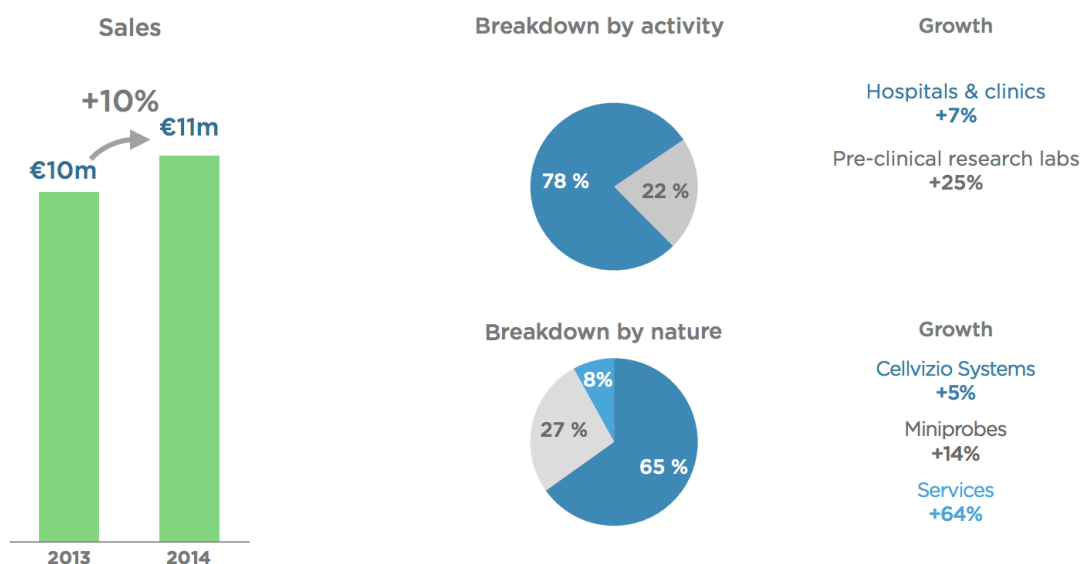
The reader is invited to read the description of the Group's activity, presented in Section 6 "Overview of activities" of this Registration Document.

#### 9.1.3. Pro-forma financial reports

None.

### 9.2. Results analysis

#### 9.2.1. Sales and other operating income



## Section 9 - EXAMINATION OF EARNINGS AND FINANCIAL POSITION

Consolidated data audited in €K	2014	2013	Change
Total sales of "equipment"	7,175	6,835	5%
Total sales of "consumables" (probes)	2,958	2,603	14%
Total sales of "services"	882	538	64%
<b>Total sales</b>	<b>11,016</b>	<b>9,977</b>	<b>10%</b>

*By business: continuation of the solid momentum in the Preclinical segment with the success of Cellvizio Dual Band*

Mauna Kea Technologies revenues for the year were up 10% to €11,016K, versus €9,977K for 2013. Clinical and Preclinical sales rose 7% to €8,591K and 25% to €2,425K, respectively, from €8,036K and €1,941K. Sales to hospitals and clinics represented 78% of activity for the year (vs. 81% in 2013).

*By product and by type: sales of consumables were up 30%, as uptake by gastroenterologists continued.*

The breakdown of revenues by product and type shows a 5% increase in system sales during the year to €7,175K, versus €6,835K in the previous year, and growth in consumable sales of +14% to €2,958K, compared with €2,603K in 2013.

In volume terms, the Company recorded sales in 2014 of 88 systems and 896 probes (versus 73 and 688 respectively in 2013), representing growth in sales of equipment and consumables of +21% and +30% respectively.

The significant growth in the number of miniprobes sold reflects the equivalent growth of clinical procedures performed with Cellvizio.

At December 31, 2014, Mauna Kea Technologies had an installed base of 444 Cellvizio systems. The net installed base of Cellvizio rose to 315 clinical systems and 129 pre-clinical systems, including 23 Cellvizio Dual Band.

The sale of related services also increased by 64% to €882K, against €538K in 2013, as a result of efforts to develop this recurring revenue stream.

*By geographical area: further strong growth in the Asia-Pacific region*

Analysis of the geographical distribution of sales once again confirms the positive momentum in Asia-Pacific, with sales growth for the area up +52% to €3,806K, compared with €2,502K in 2013. The EMEA area reported +8% growth to €3,197K, from €2,973K previously. The Americas were the only area to record a decline for the year, with sales down -11% to €4,012K (€4,502K in the previous year). The Company has struggled to find the right business dynamic in the United States. Throughout 2014, revenues in the Americas represented 36% of total sales, compared with 29% and 35% for the EMEA and APAC areas. The geographical distribution of the 444 Cellvizio systems worldwide is as follows: 144 in North America (134 in the United States), 191 in the EMEA area, 94 in the APAC area, and 15 in Latin America.

Other revenues come mainly from the non-capitalized portion of the research tax credit, for €1,178K.

### 9.2.2. Operating Expenses

Consolidated data audited in €K	2014	2013	Change
Cost of sales	(3,675)	(3,042)	21%
Gross margin	67%	70%	
Research & Development	(4,583)	(3,611)	27%
Sales & Marketing	(12,753)	(11,174)	14%
Administrative expenses	(3,837)	(3,759)	2%
Share-based payments	(1,257)	(851)	48%
<b>Total operating expenses</b>	<b>(26,106)</b>	<b>(22,437)</b>	<b>16%</b>

#### Research and development expenses

In 2014, for the systems segment, the Research and Development team continued its work on the Cellvizio Software 2.2 project. This led to the marketing of the EVA (Endomicroscopy Virtual Assistant) concept to facilitate the use of Cellvizio. Work also continued on the new generation of Cellvizio Dual Band for preclinical environments, subsequently brought to market, and on the PERSEE Surgery project.

For the work on probes, the team focused its research efforts on new models, especially in the surgical field.

In 2014, Research and Development expenses rose to €4,583K, versus €3,611K for 2013.

In 2014, the annual portion of capitalized development expenses fell to €207K. R&D expenses were mainly attributed to research. In 2013, the annual portion of capitalized development expenses was €713K. Overall, all R&D expenses (both expensed and capitalized) were up 11%. This increase is partially offset by the increase in the research tax credit, recognized in income, which is up from €984K to €1,251K. If the research tax credit is included in the calculation, R&D costs appear stable compared with 2013.

#### Marketing and sales expenses

Marketing and sales expenses are currently the largest overhead. These rose from €11,174K in 2013 to €12,753K in 2014, an increase of 14%. This is essentially due to efforts made in 2013 to expand the U.S. sales force, which was back at full strength in 2014.

This item remains the largest overhead for the Company, representing 49% of all operating expenses in 2014.

In marketing, the Group finished 2014 with a team of 23 people. This covers Operational Marketing (France, Europe, USA and Asia), Systems and Probes product development, as well as Clinical Affairs and Marketing Communication.

Sales are made directly in France, Germany and the United States, and through distributors in the rest of Europe and in Asia.

The EMEA sales team had five members at the end of 2014: three “Systems” sales managers and two “Probes” sales managers.

In the United States, at the end of December 2014, the team comprised 18 people. The team is composed of eight regional “Systems” sales managers and seven “Probes” sales managers. These sales teams are led by three Sales Managers.

Finally, in Asia, the Asian General Manager leads the Group’s activity in the region. He is assisted with development in Asia by a consultant in Japan and a country manager in China.

In total, at the end of 2014, the Group had a sales force of 26 people.

#### Administrative expenses

Administrative expenses basically consist of payroll costs, operating costs relating to the registered office in Paris, and external expenses such as audit, attorney and consultant fees.

Administrative costs were relatively stable compared with 2013. They rose from €3,759K in 2013 to €3,837K in 2014, a slight increase of 2%.

### **9.2.3. Composition of net income**

Operating expenses were up 16% to €26,106K for the year, versus €22,437K in 2013. The main contributing factor was the increase in sales and marketing expenses.

As a result of this increase and the moderate 10% rise in sales, the operating result for 2014 was -€13,823K, against -€11,521K in 2013.

After taking into account a financial result of -€168K at December 31, 2014, versus €5K at December 31, 2013, the Company posted a loss of -€13,991K, compared with -€11,516K for the year ended December 31, 2013.

### **9.2.4. Corporation tax**

In view of the losses recorded in the last three financial years, the Group has not recorded any income tax expense'.

The deferred tax assets are posted to the accounts only to the extent that it is likely that the future profits will be sufficient to absorb the losses that can be carried forward. Considering its stage of development, the Company does not post assets net of deferred taxes to the accounts.

### **9.2.5. Results per share**

The loss per issued share (weighted average number of outstanding shares during the year) came respectively to €1.01 and €0.84 per share for the financial years ended December 31, 2014 and 2013.

### 9.3. Balance sheet analysis

#### 9.3.1. Non-current assets

Consolidated data audited in €K	2014	2013	Change
Intangible assets	3,542	3,713	-5%
Tangible fixed assets	794	519	53%
Non-current financial assets	105	77	36%
<b>Non-current Assets</b>	<b>4,440</b>	<b>4,309</b>	<b>3%</b>

Non-current assets amounted to €4,440K at December 31, 2014 and are relatively stable compared with €4,309K at December 31, 2013.

Non-current assets consist of tangible and intangible assets and non-current financial investments.

The stability of this item is primarily due to a fall in intangible assets as a result of reduced capitalization of development expenses, and secondly to an increase in property, plant and equipment resulting from reclassifications from inventory to assets of demonstration or replacement equipment or equipment on loan to the Group's customers.

Non-current financial assets include only the security deposits paid under operating leases.

The breakdown of non-current assets can be found in Notes 3 to 5 to the consolidated financial statements presented in Section 20.1 "Consolidated financial statements prepared according to IFRS for the financial year ended December 31, 2014" of this Registration Document.

#### 9.3.2. Current assets

Consolidated data audited in €K	2014	2013	Change
Inventories & Work in progress	1,912	2,263	-16%
Trade receivables	3,874	3,114	24%
Other current assets	2,165	1,859	16%
Current financial assets	128	207	-38%
Cash and cash equivalents	15,018	27,792	-46%
<b>Current Assets</b>	<b>23,098</b>	<b>35,235</b>	<b>-34%</b>

Current assets amounted to €23,098K at December 31, 2014, versus €35,235K at December 31, 2013.

Negative net cash flows relating to operating activities are financed with the Group's cash. This translated as a reduction in outstanding liabilities' in cash and conventional financial instruments, which stood at €15.0 million at December 31, 2014, versus €27.8 million at December 31, 2013.

Cash and outstanding liabilities in cash represented 65% of current assets at December 31, 2014.

Benefiting from the Community SME regime, the short-term portion of the research tax credit was only impacted by changes in research and development expenses eligible for the tax credit during the financial years studied. The research tax credit receivable at December 31, 2014 amounted to €1,251K, versus €984K at December 31, 2013. (See Note 7.2 to the consolidated financial statements presented in Section 20.1 "Consolidated financial statements prepared according to IFRS for the financial year ended December 31, 2014" of this Registration Document).

### 9.3.3. Shareholders' equity

Consolidated data audited in €K	2014	2013	Change
Issued capital	560	552	1%
Share premium	58,162	57,501	1%
Reserves	(26,604)	(16,253)	64%
Foreign currency translation on reserve	23	(124)	-118%
Profit / (loss)	(13,991)	(11,516)	21%
<b>Total of equity</b>	<b>18,150</b>	<b>30,159</b>	<b>-40%</b>

The net changes in the Group's shareholders' equity are due to the annual deficits recorded in 2013 and 2014.

The deficits recorded during the two financial years studied show the efforts that the Group devoted in particular to Research and Development programs as well as to the completion of clinical studies and marketing actions. They also take into account the IFRS 2 expense relating to the granting of founders' warrants (BSPCEs), share warrants (BSAs) and stock options to employees, corporate officers or partners of the Group. This expense was offset by a positive variance in shareholders' equity in an equivalent amount.

### 9.3.4. Non-current liabilities

Consolidated data audited in €K	2014	2013	Change
Non-current Liabilities			
Long-term loans and borrowings	2,606	2,643	-1%
Non-current provisions	518	465	11%
<b>Total of non-current liabilities</b>	<b>3,124</b>	<b>3,108</b>	<b>1%</b>

Long-term loans and borrowings mainly include amounts relating to repayable BPI (formerly OSEO) and COFACE grants at December 31, 2014.

At December 31, 2014, the Company had received three BPI advances and one COFACE advance which is currently being repaid.

Reference should be made to Note 11 to the consolidated financial statements presented in Section 20 of this Registration Document.

### 9.3.5. Current liabilities

Consolidated data audited in €K	2014	2013	Change
Short-term borrowings and financial debt	638	659	-3%
Trade payables	2,238	2,439	-8%
Other current liabilities	3,388	3,178	7%
<b>Total of current liabilities</b>	<b>6,264</b>	<b>6,276</b>	<b>0%</b>

This balance sheet item groups together short-term debt to third parties, short-term financial debt as well as debts to employees and social security bodies.

This item also includes short-term financial debt made up of the OSEO and COFACE advances repayable at one year's maturity and the subsidy portion of the PERSEE project.

## SECTION 10 CASH AND CAPITAL

### 10.1. Information on the Group's capital, liquid assets and sources of financing

See also Notes 9, 10 and 11 to the consolidated financial statements prepared in accordance with IFRS, appearing in Section 20.1 of this Registration Document. At April 30, 2015, the Company's total cash and cash equivalents came to €9.3 million, plus €4.7 million received on May 12, 2015 from the capital increase through private placement, versus €27.8 million at December 31, 2013.

Cash and equivalents include cash on hand and common financial instruments held by the Company (essentially money market funds as well as fixed deposits). This cash on hand and these marketable securities serve to finance the Company's activities, especially its research and development expenses and its marketing and sales expenses.

Since its creation in 2000, the Company has financed itself by the issue of new shares (shares called "O ordinary shares" and shares called "class P preferred shares"), as well as by significant conditional advances granted by OSEO and the COFACE. Since its IPO in July 2011, the Company is funded primarily by €51.6 million in funds raised (after deducting operating costs) and new advances received under the PERSEE project.

On March 11, 2015, the Company secured an equity financing facility with Société Générale, in accordance with the 20th resolution of the Annual General Meeting of June 11, 2014.

As part of this financing facility and subject to certain terms and conditions (subscription floor price and minimum average daily volumes), Société Générale committed to subscribe 1,390,000 new shares (representing 9.9% of the current share capital) by January 11, 2016, at least half of which by July 11, 2015, at the times and at the pace it shall deem appropriate.

For each tranche, the issue price will be discounted by 5% based on the volume weighted average price of the three preceding trading sessions. At the date of this Registration Document, 210,000 share warrants have been subscribed, for an amount of €1,024,100. The Company bought back and canceled 1,180,000 share warrants issued for Société Générale for a total amount of €118 and unsubscribed as at May 31, 2015.

On May 7, 2015, the Company carried out a capital increase through a private placement, leading to the issuance of 1,189,251 new shares, i.e. 8.49% of outstanding shares, and raising a gross amount of €4.7 million.

**10.1.1. Capital financing**

The Company received a total of €32.2 million (before deduction of capital increase-related expenses) through capital increases completed between 2000 and 2010 and €56.5 million at the time of its IPO in July 2011. The following table summarizes the principal capital increases, in value, between the Company's creation date and December 31, 2014:

Period	Gross Amounts raised (in €M)	Transactions
2000 - 2001	1.7	Seed capital
2003 - 2006	7.2	1st round of financing
2007 - 2008	22.5	2nd round of financing
2000 - 2010	0.8	Exercise of securities giving access to the capital (BSA, BSPCE)
2011	56.5	IPO in July
2011 - 2014	2.4	Exercise of securities giving access to the capital (BSA, BSPCE, stock options)
<b>Total</b>	<b>91.1</b>	

**10.1.2. Financing by repayable advances**

The Company has taken out no loans during the three financial years presented.

**10.1.3. Financing by repayable advances**

The Company received three conditional advances that were the subject of an agreement with OSEO as well as an advance from the COFACE.

The repayable advances are described in Note 11 to the consolidated financial statements presented in Section 20.1 of this Registration Document.

**10.1.4. Financing by the research tax credit**

The Company benefits from the provisions of Articles 244 quater B and 49 septies F of the French Tax Code relating to the research tax credit. The latter is recognized as other income. (refer to Notes 1, 7.2 and 18 to the consolidated financial statements presented in Section 20.1 of this Registration Document).

**10.1.5. Off-balance-sheet commitments**

The Company's off-balance-sheet commitments are described in Note 21 to the financial statements in accordance with IFRS as of December 31, 2014 appearing in Section 20.1 of this Registration Document.

## 10.2. Cash flows variation

### Simplified consolidated cash-flow statements

Consolidated data audited in €K

	As at December 31	
	2014	2013
Net cash flows from operating activities	(12,731)	(9,612)
Of which self-financing capacity	(11,751)	(10,016)
Of which change in WCR related to business activities	(980)	405
Net cash flows from investing activities	(567)	(1,146)
Net cash flows from financing activities	483	923
<b>Cash flows variations</b>	<b>(12,774)</b>	<b>(9,846)</b>

#### 10.2.1. Cash flows from operating activities

Cash consumption relating to operating activities for the financial years ended December 31, 2014 and 2013 came to €12,731K and €9,612K respectively.

The difference is due to an increased negative self-financing capacity linked to the higher loss for the financial year, and to the WCR increase generated primarily by higher trade receivables.

#### 10.2.2. Cash flows relating to investment activities

The Company's production operations do not require great investment in tangible assets, insofar as the Company sub-contracts some manufacturing. However, the last manufacturing operations: assembly, inspection and validation are conducted internally.

These investments in tangible assets, in particular prototypes, demonstration apparatus and office equipment, came to €208K and €253K respectively for the financial years ended December 31, 2013 and 2014.

On the other hand, the Company activated intangible assets in the course of the 2013 and 2014 financial years, mainly development expenses and its patents. In this respect, the Company invested €973K and €403K respectively for the 2013 and 2014 financial years. This fall is the result of the reduced activation of development costs. In 2014, research and development expenses primarily concerned research without an activation option under IAS 38.

#### 10.2.3. Cash flows from financing activities

The Company carried out a capital increase of €56.5 million in 2011 (see 10.1.1). It also obtained three repayable OSEO grants as well as a conditional COFACE grant during the period studied (see 10.1.2).

The Company recorded a cash flow relating to financing activities of €483K and €923K for the 2014 and 2013 financial years.

In 2014, cash flow relating to financing activities of €483K came mainly from the exercise of BSPCE and Stock Options for €668K, reduced by the repayment of the COFACE advance for €203K.

In 2013, cash flow relating to financing activities of €923K came mainly from the exercise of BPCE and Stock Options for €706K, reduced by the repayment of the COFACE advance for €324K. In addition, the Company also received a repayable BPI advance of €535K.

### **10.3. Information on the repayable advance conditions and financing structure**

See Notes 11.1 and 11.2 to the financial statements prepared in accordance with IFRS, appearing in Section 20.1 of this Registration Document.

### **10.4. Restriction on the use of capital**

None.

### **10.5. Sources of financing required in the future**

The Company's cash and cash equivalents stood at €9.3 million as at April 30, 2015, versus €27.8 million on December 31, 2013.

The Group expects that the cash available at April 30, 2015, plus the equity financing facility secured from Société Générale in March 2015 (see Note 10.1) and the capital increase of May 7, 2015 - which raised €4.7 million - will ensure operational continuity.

Furthermore, given that the Company is listed on a regulated market, it may, depending on the strategy, issue new shares.

The Company considers different sources of financing and expects another capital increase through the exercise of stock options (Paceo) in the second half of 2015.

## SECTION 11

# INNOVATION, PATENTS, LICENSES, TRADEMARKS AND DOMAIN NAMES

Research and development costs are recognized in accordance with the IAS 38 standard. These costs are described in Note 1.4 to the 2014 consolidated financial statements presented in Section 20.1 of this Registration Document.

### 11.1. Innovation policy

The Company positions itself intrinsically as an innovative company in the field of medical devices. Its products and their applications reflect this positioning.

These products aim to contribute to the medical and research fields either new solutions, offering to improve a service rendered, such as minimally-invasive real-time diagnostic imaging, for example, or a new approach, paving the way for new medical or scientific practices, such as *in situ in vivo* optical biopsies of tissues inaccessible for histopathological examination.

In terms of the Group itself, its innovative nature demonstrates both its ability to develop such products, but also to place itself within a corporate approach likely to favor a new insight into problems relating to its activities. This ability appears transversally in the management, communication, product development, research and development, client relations, production, quality control and regulatory affairs, human resource management and administration.

The Group's innovation policy is made up of all the steps taken by the Group to ensure an approach that guides recruitment, personnel training, internal and external communication, working methods and coordination.

This policy favors the emergence and collection of ideas, in particular through the implementation of group working sessions, such as Strategy Days, clinical meetings (MED), LAB meetings and Patent Brainstorming, for example, supported by continual cross-disciplinary (medical, scientific and technological) monitoring. The multidisciplinary nature of the representation of the Group's skills in these activities is an essential key to their success.

The R&D policy, the functioning of the teams concerned, as well as the R&D projects and fields on which the Company focuses, and the collaboration agreements entered into with third parties in the context of these projects, are described in Section 6.4.4. "The innovation strategy".

### 11.2. Patents and patent applications

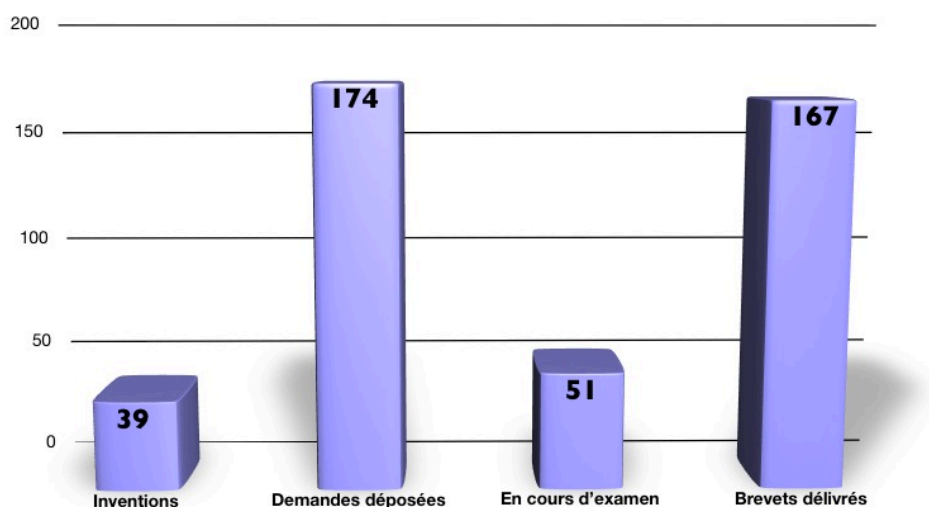
#### 11.2.1. Intellectual property protection policy

The Group's commercial success depends largely on its ability to protect its products, in particular by obtaining patents and maintaining them in force in France and the rest of the world. That is why the Group has implemented and maintains a continuous patent filing policy at an average rate of 2.7 new patents filed every year.

At the start of April, 39 inventions have thus been protected by filing patents, grouped into 31 separate patent families. To date, the 39 inventions have generated 174 national applications, which led to the granting of 167 patents.

To date the Company believes that its technology has not been used or copied illegally, in part or entirely, by third parties or competitors and is not aware of third parties challenging its intellectual property or its rights to use its IP as it has been doing.

### Situation Globale du Portefeuille de Brevets



#### 11.2.2. Nature and coverage of patents

These patents or patent applications accompany and reflect the Group's research and development work by their nature and the pace of the filings. Of course, they do not only concern the products currently marketed by the Company, but also cover complementary technologies that could form an integral part of its future products, in the clinical or research fields.

Among these families of patents or patent applications, seven of them result from partnerships or collaboration with academic partners such as the CNRS (French National Center for Scientific Research), the Paris Observatory, the Université de Rouen, the Université de Limoges and the Université Pierre & Marie Curie, and are jointly held with these institutions.

The Company is also the exclusive licensee of two patents relating, for the first (INSERM-APHP patent, or Endoscope, in the following table), to an endoscopic method specific to the Cellvizio, and for the second (patent of Université Denis Diderot - Paris 7 - or P7 in the same table) to in vivo high-resolution tomographic solutions for the human retina, not yet used. In both cases, the Company has filed (and obtained) in agreement with its co-contractors, several improvement patents for these technologies.

Generally, the coverage of the Company's patents or patent applications rather accurately reflects the main aspects of the architecture of the technical solutions developed by the Company, namely:

- the system strictly speaking (light excitation, detection, means of scanning, etc.);
- the endomicroscopic probes (optical probes + distal optics);
- the image processing algorithms.

The Company also filed and continues to file patent applications aimed at protecting certain applications related to its products, such as:

- alveolar imaging;
- biliary duct imaging;
- solid organ imaging; and
- deep intra-cerebral imaging of animals.

### 11.2.3. Territories protected

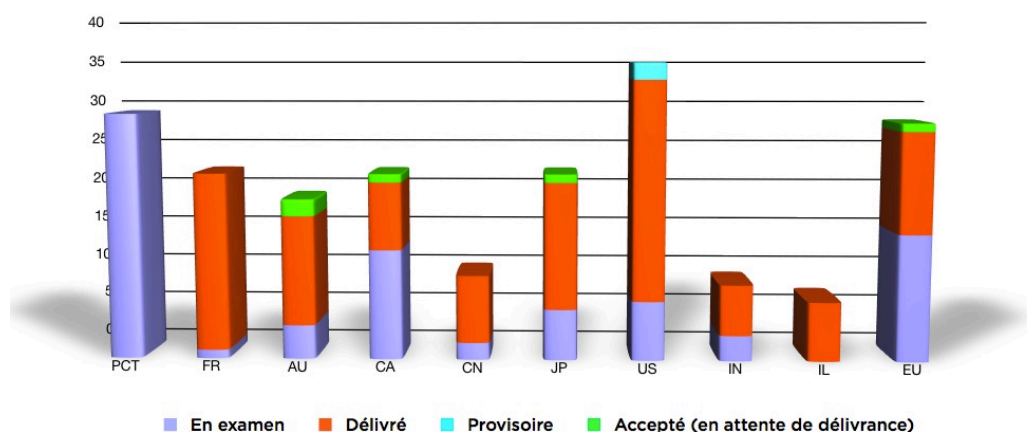
All the patent applications of the Company, with only rare exceptions, are systematically extended for application abroad, via the PCT procedure (29 entries to date). The minimum territories selected are still:

- United States
- Europe
- Japan
- Canada
- Australia

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

The following bar graph gives the distribution by number of the various patent applications / patents issued according to country and according to their status (pending / issued).

**Nombre et situation des brevets (par pays)**



#### 11.2.4. Dispute

The Company is not currently subject to any infringement proceedings brought by a third party. Likewise, to date the Company has not brought any such proceedings against a third party. However, the Company is doing its utmost to closely monitor the commercial activity of players in the field and the development of the patent landscape in order to fully ensure the freedom to use its products and guarantee that its rights are respected.

### 11.3. Collaboration, research, service and license agreements granted by or to the Company

Among the collaboration agreements currently in force, we cite the agreements relating to the PERSEE project, a collaborative project supported by OSEO in 2010 in the context of ISI (Industrial Strategic Innovation) projects.

PERSEE seeks to develop a robotic endoscopic solution, applied to the surgical treatment of digestive cancers. PERSEE has allied two industrial partners, Mauna Kea Technologies and Endocontrol, specializing in the development of robot-assisted surgical tools, an academic partner, the *Institut des Systèmes Intelligent et de Robotique* (ISIR) of the *Université Pierre et Marie Curie*, and two hospitals, the *Institut de Cancérologie Gustave Roussy* and the *Institut Mutualiste Montsouris*.

The Consortium thus formed aims to develop, industrialize and market a device able to improve diagnosis and preoperative staging techniques for cancer patients.

The project is financed by OSEO, from which each party receives financing corresponding to its part of the research program. Furthermore, each party must individually bear the additional financing necessary to perform its part of the program.

Each party is responsible for its part of the research program and, vis-à-vis third parties, for its errors and omissions as well as those of its employees. The agreement provides that the parties mutually waive seeking damages for any indirect losses that they could come to cause one another mutually. In addition, the parties cannot conduct R&D work on a project the end result of which is the development of products or technologies competing with those that are the subject of the PERSEE project.

The agreement provides that the results of the project specific to each party remain its property. However, the joint results are the joint property of the parties having contributed to obtaining such results and must be the subject of rules of joint ownership.

In terms of commercial use, the agreement provides that the Company enjoys, during the entire term of the agreement and for a period of six months following its expiry or termination, an irrevocable option to license a non-exclusive right of use to the preexisting elements and the results of the other parties necessary for the industrial and commercial use of the project's results in its field of operations.

The agreement is entered into for a term of 72 months from May 31, 2010. If a party wishes to withdraw from the project, for this it must obtain the consent of the steering committee and of OSEO, which may approve the proposal to withdraw, approve it under conditions, or refuse it. The agreement can also be terminated with respect to a party in the case of its failing to comply with its obligations, subject to the consent of OSEO. In this case, the defaulting party will lose all rights to the results arising from the performance of the agreement. Lastly, the agreement may be terminated in case the project's financing by OSEO is stopped, or by a unanimous decision of the parties.

### 11.3.1. License agreements granted by third parties

As indicated above, the Company also holds two exclusive operating licenses for the entire world for technologies intended for *in vivo* and *in situ* microscopy, in humans and animals.

The first was granted by the Université Denis Diderot (or Paris 7) on November 22, 2000. It concerns *in vivo* microscopic tomography techniques of the human (or animal) retina still relatively far from an industrial and commercial application, which the Company therefore does not use yet. As of the registration date of this Registration Document, the commercial and competitive consequences that the Company can expect from the future marketing of the products covered by the patents under license are difficult to quantify.

In the context of this license agreement, the Université Denis Diderot (Paris 7) granted the Company an exclusive operating license to some patents and patent applications, in all the countries covered by these patents, with the option to sub-license them.

Under this license, the Company undertook to pay, on top of an initial lump-sum fee, a proportional fee of 5% that will be calculated depending on the sale price of the products, which involves the payment of a “minimum” amount owed from the seventh year of the agreement.

This agreement is entered into for the term of validity of the last of the patents and may be terminated automatically in the case of full or partial transfer, court-ordered or voluntary liquidation, cessation of operations, or dissolution of the Company. Each party may furthermore terminate the agreement in case of non-performance of its obligations by the other party. The Université Denis Diderot (Paris 7) also has the option of terminating the agreement if the Company has not made any sales in a followed-up manner for a period of two consecutive years from the product's first release on the market.

The agreement provides for the option, for each party, to file patent applications on the improvements made to the licensed patents, subject to having communicated said improvements to the other party.

The license is granted with the sole guarantee of the material existence of the patents. In case of an action for infringement lodged against the Company at the time of the manufacture or operation of the products, no indemnification may be claimed from the Université Denis Diderot (Paris 7).

The second was granted by the INSERM-APHP on January 2, 2001. It concerns a fiber optic endomicroscopic technology complementary to the Cellvizio.

In the context of this license agreement, the INSERM-APHP granted the Company an exclusive, worldwide operating license to a technology protected in part by patents and know-how.

Under this license, the Company undertook to pay a fee calculated on the net sales of the products marketed by the Group. The calculation basis for this fee is 0.25% of the proceeds from the sale of these systems. The Company additionally undertook to contribute the financing necessary for the development work and to cover the costs of filing patents and maintaining them in force.

This agreement is entered into for a term valid until the later of the two following expiry dates: either the expiry date of the last patent, or expiry of a ten-year period from the product's release on the market if this product is not protected by a patent in the country where it is being marketed.

The Company believes that neither the ongoing negotiations of these agreements nor the loss of exclusivity on these licenses will have a significant negative impact on its business.

#### 11.4. Other elements of intellectual property

The Company holds the “Cellvizio<sup>®</sup>” trademark in numerous countries, in particular France, Europe, Australia, Japan, the United States of America, China, India, Israel and Canada.

It also holds in France the trademarks “MKT”, “Mauna Kea Technologies”, “Proflex” and “Confocal Miniprobe”.

The Company holds more than 70 domain names, including: “cellvizio.fr”, “diagnosingbarretts.com”, “maunakeatech.fr”, “cellvizio.com”, “maunakeatech.com”, etc.

## SECTION 12

### TRENDS

#### 12.1. Principal trends since the end of the last financial year

##### Q1 2015 Sales:

2015 first-quarter sales came to €1,855K, a decline of 14% compared to €2,164K in 2014. Strong growth in the pre-clinical business to €581K (+160%) did not offset a downturn in the clinical business to €1,274K (-34%). Revenue generated by sales to hospitals and clinics accounted for 69% of activity during the quarter (compared with 90% in Q1 2014).

An analysis of sales per product and per type highlights a decline in Systems sales to €1,222K and Consumables to €479K (-12% and -19% respectively). Services also declined to €154K (-20%).

By volume, the company recorded the sale of 12 systems and 134 probes (compared with 16 and 157 respectively) in Q1 2014, representing a decrease of 25% for systems and 15% for probes. The net installed Cellvizio clinical base increased by 12 systems during the 1st quarter of 2015 and the total installed base, including pre-clinical systems, has reached 456 systems at March 31, 2015.

Sales in the United States grew by 36% (12% in USD) in the first quarter this year. Overall, the Americas region showed a slight decline to €934K (-6%) compared to the same period in 2014 as the growth in the US was offset by a decline in South America. EMEA demonstrated sustained performance with a sales increasing of 16% to €699K.

The APAC region declined to €222K (-61%), in part due to a delay in obtaining the regulatory agreement in China for the Cellvizio 100s and to a high volume of sales in Q4 2014 in Japan.

At March 31, 2015, the Americas, EMEA and APAC regions respectively represent 50%, 38% and 12% of sales.

##### Positive results from the Focus clinical trial

In January 2015 the Company announced the publication of the final results of FOCUS, an international, multi-center, prospective clinical study evaluating the use of Cellvizio in diagnosing biliary cancer during an ERCP procedure (endoscopic retrograde cholangiopancreatography).

The results of the study are published in the peer-reviewed journal *Gastrointestinal Endoscopy* and are accompanied by an editorial emphasizing that the study "pushes back the frontiers of diagnosing indeterminate biliary strictures".

Study results support the use of endomicroscopy with Cellvizio for the evaluation of indeterminate biliary strictures.

##### Obtaining a CPT reimbursement code in the United States for a Cellvizio biliary application

In March 2015 the American Medical Association (AMA) Editorial Panel awarded a new CPT Code related to the use of endomicroscopy during endoscopic retrograde cholangiopancreatography (ERCP) procedures to enable physicians to diagnose health problems in the biliary tract including diagnosis of biliary strictures and the presence of biliary cancer. More than 500,000 ERCPs are completed annually in the United States.

**Establishment of a new line of equity financing**

On March 11, 2015 the Company established a line of equity financing with Société Générale based on the 20th resolution of the General Meeting of Shareholders on June 11, 2014.

At the share price on that date, the total use of this financing line would bring the Company additional financing of €7 million. As part of this financing line, and subject to compliance with certain conditions, Société Générale agreed to subscribe 1,390,000 new shares, representing 9.9% of the current capital stock, over the next ten months, at what times and in what fractions Société Générale may choose.

For each tranche, the issue price will bear a 5% discount off the average price, weighted by the volumes traded in the preceding three sessions. This discount allows Société Générale, which does not wish to remain a shareholder in the Company, to guarantee that it would subscribe the shares despite any possible volatility in the financial markets.

CE marking obtained for the use of the Cellvizio in interventional radiology

On June 9, 2015, the Company obtained the CE Marking for the use of the Cellvizio in interventional radiology indications. By reaching this regulatory milestone, the Cellvizio has become the go-to technology for major therapeutic procedures for which real-time, direct imaging guidance has now become a necessity.

Having obtained the CE Marking, the AQFlex 19 IR Cellvizio probe is inserted through a needle using a standard percutaneous technique to obtain microscopic images of the lesions in solid organs such as the liver, the kidneys or the lungs. Access to Cellvizio imaging during the procedure may provide a wide range of benefits to patients, such as real-time assessment of needle-placement before focal therapeutic interventions and evaluation of completeness of tumor ablation.

**12.2. Known trend, uncertainty, request for commitment, or event reasonably likely to influence Company outlook**

None.

## SECTION 13 PROFIT PROJECTIONS AND ESTIMATES

The Company does not intend to make any profit projections or estimates.

## SECTION 14

# ADMINISTRATIVE, EXECUTIVE AND OVERSIGHT BODIES AND GENERAL MANAGEMENT

### 14.1. Executives and directors

#### 14.1.1. Members of the Board of Directors

In accordance with the applicable legal provisions and bylaws, the Board of Directors is composed of at least three and at most 18 members, appointed by the Annual General Meeting for a three-year term and re-eligible for office at the end of their tenure. In the event of a vacancy, Board members may be co-opted under the conditions provided for by applicable law and regulations.

Under its internal rules of procedure, the Board of Directors is obliged to make every effort to have at least two independent directors in accordance with the MiddleNext Code. Board members are considered independent if they have no relationship with the Company, its group or its management likely to influence their judgment.

In Christopher McFadden, André-Michel Ballester, Jean-Luc Boulnois and Marie Meynadier, the Company has four independent directors as defined by the MiddleNext Code.

The recruitment of one or more other independent directors is envisaged by the Company in the context of the improvement of its corporate governance.

The independence of Board members is examined by the Board based on the following criteria stipulated by the MiddleNext Code:

- is not an employee or executive officer of the Company, or an employee or executive officer of one of its subsidiaries, and has not been in the last three years;
- is not a material client, supplier or banker of the Company or its group, or for a significant part of whose business the Company or its group accounts;
- is not the Company's reference shareholder;
- does not have close family ties with a corporate officer or reference shareholder of the Company; and
- has not been an auditor of the Company during the last three years.

Furthermore, at least one of the independent members must have special expertise in financial or accounting matters to be able to be appointed to the Audit Committee.

The following table indicates the members of the Board of Directors as appointed following the Annual General Meeting on June 11, 2014.

Section 14 - ADMINISTRATIVE, executive and oversight bodies  
and general management

As of December 31, 2014, the Company's Board of Directors had five members. No non-voting Board member was appointed by the last Annual General Meeting on June 11, 2014.

Name or company name	Role	Date of appointment	Expiration of term of office
Christopher McFadden	Chairman of the Board of Directors, independent director	OGM of 06/11/2014	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016
Alexandre Loiseau	Director and Chief Executive Officer	OGM of 05/25/2011, re-elected at the OGM of 06/11/2014	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016
André-Michel Ballester	Independent director	OGM of 05/25/2011, re-elected at the OGM of 06/11/2014	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016
Jean-Luc Boulnois	Independent director	OGM of 06/11/2014	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016
Marie Meynadier	Independent director	OGM of 06/11/2014	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016

The CEO uses the Company's registered office as his professional address.

The professional addresses of the other directors are as follows:

- Christopher McFadden is domiciled at Canyon Healthcare Partners, 4 Canyon Road, P.O. Box 864, Ross, California, United States;
- André-Michel Ballester is domiciled at Sorin Group, Via Benigno Crespi, 17, 20159 Milan, Italy;
- Jean-Luc Boulnois is domiciled at Microline Surgical Inc., 50 Dunham Road, Suite 1500, Beverly, MA 01915, United States;
- Marie Meynadier is domiciled at EOS Imaging, 10 rue Mercoeur, 75011, Paris, France.

The management expertise and experience of these persons come from the various employee and management positions that they previously held (see Section 14.1.3).

There are no ties of blood or marriage between the persons listed above.

Over the past five years, none of these persons has:

- been convicted of fraud;
- been associated in their capacity as executive or director with a bankruptcy, sequestration or liquidation;
- been prohibited from acting in a managerial capacity; or
- been subject to incriminations or official public sanctions pronounced by legal or regulatory authorities.

Section 14 - ADMINISTRATIVE, executive and oversight bodies  
and general management

**14.1.2. Other corporate positions**

Name and roles held within the Company	Main roles held in all companies	Other appointments held in all companies
Christopher McFadden - Chairman of the Board of Directors	N/A	- Montefiore Medical Center, Trustee - The Natural History Museum of the Adirondacks, Trustee
Alexandre Loiseau - Chief Executive Officer	N/A	- Mauna Kea Technologies Inc., Chief Executive Officer
André-Michel Ballester - independent director	CEO and member of the Board of Directors of Sorin Group	- CARMAT, independent director - PIXUM VISION, director
Jean-Luc Boulnois - independent director	Executive Chairman and CEO of Microline Surgical Inc.	- BIOSPACE Lab, Chairman - INTERACTIVE CONSULTING Inc., Chairman
Marie Meynadier - independent director	CEO of EOS Imaging	- STENTYS, director

### 14.1.3. Director biographies



**Christopher D. McFadden**  
Chairman of the board

Christopher McFadden is the founder of the Canyon Healthcare Partners, an investment fund. Between 2008 and 2013, he was a Managing Partner at Health Evolution Partners, an American healthcare-focused private equity fund. Between 1999 and 2008, he was Senior Financial Analyst at Goldman, Sachs & Co. in New York before heading healthcare-sector investment activities for Goldman Sachs' Americas Special Situations Group (AmSSG). Mr. McFadden is also a Trustee for Montefiore Medical Center in New York and the Natural History Museum of the Adirondacks.



**André-Michel Ballester**  
Member of the Board

André-Michel Ballester is, since 2007, the CEO of Sorin Group, the largest European cardiovascular company and the world leader in medical technologies for cardiac surgery, a company he joined in 2004 as Head of the Cardiac Rhythm Management unit. Prior to that Mr. Ballester held a number of senior positions, including Vice-President EMEA, Asia and Latin America at Edwards Lifesciences, a US manufacturer of products for treating cardiovascular diseases. For more than a decade, he also held several executive positions in Europe and the USA. Also a member of the Board of Directors of both Carmat and Pixium Vision, Mr. Ballester has a degree in Engineering from École Centrale in Lille and an MBA from INSEAD.



**Jean-Luc Boulnois**  
Member of the Board

Jean-Luc Boulnois is the Executive Chairman of the Board at Microline Surgical, an innovative minimally-invasive surgical instrument company with which he has been involved for 18 years as an investor and then, from 2005 to 2013 as CEO, heading a period of uninterrupted growth. He was also CEO of Sometec from 1995 to 1999 and CEO of Technomed International from 1989 to 1994, two medical technology companies. With French and American dual citizenship, Mr. Boulnois has been living in Boston for close to 30 years. He holds a PhD in Aerospace Engineering from Princeton University and an Executive MBA from HEC.

Section 14 - ADMINISTRATIVE, executive and oversight bodies  
and general management



**Alexandre Loiseau, Ph.D.**  
CEO & Member of the Board

Alexandre Loiseau founded Mauna Kea Technologies in May 2000 and has been the CEO ever since.

He piloted the development of the Cellvizio product line and brought together a world-class executive team to raise over €32 million with investors specialized in the health industry. In July 2011, he successfully led the company to an initial public offering on the NYSE Euronext Paris index and raised €56.5 million to fund a large-scale commercial development. Alexandre started his career at the National Center for Space Studies (CNES) in Toulouse and at the Paris Observatory, then joined NASA's Jet Propulsion Laboratory (JPL) in Pasadena, California, as a research scientist. Alexandre is a graduate of the École Polytechnique in Paris and has a Ph.D. in Astrophysics and Optical Instrumentation.



**Marie Meynadier**  
Member of the Board

Marie Meynadier is the CEO of EOS Imaging (Euronext: EOSI, FR0011191766). She began her career at the prestigious Bell Labs, and then steered the management of major development programs in France in the fields of electronics, optics and microelectronics, which led to the creation of several start-ups. Marie Meynadier is a graduate of Sup Telecom and has a PhD in Physics from École Normale Supérieure on rue d'Ulm, Paris.

## **14.2. Conflicts of interest within the administrative and management bodies and General Management**

The Chairman, Chief Executive Officer and certain directors, who comprise the management team, are shareholders, directly or indirectly, of the Company and/or holders of financial instruments granting access to the Company's share capital. See Section 17.2 for details.

As of the date of this Registration Document, there were no related party agreements.

To the knowledge of the Company, there exists no current or potential conflict of interest between the duties with regard to the Company and the private interests and/or other duties of persons comprising the administrative and executive bodies and general management, as described in Section 14.1 above.

## SECTION 15

### COMPENSATION AND BENEFITS

#### 15.1. Compensation of directors and executives

In accordance with the provisions of Article L. 225-102-1 of the French Commercial Code, we hereby report to you on the total compensation and benefits of any nature whatsoever paid during the financial year to each corporate officer, both by the Company and by companies controlled by the Company within the meaning of Article L. 233-16 of the French Commercial Code.

The Company applies all of the recommendations of the MiddleNext Code on executive and non-executive pay.

For 2014, the variable compensation targets for the Chief Executive Officer were set and approved by the Board of Directors on the recommendation of the Compensation Committee dated February 12, 2014. These objectives took into account, inter alia, the Company's sales growth.

At its meeting on February 9, 2015, the Board of Directors, on the proposal of the Compensation Committee meeting of the same date, examined the level of achievement of said targets and resolved to pay the Chief Executive Officer the variable compensation corresponding to those targets, which are contingent on the Company's performance.

As part of its executive and staff pay and incentives policy, the Company granted founders' warrants to Company employees and stock options to employees of its subsidiary on February 12, 2014 and September 1, 2014 respectively.

##### 15.1.1. Executive compensation

The following information was prepared by referring to the Code on Corporate Governance for small- and mid-caps, as published in December 2009 by MiddleNext.

Summary of compensation and options and shares granted to each executive officer		
(Chairman of the Board of Directors since June 11, 2014) Christopher McFadden	Year ended 12/31/2014 (in euros) (from 06/11/2014 to 12/31/2014)	Year ended 12/31/2013 (in euros)
Compensation due for the period	32,571	Not applicable
Valuation of options granted during the period	32,413	Not applicable
Valuation of performance shares granted during the period	N/A	Not applicable
(Chief Executive Officer) Alexandre Loiseau	Year ended 12/31/2014 (in euros)	Year ended 12/31/2013 (in euros)
Compensation due for the period	219,169	283,263
Valuation of options granted during the period	333,333	N/A
Valuation of performance shares granted during the period	N/A	N/A
Summary of compensation for each executive officer		

## Section 15 - COMPENSATION and benefits

(Chairman of the Board of Directors since June 11, 2014) Christopher McFadden	Amounts due for the year ended 12/31/2014 (in euros)		Amounts due for the year ended 12/31/2013 (in euros)	
	Amounts due	Amounts paid	Amounts due	Amounts paid
- fixed compensation	0	0	N/A	N/A
- variable compensation	0	0	N/A	N/A
- exceptional compensation	0	0	N/A	N/A
- directors' fees	32,571	17,821	N/A	N/A
- benefits in kind	0	0	N/A	N/A
<b>TOTAL</b>	<b>32,571</b>	<b>17,821</b>	<b>N/A</b>	<b>N/A</b>
(Chief Executive Officer) Alexandre Loiseau	Amounts due for the year ended 12/31/2014 (in euros)		Amounts due for the year ended 12/31/2013 (in euros)	
	Amounts due	Amounts paid	Amounts due	Amounts paid
- fixed compensation	205,000	205,000	200,000	200,000
- variable compensation	0	70,000 (1)	70,000	85,000 (1)
- exceptional compensation	0	0	0	0
- directors' fees	0	0	0	0
- benefits in kind (2)	14,169	14,169	13,263	13,263
<b>TOTAL</b>	<b>219,169</b>	<b>289,169</b>	<b>283,263</b>	<b>298,263</b>

(1) Premium due for the previous financial year

(2) Benefits in kind consist of a lease and unemployment insurance for company managers and executives

Subscription or purchase options for shares granted during the financial year to each executive officer by the issuer and by each Group company

Name of the executive officer	Plan No. and date	Type of options (purchase or subscription)	Valuation of the options according to the method used for the consolidated financial statements	Number of options granted during the period	Exercise price	Exercise period
Christopher McFadden	09/01/2014	Share warrants (BSA)	6,804	30,000	6.12	10 years
Alexandre Loiseau	02/12/2014	Founders' warrants (BSPCE)	333,333	100,000	10.56	10 years

Section 15 - COMPENSATION and benefits

Subscription or purchase options for shares exercised during the period by each executive officer				
Christopher McFadden (Chairman of the Board of Directors since 06/11/2014)	Plan No. and date	Number of options exercised during the period	Exercise price	Year of grant
N/A				
	Plan No. and date	Number of options exercised during the period	Exercise price	Year of grant
Alexandre Loiseau (Chief Executive Officer)	BSPCE of 05/18/2004	Subscription of 230,000 BSPCE	€2.2684 per share	2004

Bonus shares granted to each executive officer							
Performance shares granted during the period by the issuer and by each Group company	Plan No. and date	Number of shares granted during the period	Valuation of the shares according to the method used for the consolidated financial statements	Acquisition date	Vesting date	Performance conditions	
N/A							

Bonus shares vesting during the period for each executive officer				
Performance shares vesting for each executive officer	Plan No. and date	Number of shares vesting during the period	Vesting condition	Year of grant
N/A				

The following table contains details of the conditions of compensation and other benefits granted to corporate officers:

Executive officers	Employment contract		Supplementary pension plan		Compensation or benefits due or likely to be due owing to termination or change of office		Compensation for non-compete clause	
	Yes	No	Yes	No	Yes	No	Yes	No
Christopher McFadden, Chairman of the Board of Directors		X		X		X		X
Date on which term of office began:	Ordinary General Meeting of June 11, 2014							
Date on which term	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016							

Section 15 - COMPENSATION and benefits

Executive officers	Employment contract		Supplementary pension plan		Compensation or benefits due or likely to be due owing to termination or change of office		Compensation for non-compete clause	
	Yes	No	Yes	No	Yes	No	Yes	No
of office expired:								
Alexandre Loiseau, Chief Executive Officer		X		X		X		X
Date on which term of office began:	Ordinary General Meeting of May 25, 2011							
Date on which term of office expired:	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016							

### 15.1.2. Directors' fees and other compensation received by non-executive directors

Table on directors' fees and other compensation received by non-executive officers				
Members of the Board of Directors	Directors' fees paid for the year ended 12/31/2014 (in euros)	Directors' fees paid for the year ended 12/31/2013 (in euros)	Plans granted in 2014	Plans granted in 2013
<b>André-Michel Ballester</b>				
- directors' fees	8,011	9,750		
- other compensation	-			
- Value of BSA granted	-			
<b>TOTAL</b>	<b>8,011</b>	<b>9,750</b>		
<b>Jean-Luc Boulnois</b>				
- directors' fees	-	N/A		
- other compensation	-	N/A		
- Value of BSA granted			32,413	
<b>TOTAL</b>				
<b>Marie Meynadier</b>				
- directors' fees	-	N/A		
- other compensation	-	N/A		
- Value of BSA granted				
<b>TOTAL</b>				

At its meeting on August 28, 2014, the Board of Directors set its members' compensation as follows, subject to shareholder approval at the Annual General Meeting on May 27, 2015:

- the Board of Directors allocates directors' fees annually, with payment on a quarterly basis;
- the Chairman of the Board of Directors is allocated €45,000 per annum, on a pro-rata basis;
- independent directors, excluding the Chairman of the Board of Directors, are each allocated €20,000, on a pro-rata basis, depending on their attendance at Board meetings;
- the chairmen of the Audit and Compensation Committees each receive €7,000 per annum;
- members of the Audit and Compensation Committees (other than the chairmen) each receive €5,000.

Directors receive no special pension, termination benefit or non-compete compensation.

The information contained in Table 8 on historical stock options granted for the subscription or purchase of shares to corporate officers illustrates, as of the filing date of this Registration Document, all stock options issued by the Company to its corporate officers and employees:

HISTORICAL STOCK OPTION GRANTS				
INFORMATION ON STOCK OPTIONS				
Date of Annual General Meeting	06/11/2014	Plan No. 2	Plan No. 3	Etc.
Date of the Board of Directors' meeting	09/01/2014			
Total number of shares that may be	120,000	N/A	N/A	N/A

Section 15 - COMPENSATION and benefits

subscribed for or bought, including the number that may be subscribed for or bought by corporate officers				
Start date for exercise of the options	09/01/2015			
Expiration date	09/01/2014			
Issue price	€0.61			
Exercise price	€6.12			
Exercise procedures (where the plan consists of several tranches)	One-third every three years			
Number of shares subscribed at 12/31/2015	N/A			
Cumulative number of stock options canceled or invalid	60,000			
Stock options remaining at year-end	60,000			

Stock options granted to the top ten employees who are not corporate officers and options exercised by them	Total number of options granted/shares subscribed for or bought	Weighted average price	Plan No. X	Plan No. X
Options granted during the period by the issuer and by any company within the scope of the option grant, to the ten employees of the issuer and any company within that scope granted the highest number of options (aggregate information)	N/A			
Options held on the issuer and the companies referred to above, exercised during the period by the ten employees of the issuer and such companies having bought or subscribed for the highest number of options (aggregate information)				

Historical bonus share grants Information on bonus shares	
Date of shareholder's Meeting	N/A
Date of the Board of Directors' meeting	
Total number of bonus shares granted	
Share vesting date	
Expiration of the holding period	
Number of shares subscribed for	
Cumulative number of shares canceled or invalid	
Bonus shares remaining at year-end	

### 15.2. Amounts allocated by the Company for the purposes of paying pensions and retirement and other benefits to directors and executives

The Company has not allocated any amounts for the purposes of paying pensions, retirement and other benefits to directors and executives.

The Company has not granted any signing or departure bonuses to these persons.

### 15.3. Options granted to directors and executives

The following table shows, as of the filing date of this Registration Document, all share warrants (BSA), founders' warrants (BSPCE), and stock options issued by the Company to its corporate officers and executives, whether subscribed for by the beneficiaries or not:

Beneficiaries		Stock options	Founders' warrants (BSPCE)	Share warrants (BSA)
Christopher McFadden	Chairman of the Board of Directors	-	-	30,000 (09/01/2014)
André-Michel Ballester	Director	-	-	-
Jean-Luc Boulnois	Director	-	-	30,000 (09/01/2014)
Alexandre Loiseau	Director and Chief Executive Officer	-	100,000 (02/12/2014)	-
Marie Meynadier	Director	-	-	-

The exercise of each share warrant entitles the holder to one new share.

For a detailed description of the features of these founders' warrants, share warrants and stock options, see Section 21.1.4, "Financial instruments giving access to the capital", detailing the various plans still current as of the filing date of the Registration Document.

## SECTION 16

# FUNCTIONS OF ADMINISTRATIVE AND EXECUTIVE BODIES

### 16.1. Company management

Details on the members of the Board of Directors are given in Section 14.1.1.

In 2014, the Board of Directors of the Company, as a French public limited company (*société anonyme*), met on seven separate occasions, on February 12, April 9, June 11, August 28, October 15, October 30 and December 16. All meetings were chaired by the Chairman of the Board. The directors' attendance rate is around 90%.

#### Exercise of general management of the Company

In a decision dated May 25, 2011, the Board of Directors chose to separate the functions of Chairman and Chief Executive Officer.

At the Board meeting on June 11, 2014, Christopher McFadden was elected as Chairman of the Board of Directors, representing the Company with third parties, and Alexandre Loiseau was re-elected as Chief Executive Officer.

### 16.2. Information on agreements between executives and the Company

As of the date of this Registration Document, there were no agreements between executives and the Company.

### 16.3. Specialized committees - Corporate governance

The Board of Directors has decided to create two specialized committees: an Audit Committee and a Compensation Committee.

#### 16.3.1. Audit Committee

##### Composition

In the meeting of May 25, 2011, the Board of Directors established an Audit Committee, the members of which adopted the internal rules described below.

The Audit Committee is, if possible, comprised of at least three members appointed by the Board of Directors upon the recommendation of the Compensation Committee. The members of the Audit Committee are chosen from among the members of the Board of Directors and, to the extent possible, two-thirds of them are independent Directors, at least one of them having particular competence in financial or accounting matters, with the understanding that all the members have minimum competence in financial or accounting matters.

The members of the Audit Committee appointed on June 11, 2014 are:

- Christopher McFadden, Chairman of the Board of Directors, independent director; and
- Jean-Luc Boulnois, independent director.

The appointment of two members was deemed sufficient in view of the total number of directors of the Company. The internal rules of procedure of the Audit Committee, adopted on May 25, 2011 after approval by the Board of Directors, outline the legal responsibilities and practices of the Audit Committee, including the minimum number of committee meetings each year. They also state that the Committee may interview any member of the Company's Board of Directors and request any internal or external audit for any matter that it considers within its remit. The chairman of the Audit

Committee shall give prior notice of this act to the Board of Directors. In particular, the Audit Committee has the authority to hear persons who participate in the preparation of the financial statements or their review (Vice President of Finance, head of administration and finance). It has the right of direct, independent and confidential consultation with the statutory auditors.

## Responsibilities

The Audit Committee is responsible in particular for:

- monitoring the process of preparing the financial information;
- monitoring the efficacy of the internal control and risk management systems;
- monitoring the auditing of the annual financial statements and the consolidated financial statements by the statutory auditors;
- issuing a recommendation on the auditors proposed for appointment by the general meeting and reviewing the conditions for their compensation;
- monitoring the independence of the auditors;
- examining the conditions for use of derivatives;
- periodically reviewing the status of major litigation;
- examining the Company's procedures for the receipt, filing and processing of claims involving accounting and internally conducted accounting reviews, issues relating to the audit of the financial statements and to documents sent by employees on an anonymous and confidential basis and criticizing accounting or auditing practices; and
- in general, providing any advice and making any appropriate recommendation in the above areas.

## Operations

The Audit Committee meets at least twice a year, according to a schedule set by its chairman, to examine the annual, semi-annual and, where applicable, quarterly consolidated financial statements, on an agenda drawn up by its chairman and sent to the members of the Audit Committee at least seven days before the date of the meeting. It also meets at the request of its chairman, two of its members or the chairman of the Board of Directors of the Company.

The Audit Committee may hear any member of the Company's Board of Directors and request the conducting of any internal or external audit for any matter that it deems to fall within its mission. The chairman of the Audit Committee shall give prior notice of this act to the Board of Directors. In particular, the Audit Committee has the authority to hear persons who participate in the preparation of the financial statements or their review (administrative and financial officer and principal persons in charge of the finance department).

The Audit Committee interviews the statutory auditors. It may hear them without the presence of any Company representative.

The Audit Committee met twice in 2014, on April 2 and August 28.

## Reports

The chairman of the Audit Committee sees to it that the committee's activity reports to the Board of Directors enable them to be fully informed, thereby facilitating their deliberations.

The annual report shall contain an account of the committee's activities during the past year.

If, in the course of its work, the Audit Committee uncovers a significant risk that does not appear to have been handled properly, the chairman alerts the chairman of the Board of Directors of this fact immediately.

### 16.3.2. Compensation Committee

#### Composition

In the meeting of May 25, 2011, the Board of Directors established a Compensation Committee, the members of which adopted the internal rules described below.

The Compensation Committee is, if possible, composed of at least two members of the Board of Directors, appointed by the Board of Directors. The independent members represent, to the extent possible, the majority of its members.

It is stated to the extent necessary that no member of the Board of Directors who carries out executive duties in the Company may be a member of the Compensation Committee.

The members of the Compensation Committee appointed on May 25, 2011 and June 11, 2014 are:

- Christopher McFadden, Chairman of the Compensation Committee;
- André-Michel Ballester;
- Marie Meynadier.

#### Responsibilities

The Compensation Committee is responsible in particular for:

- examining the main objectives proposed by general management with respect to the compensation of executives who are not corporate officers of the Group, including the bonus share and stock option plans;
- examining the compensation of executives who are not corporate officers, including the bonus share and stock option plans, the pension and insurance benefit plans and the benefits in kind;
- making recommendations and proposals to the Board of Directors on:
  - the compensation, the pension and insurance benefit plans, the benefits in kind, the other financial rights, including those in the event of retirement, of the members of the Board of Directors. The committee proposes compensation amounts and structures, in particular, rules for determining the variable portion, taking into account the Company's strategy, objectives and results as well as market practices, and
  - the bonus share and stock option plans and any other similar profit-sharing arrangement, in particular, the personal allocations to the members of the Board of Directors;
- examining the total amount of directors' fees and the arrangements for distribution among the members of the Board of Directors, as well as the conditions for reimbursement of expenses that might have been incurred by members of the Board of Directors;
- preparing and presenting the reports, where applicable, set forth in the Board of Directors' internal rules; and
- preparing any other recommendation that might be asked of it by the Board of Directors with respect to compensation.

In general, the Compensation Committee provides any advice and makes any appropriate recommendation in the above areas.

### **Operating arrangements**

The Compensation Committee meets at least two times a year, according to a schedule set by its chairman, on an agenda drawn up by its chairman and sent to the members of the Compensation Committee at least seven days before the date of the meeting. It also meets at the request of its chairman, two of its members or the Board of Directors.

The Board of Directors' non-executive members who are not members of the Compensation Committee may participate freely in its meetings.

The chairman of the Company's Board of Directors, if he is not a member of the committee, may be invited to participate in the committee's meetings. The committee invites him to present his proposals to them. He cannot vote in the deliberations and does not attend deliberations involving his own situation.

The Compensation Committee may ask the chairman of the Board of Directors to obtain assistance from any Company executive whose expertise might facilitate the handling of any item on the agenda. The chairman of the Compensation Committee or the meeting chairman points out to any person participating in the proceedings the confidentiality obligations required of him.

### **Reports**

The chairman of the Compensation Committee sees to it that the committee's activity reports to the Board of Directors enable them to be fully informed, thereby facilitating their deliberations.

The annual report shall contain an account of the committee's activities during the past year.

The Compensation Committee examines in particular the Company's draft report with respect to executive compensation.

#### 16.4. Statement relating to corporate governance

In the interests of transparency and public information, the Company has embarked on a comprehensive review of its corporate governance practices.

In view of the Company's organization, its size and resources, it has decided to refer to the MiddleNext Corporate Governance Code for small- and mid-caps, published on December 17, 2009 (the "MiddleNext Code"), with effect from the admission to trading of the Company's shares on the NYSE Euronext Paris market.

To meet the corporate governance standards that the Company has set itself, the following measures have already been put in place.

Recommendations of the MiddleNext Code	Already adopted	Will be adopted	Will not be adopted	Under consideration
<b><i>I. Executive power</i></b>				
R1: concurrent employee and corporate officer status	X			
R2: definition and transparency of compensation of executive officers	X			
R3: termination benefits *	X			
R4: supplementary pension plans *	X			
R5: stock options and bonus grants *	X			
<b><i>II. Supervisory power</i></b>				
R6: adoption of internal rules	X			
R7: code of conduct for Board members	X			
R8: composition of the Board, presence of independent members	X			
R9: selection of directors	X			
R11: information for Board members	X			
R12: formation of committees	X			
R13: Board and committee meetings	X			
R14: compensation of directors	X			
R15: evaluation of the Board's work	x			

## 16.5. Report of the Chairman on internal controls

In accordance with the provisions of Article L. 225-37 of the French Commercial Code, the Chairman of the Board of Directors prepares a report on internal control accounting for the composition, conditions of preparation and organization of the Board's work and the internal control and risk management procedures put in place by the Company.

The first part of the Chairman's report covers the operations of the Board of Directors and specialized committees described in Sections 16.1 to 16.4. Below is an extract from the report corresponding to the Section on internal control:

### EXTRACT FROM THE REPORT BY THE CHAIRMAN OF THE BOARD OF DIRECTORS ON CORPORATE GOVERNANCE, INTERNAL CONTROL AND RISK MANAGEMENT

#### 2.3. General principles of internal control

##### **A) Definition**

Mauna Kea Technologies adopts the definition of internal control proposed by the *Autorité des Marchés Financiers* (AMF)<sup>9</sup>, whereby internal control is a system implemented by the Company to ensure:

- compliance with laws and regulations;
- the enforcement of instructions and guidelines set by general management;
- the satisfactory functioning of the Company's internal processes;
- the reliability of financial disclosures; and

in general contributes to the management of its activities, the efficacy of its operations and the efficient utilization of its resources.

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

##### **B) Components of internal control**

###### Organization and implementation of integrated management software

The internal control system is based on a clear organization of responsibilities, guidelines, resources and procedures. The Company has always had a quality assurance system. The processes applied in all areas of the business are defined in written procedures, operating methods, forms and notices. These documents outline the workflow, define the resources and responsibilities of participants, specify the know-how of the Company and give precise instructions on how to perform a given operation.

In 2013, to enhance its quality system and internal control, the Company opted to introduce SAP integrated management software with a pre-configured package designed for small and medium-sized enterprises.

The effective launch of this software in early January 2013 took place in accordance with the implementation schedule. This initial roll-out concerned Purchasing/Suppliers, Sales/Customers, Accounts and Management Control.

In 2013, the procedures covered by the software were reviewed to factor in changes in operational processes and financial disclosures requiring the use of the software.

<sup>9</sup> Guide to the implementation of the reference framework for internal control adapted to small- and mid-caps (updated on July 22, 2010)

Everyone in the Company is affected by the internal control system.

#### Procedures relating to operational processes

All documentation relating to the quality management system (QMS) is stored on a dedicated intranet which optimizes access to the documents and their ongoing adaptation to business developments (document life cycle management). The aim is to foster a continuous improvement in the quality and functional processes of the Company and the Group, be they operational, management or support processes.

The quality assurance system covers the following areas:

- Business management
- Innovation
- Quality management
- Customer engagement
- Developing and refining products
- Demonstrating the value proposition
- Sales
- Product manufacture
- Managing assets and resources
- Purchasing
- Certification
- Risk management

The quality management system underwent its first routine inspection by the FDA (U.S. Food and Drug Administration) in January 2014. This went smoothly, confirming the robustness of the Company's quality management system. The FDA highlighted two minor "483" issues, which the Company responded to within 15 days.

#### Financial reporting procedures

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

- The Company's General Management, and more specifically staff from the Finance Department, are responsible for improving internal control and adopting the recommendations of the external auditors and Audit Committee;
- The Company maintains an internal separation between the production and supervision of its financial statements and relies on independent experts to examine complex accounting entries such as the Research Tax Credit and valuation of stock options or founders' warrants;
- A certified public accountant is in charge of preparing the consolidated financial statements under IFRS;
- The financial and accounting management of the U.S. subsidiary, Mauna Kea Technologies Inc., undergoes a regular internal review on site by the accounting team at the head office;
- Payroll management in France and the U.S. is outsourced to a specialized independent firm.

In general, all of the Company's accounting options are defined by the Finance Department following a discussion with the General Management and Statutory Auditors, before being presented to and examined jointly with the Audit Committee. This ensures that the Company's practices are fully compliant with French and international standards (IFRS), as well as maintaining consistency in the presentation of the financial statements.

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

The analytical validation of entries and a comprehensive spending review are carried out during periodic budget reviews organized with all operational managers. The Finance Department reports to the General Management and directors at each Board meeting. The reports are presented and discussed periodically at Board meetings.

#### **2.4. Risk management and internal control actors**

Since the Company's inception, the General Management has always played a key role in defining and driving the internal control and risk management system.

#### **2.5. Risk management and internal control limits and opportunities for improvement**

Since 2014, the Company has sought to adapt its risk management system to its new information system (ERP) and to improve the monitoring of the action plans identified.

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.

### **3. Gender representation on the Board of Directors**

In accordance with the provisions of Law No. 2011-103 of January 27, 2011 on balanced gender representation on boards of directors and supervisory boards and on gender equality, the Board of Directors currently has one female member.

The Board of Directors has endorsed the content of this report, which will be presented to the Annual General Meeting held to approve the 2014 financial statements.

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**Chairman of the Board of Directors**

## 16.6. Statutory auditors' report on the report prepared by the Chairman of the Board of Directors

COFIDEC  
155, boulevard Haussmann  
75008 Paris  
S.A.R.L. au capital de € 32.800

Commissaire aux Comptes  
Membre de la compagnie  
régionale de Paris

ERNST & YOUNG et Autres  
1/2, place des Saisons  
92400 Courbevoie - Paris-La Défense 1  
S.A.S. à capital variable

Commissaire aux Comptes  
Membre de la compagnie  
régionale de Versailles

Mauna Kea Technologies

Year ended December 31, 2014

Statutory auditors' report prepared in accordance with article L. 225-235 of the French commercial code (*Code de commerce*), on the report prepared by the chairman of the board of directors of Mauna Kea Technologies

To the Shareholders,

In our capacity as statutory auditors of Mauna Kea Technologies and in accordance with article L. 225-235 of the French commercial code (*Code de commerce*), we hereby report on the report prepared by the chairman of your company in accordance with article L. 225-37 of the French commercial code (*Code de commerce*) for the year ended December 31, 2014.

It is the chairman's responsibility to prepare and submit for the board of directors' approval a report on the internal control and risk management procedures implemented by the company and to provide the other information required by article L. 225-37 of the French commercial code (*Code de commerce*) relating to matters such as corporate governance.

Our role is to:

- report on any matters as to the information contained in the chairman's report in respect of the internal control and risk management procedures relating to the preparation and processing of the accounting and financial information, and
- confirm that the report also includes the other information required by article L. 225-37 of the French commercial code (*Code de commerce*). It should be noted that our role is not to verify the fairness of this other information.

We conducted our work in accordance with professional standards applicable in France.

Information on the internal control and risk management procedures relating to the preparation and processing of the accounting and financial information

The professional standards require that we perform the necessary procedures to assess the fairness of the information provided in the chairman's report in respect of the internal control and risk management procedures relating to the preparation and processing of the accounting and financial information. These procedures consist mainly in:

- obtaining an understanding of the internal control and risk management procedures relating to the preparation and processing of the accounting and financial information on which the information presented in the chairman's report is based and of the existing documentation;

## Section 16 - FUNCTIONS of administrative and executive bodies

- obtaining an understanding of the work involved in the preparation of this information and of the existing documentation;
- determining if any material weaknesses in the internal control procedures relating to the preparation and processing of the accounting and financial information that we would have noted in the course of our work are properly disclosed in the chairman's report.

On the basis of our work, we have no matters to report on the information relating to the company's internal control and risk management procedures relating to the preparation and processing of the accounting and financial information contained in the report prepared by the chairman of the board of directors in accordance with article L. 225-37 of the French commercial code (*Code de commerce*).

Other information

We confirm that the report prepared by the chairman of the board of directors also contains the other information required by article L. 225-37 of the French commercial code (*Code de commerce*).

Paris and Paris-La Défense, April 21, 2015

The statutory auditors  
*French original signed by*

COFIDEC  
Thibault Faure

ERNST & YOUNG et Autres  
Cédric Garcia

## SECTION 17 EMPLOYEES

### 17.1. Human resources

#### 17.1.1. Number and distribution of employees

The number of full-time equivalent staff rose by 7.91% and is distributed as follows

Distribution of employees by category:

	12/31/2014	12/31/2013	Change
Permanent contract	116.6	104.2	11.90%
Fixed-term contract	3.5	7.1	-50.70%
<b>Total workforce</b>	<b>120.1</b>	<b>111.3</b>	<b>7.91%</b>
Executives	104.6	93.8	11.51%
Non-executives	14.1	12.2	15.57%
Apprentices	1.4	5.3	-73.58%

Distribution of employees by gender:

	12/31/2014	12/31/2013	Change
Men	74.2	69.5	6.76%
Women	45.8	41.8	9.57%
<b>Total workforce</b>	<b>120.1</b>	<b>111.3</b>	<b>7.91%</b>

Distribution of workforce by geographical region:

	12/31/2014	12/31/2013	Change
France	84.6	86.7	-2.42%
Europe excluding France	2.4	1.9	26.32%
America	28.1	20.9	34.45%
Asia-Pacific	5	1.8	177.78%
<b>Total employees</b>	<b>120.1</b>	<b>111.3</b>	<b>7.91%</b>

The significant increase in the U.S. workforce is due to efforts to expand the sales force in this region, after a year of restructuring in 2013.

A new R&D office has opened in Vietnam.

Entries and departures:

Number of new hires	2014	2013
Permanent contracts	37	21
Fixed-term contracts	3	3
Apprentice/intern	3	
<b>Total</b>	<b>43</b>	<b>24</b>

In 2014, the Company continued its policy of expanding the sales force.

Departures by reason	2014	2013
Redundancies/dismissals	5	1
Voluntary departure	14	23
End of fixed-term contract	3	7
Others	7	3
<b>Total</b>	<b>29</b>	<b>34</b>

Most of the workforce is on a permanent contract. It is Company policy to invest significantly in training for its new employees, hence it is keen to retain them.

The gender distribution is due to the sales force being predominantly male.

## 17.2. Equity stakes and stock options of directors and executives

As of the date of this Registration Document, the direct and indirect equity stakes of the members of the Board of Directors and the number of financial instruments granting access to the Company's share capital that they hold are as follows:

Names	Shares		Financial instruments giving access to the capital
	By number	% of the capital	
Christopher McFadden	-	-	30,000 BSA 2014
Alexandre Loiseau	604,240	4.33%	499,996 BSPCE A 08 to be exercised at the rate of 4 BSPCE A 08 for 1 new share, which equals 124,999 shares.  100,000 BSPCE 2014 to be exercised at the rate of 1 BSPCE 2014 for 1 new share (see Section 21.1.4 of this document for the conditions of exercise)
André-Michel Ballester	-	-	40,000 BSA 2011
Jean-Luc Boulnois	-	-	30,000 BSA 2014
Marie Meynadier	-	-	

After taking into account the 4-for-1 reverse stock split authorized by the general meeting of May 25, 2011, the exercise price of the BSPCE A 08 allocated to Alexandre Loiseau was adjusted to €4.00 per share.

## 17.3. Employee participation in Company share capital

At March 31, 2015, Group employees held 64,775 shares and 68,900 voting rights, or 0.46% of the capital and 0.41% of Company voting rights.

## 17.4. Profit-sharing and participation agreements

None.

## SECTION 18 PRINCIPAL SHAREHOLDERS

### 18.1. Breakdown of the capital and voting rights

The following detailed table of shareholders takes into account the 4-for-1 reverse share split approved by the General Shareholders' Meeting of May 25, 2011 and the conversion of all the shares into ordinary shares as of the date of the admission of the Company' securities for trading on the regulated market of NYSE Euronext in Paris.

#### Memorandum and bylaws

Shareholders	5/31/2015						12/31/2014					
	number of shares	% of the capital	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM	number of shares	% of the capital	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM
Coöperatie PSILOS (*)	-	-	-	-	-	-	-	-	-	-	-	-
PSILOS GROUP PARTNER	-	-	-	-	-	-	-	-	-	-	-	-
CREADEV (**)	-	-	-	-	-	-	-	-	-	-	-	-
Alexandre Loiseau	604,240	3.91%	1,150,980	6.42%	1,150,980	6.43%	604,240	4.32%	1,150,980	6.99%	1,150,980	6.99%
<b>Subtotal Board of Directors</b>	<b>604,240</b>	<b>3.91%</b>	<b>1,150,980</b>	<b>6.42%</b>	<b>1,150,980</b>	<b>6.43%</b>	<b>604,240</b>	<b>4.32%</b>	<b>1,150,980</b>	<b>6.99%</b>	<b>1,150,980</b>	<b>6.99%</b>
Finavance	717,059	4.64%	1,434,118	8.00%	1,434,118	8.01%	717,059	5.12%	1,434,118	8.70%	1,434,118	8.71%
Seventures (4 funds)	660,021	4.27%	1,320,042	7.36%	1,320,042	7.37%	660,021	4.72%	1,320,042	8.01%	1,320,042	8.02%
Health Evolution partner (***)												
Callpers (***)	607,021	3.93%	607,021	3.39%	607,021	3.39%	607,021	4.34%	607,021	3.68%	607,021	3.69%
The Capital Group Companies, Inc. (***)	958,400	6.20%	958,400	5.35%	958,400	5.35%	881,400	6.30%	881,400	5.35%	881,400	5.36%
<b>Subtotal major shareholders</b>	<b>2,942,501</b>	<b>19.04%</b>	<b>4,319,581</b>	<b>24.09%</b>	<b>4,319,581</b>	<b>24.12%</b>	<b>2,865,501</b>	<b>20.48%</b>	<b>4,242,581</b>	<b>25.75%</b>	<b>4,242,581</b>	<b>25.78%</b>
Other registered	725,879	4.70%	1,275,478	7.11%	1,275,478	7.12%	739,998	5.29%	1,300,245	7.89%	1,300,245	7.90%
Other free float	11,163,861	72.23%	11,163,861	62.26%	11,163,861	62.33%	9,765,243	69.79%	9,765,243	59.27%	9,765,243	59.33%
Own shares	20,226	0.13%	20,226	0.11%	0	0.00%	17,537	0.13%	17,537	0.11%	0	0.00%
<b>Total shares comprising the share capital</b>	<b>15,456,707</b>	<b>100.00%</b>	<b>17,930,126</b>	<b>100.00%</b>	<b>17,909,900</b>	<b>100.00%</b>	<b>13,992,519</b>	<b>100.00%</b>	<b>16,476,586</b>	<b>100.00%</b>	<b>16,459,049</b>	<b>100.00%</b>

Shareholders	12/31/2013						12/31/2012					
	number of shares	% of the capital	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM	number of shares	% of the capital	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM
Coöperatie PSILOS (*)	-	-	-	-	-	-	-	-	-	-	-	-
PSILOS GROUP PARTNER	-	-	-	-	-	-	1,821,064	13.43%	1,821,064	9.96%	1,821,064	9.97%
CREADEV (**)	2,332,375	16.90%	4,449,317	24.27%	4,449,317	24.29%	2,332,375	17.20%	4,449,317	24.33%	4,449,317	24.35%
Alexandre Loiseau	546,740	3.96%	1,093,480	5.97%	1,093,480	5.97%	546,740	4.03%	1,093,480	5.98%	1,093,480	5.98%
<b>Subtotal Board of Directors</b>	<b>2,879,115</b>	<b>20.86%</b>	<b>5,542,797</b>	<b>30.24%</b>	<b>5,542,797</b>	<b>30.26%</b>	<b>4,700,179</b>	<b>34.66%</b>	<b>7,363,861</b>	<b>40.27%</b>	<b>7,363,861</b>	<b>40.30%</b>
Finavance	717,059	5.19%	1,367,886	7.46%	1,367,886	7.47%	717,059	5.29%	1,367,886	7.48%	1,367,886	7.49%
Seventures (4 funds)	660,021	4.78%	1,259,079	6.87%	1,259,079	6.87%	660,021	4.87%	1,259,079	6.88%	1,259,079	6.89%
Health Evolution partner (***)	607,021	4.40%	607,021	3.31%	607,021	3.31%	607,021	4.48%	607,021	3.32%	607,021	3.32%
Callpers (***)												
The Capital Group Companies, Inc. (***)	881,400	6.39%	881,400	4.81%	881,400	4.81%	-	-	-	-	-	-
<b>Subtotal major shareholders</b>	<b>2,865,501</b>	<b>20.76%</b>	<b>4,115,386</b>	<b>22.45%</b>	<b>4,115,386</b>	<b>22.47%</b>	<b>1,984,101</b>	<b>14.63%</b>	<b>3,233,986</b>	<b>17.68%</b>	<b>3,233,986</b>	<b>17.70%</b>
Other registered	775,047	5.61%	1,387,878	7.57%	1,387,878	7.58%	937,054	6.91%	1,750,093	9.57%	1,750,093	9.58%
Other free float	7,270,313	52.67%	7,270,313	39.66%	7,270,313	39.69%	5,925,274	43.69%	5,925,274	32.40%	5,925,274	32.43%
Own shares	13,481	0.10%	13,481	0.07%	0	0.00%	15,138	0.11%	15,138	0.08%	0	0.00%
<b>Total shares comprising the share capital</b>	<b>13,803,457</b>	<b>100.00%</b>	<b>18,329,855</b>	<b>100.00%</b>	<b>18,316,374</b>	<b>100.00%</b>	<b>13,561,746</b>	<b>100.00%</b>	<b>18,288,352</b>	<b>100.00%</b>	<b>18,273,214</b>	<b>100.00%</b>

(\*) A company under Dutch law owned by PSILOS and Health Evolution Partners, two U.S. venture capital funds. This company was dissolved on May 14, 2012. The shares were directly held by these two companies. PSILOS sold the majority of its shares in July 2013.

(\*\*) Investment company owned by the Mulliez family which sold the majority of its shares on May 15, 2014.

(\*\*\*) Bearer shares.

To the knowledge of the Company, no action in concert between shareholders exists.

### 18.2. Significant shareholders not represented on the Board of Directors

None.

### 18.3. Voting rights of the principal shareholders

By a decision of the general meeting dated May 25, 2011, a double voting right was created for all the 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 the capital they represent and each share confers the right to at least one vote.

However, under Article 9 of the bylaws and in accordance with the provisions of the French Commercial Code, all fully paid-up shares which are proven to have been registered for at least three years in the name of the same shareholder qualify for double the voting rights of other shares in view of the percentage of the share capital they represent.

As of the date of this Registration Document, the following shareholders are eligible for double voting rights.

Shareholders	Shares with double voting rights
FINADVANCE VENTURE I	717,059
ALEXANDRE LOISEAU	546,740
SEVENTURE (through four funds)	660,021
FUJIKURA	212,441
CREDIT AGRICOLE LUXEMBOURG	114,619
JACQUES BOGART SA	22,457
SBN	19,131
Various individuals and legal entities	180,951
<b>TOTAL</b>	<b>2,473,419</b>

#### 18.4. Control of the Company

As of the date of this Registration Document, no single shareholder holds a high enough percentage to presume control of the Company as defined by the provisions of Article L. 233-3 of the French Commercial Code.

The Company has thus not implemented measures to guarantee that this control is not exercised abusively.

To the knowledge of the Company, no action in concert between shareholders exists.

#### 18.5. Agreement that may cause a change in control

No specific item in the articles of incorporation, bylaws, charter or rules of the issuer could have the effect of delaying, deferring, or preventing a change in its control.

#### 18.6. Statement of pledges

None.

## SECTION 19

### TRANSACTIONS WITH RELATED PARTIES

The existing regulated agreements as of this date are mentioned in the special reports of the statutory auditors presented below.

#### 19.1. Intra-group transactions

The intra-group transactions are described in Section 7.3 "Principal intra-group flows" of this Registration Document.

#### 19.2. Transactions with related parties

See Section 16.2 of this Registration Document.

#### 19.3. Statutory auditors' reports on regulated agreements prepared for the financial year ended December 31, 2014

COFIDEC  
155, boulevard Haussmann  
75008 Paris  
S.A.R.L. au capital de € 32.800

Commissaire aux Comptes  
Membre de la compagnie  
régionale de Paris

ERNST & YOUNG et Autres  
1/2, place des Saisons  
92400 Courbevoie - Paris-La Défense 1  
S.A.S. à capital variable

Commissaire aux Comptes  
Membre de la compagnie  
régionale de Versailles

Mauna Kea Technologies  
General meeting of shareholders to approve the financial statements for the year ended December 31, 2014

#### Statutory auditors' report on related party agreements and commitments

To the Shareholders,

In our capacity as statutory auditors of your company, we hereby report on certain related party agreements and commitments.

We are required to inform you, on the basis of the information provided to us, of the terms and conditions of those agreements and commitments indicated to us, or that we may have identified in the performance of our engagement. We are not required to comment as to whether they are beneficial or appropriate or to ascertain the existence of any such agreements and commitments. It is your responsibility, in accordance with article R. 225-31 of the French commercial code (Code de commerce), to evaluate the benefits resulting from these agreements and commitments prior to their approval.

In addition, we are required, where applicable, to inform you in accordance with article R. 225-31 of the French commercial code (Code de commerce) concerning the implementation, during the year, of the agreements and commitments already approved by the general meeting of shareholders.

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 type of engagement.

#### Agreements and commitments submitted for approval by the general meeting of shareholders

We hereby inform you that we have not been advised of any agreements or commitments authorized in the course of the year to be submitted to the general meeting of shareholders for approval in accordance with article L. 225-38 of the French commercial code (*Code de commerce*).

**Agreements and commitments already approved by the general meeting of shareholders**

We hereby inform you that we have not been advised of any agreements or commitments already approved by the general meeting of shareholders, whose implementation continued during the year.

Paris and Paris-La Défense, April 21, 2015

The statutory auditors  
French original signed by

COFIDEC  
Thibault Faure

ERNST & YOUNG et Autres  
Cédric Garcia

SECTION 20  
FINANCIAL INFORMATION CONCERNING THE ISSUER'S  
ASSETS AND LIABILITIES, FINANCIAL POSITION AND  
PROFITS AND LOSSES

20.1. Consolidated financial statements prepared under IFRS for  
the year ended December 31, 2014

**STATEMENT OF FINANCIAL POSITION**

(Amounts in thousands of euros)

	Note	As of 31 December	
		2014	2013
<b>ASSETS</b>			
<b>Non-current Assets</b>			
Intangible assets	3	3,542	3,713
Property, plant, and equipment	4	794	519
Non-current financial assets	5	105	77
<b>Total of non-current assets</b>		<b>4,440</b>	<b>4,309</b>
<b>Current assets</b>			
Inventories & Work in progress	6	1,912	2,263
Trade receivables	7	3,874	3,114
Other current assets	7	2,165	1,859
Current financial assets	8	128	207
Cash and cash equivalents	9	15,018	27,792
<b>Total of current assets</b>		<b>23,098</b>	<b>35,235</b>
<b>TOTAL OF ASSETS</b>		<b>27,538</b>	<b>39,544</b>

**STATEMENT OF FINANCIAL POSITION**

(Amounts in thousands of euros)

	Note	As of 31 December	
		2014	2013
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Issued capital	10	560	552
Share premium	10	58,162	57,501
Reserves		(26,604)	(16,253)
Foreign currency translation on reserve		23	(124)
Profit / (loss)		(13,991)	(11,516)
<b>Total of equity</b>		<b>18,150</b>	<b>30,159</b>
<b>Non-current Liabilities</b>			
Long-term loans and borrowings	11	2,606	2,643
Non-current provisions	12	518	465
<b>Total of non-current liabilities</b>		<b>3,124</b>	<b>3,108</b>
<b>Current liabilities</b>			
Short-term loans and borrowings	11	638	659
Trade payables	13	2,238	2,439
Other current liabilities	13	3,388	3,178
<b>Total of current liabilities</b>		<b>6,264</b>	<b>6,276</b>
<b>TOTAL OF EQUITY AND LIABILITIES</b>		<b>27,538</b>	<b>39,544</b>

## COMPREHENSIVE INCOME STATEMENT

(Amounts in thousands of euros)

	Note	As of 31 December	
		2014	2013
<b>Operating Revenue</b>			
Sales	15	11,016	9,977
Other income	15	1,267	939
<b>Total of revenue</b>		<b>12,282</b>	<b>10,915</b>
<b>Operating Expenses</b>			
Cost of sales		(3,675)	(3,042)
<i>Gross margin</i>		<i>67%</i>	<i>70%</i>
Research & Development	18	(4,583)	(3,611)
Sales & Marketing	18	(12,753)	(11,174)
Administrative expenses	18	(3,837)	(3,759)
Share-based payments	17	(1,257)	(851)
<b>Total of expenses</b>		<b>(26,106)</b>	<b>(22,437)</b>
<b>Operating profit</b>		<b>(13,823)</b>	<b>(11,521)</b>
Financial revenue	19	251	207
Financial expenses	19	(419)	(202)
<b>Profit before tax</b>		<b>(13,991)</b>	<b>(11,516)</b>
Income tax expense	20	0	0
<b>Profit / (loss)</b>		<b>(13,991)</b>	<b>(11,516)</b>
<b>Other comprehensive income</b>			
<i>Items that will not be reclassified to profit or loss</i>			
Actuarial differences on defined benefit plans	12	(79)	6
<b>Total of items that will not be reclassified to profit or loss</b>		<b>(79)</b>	<b>6</b>
<i>Items that will be reclassified subsequently to profit or loss</i>			
Exchange differences on translation of foreign operations		147	(49)
Cash flow hedge	11	30	(30)
<b>Total of items that will be reclassified subsequently to profit or loss</b>		<b>178</b>	<b>(49)</b>
<b>Other comprehensive income for the year, net of tax</b>		<b>99</b>	<b>(73)</b>
<b>Comprehensive income</b>		<b>(13,892)</b>	<b>(11,589)</b>
Weighted average number of shares outstanding (in thousands)	23	13,905	13,727
<b>Basic earnings per share (EUR/share)</b>	23	<b>(1.01)</b>	<b>(0.84)</b>
Weighted average number of potential shares (in thousands)	23	15,588	15,317

**STATEMENT OF CHANGES IN EQUITY**

(Amounts in thousands of euros)

		<b>Issued capital</b>	<b>Share premium</b>	<b>Treasury shares</b>	<b>Reserves</b>	<b>Foreign currency translation on reserve</b>	<b>Profit / (loss)</b>	<b>Total of equity</b>
<b>Equity as of</b>	<b>12/31/2012</b>	<b>542</b>	<b>56,805</b>	<b>(184)</b>	<b>(3,869)</b>	<b>(76)</b>	<b>(13,056)</b>	<b>40,162</b>
Allocation of the profit / (loss)					(13,056)		13,056	
Capital transactions		10	697					706
Share-based payment transactions					885			885
Treasury shares transactions				46	(51)			(4)
Comprehensive income as of	12/31/2013				(24)	(49)	(11,516)	(11,589)
<b>Equity as of</b>	<b>12/31/2013</b>	<b>552</b>	<b>57,501</b>	<b>(138)</b>	<b>(16,115)</b>	<b>(124)</b>	<b>(11,516)</b>	<b>30,159</b>
Allocation of the profit / (loss)					(11,516)		11,516	
Capital transactions		8	660					668
Share-based payment transactions					1,295			1,295
Treasury shares transactions				33	(114)			(81)
Comprehensive income as of	12/31/2014				(48)	147	(13,991)	(13,892)
<b>Equity as of</b>	<b>12/31/2014</b>	<b>560</b>	<b>58,162</b>	<b>(105)</b>	<b>(26,499)</b>	<b>23</b>	<b>(13,991)</b>	<b>18,150</b>

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

**CASH-FLOW STATEMENT**  
(Amounts in thousands of euros)

	Note	As of 31 December	
		2014	2013
<b>Cash flows from operating activities</b>			
Profit / (loss)		(13,991)	(11,516)
Elimination of amortisations, depreciations and provisions		884	676
Share-based payment transaction expense and revenue	16/17	1,257	851
Other items excluded from the auto-financing capacity		99	(26)
<i>Revenue and expenses related to the discounting of repayable advances</i>	11	153	(34)
<i>Net financial interest paid</i>		(99)	(10)
<i>Other non-cash items</i>		44	17
Capital gain or loss from asset sales			
Elimination of the income tax expense	20		
<b>Auto-financing capacity</b>		<b>(11,751)</b>	<b>(10,016)</b>
Income tax expense paid			
Change in WCR related to business activities		(980)	405
<i>Inventories &amp; Work in progress</i>		153	(383)
<i>Trade receivables</i>		(673)	178
<i>Other current assets</i>		(303)	282
<i>Trade payables</i>		(211)	266
<i>Other current liabilities</i>		54	62
<b>Net cash flows from operating activities (A)</b>		<b>(12,731)</b>	<b>(9,612)</b>
<b>Cash flows from investing activities</b>			
Purchase of property, plant and equipment and intangible assets	3/4	(618)	(1,146)
Proceeds from sale of property, plant and equipment and intangible assets			
Proceeds from sale of current financial assets			
Change in loans and advances granted		51	
Other cash flows from investing operations			
<b>Net cash flows from investing activities (B)</b>		<b>(567)</b>	<b>(1,146)</b>
<b>Cash flows from financing activities</b>			
Proceeds from exercise of share options	10	668	706
Repurchases and resales of treasury shares		(81)	(4)
Net financial interests paid		99	10
<i>Gain from cash equivalents</i>	19	123	110
<i>Loss from cash equivalents</i>		(25)	(100)
Other cash flows from financing operations	11	(203)	210
<b>Net cash flows from financing activities (C)</b>		<b>483</b>	<b>923</b>
Net foreign exchange difference (D)		41	(10)
<b>Change in cash (A) + (B) + (C) + (D)</b>		<b>(12,774)</b>	<b>(9,846)</b>
Cash at the beginning of the period	9	27,792	37,638
Cash at the end of the period	9	15,018	27,792
<b>Change in cash</b>		<b>(12,774)</b>	<b>(9,846)</b>

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

### Note 1: Accounting Principles

#### ***1.1 Accounting principles applied by the Group***

The financial statements are presented in thousands of euros. Rounding may in some cases cause insignificant variances in totals.

They were approved by the Board of Directors on April 13, 2015. These financial statements will be definitive only after their approval by the Annual General meeting.

The financial statements are prepared on the basis of their historical cost, with the exception of the financial assets, which are valued at their fair value. Preparing the financial statements according to IFRS means making estimates and assumptions that affect the amounts and the disclosures in the statements, particularly in measuring the cost of share-based payments and in the values in use applied to impairment tests. These assumptions and estimates have been made on the basis of situations at the date of drawing up the accounts and may turn out in the future to differ from the actual results. As applicable, a sensitivity analysis may be implemented if this variation is significant.

The assumption of going concern was adopted by the Board of Directors considering the cash available on December 31, 2014 amounting to €15 million ensuring that the Company meets its cash flow needs in the period to December 31, 2015.

In addition, the Company intends to employ appropriate financing solutions to meet its future cash needs. A line of equity financing was notably finalized with Société Générale on March 11, 2015 as detailed in Note 25: Subsequent events.

The principles adopted for the preparation of this financial information result from the application of all the standards and interpretations adopted by the European Union, the application of which was mandatory at December 31, 2014. These are available on the website of the European Commission: [http://ec.europa.eu/internal\\_market/accounting/ias/index\\_fr.htm](http://ec.europa.eu/internal_market/accounting/ias/index_fr.htm).

The new standards, amendments, revisions and interpretations of standards adopted by the European Union with mandatory application for accounting periods beginning on or after January 1, 2014 and applied for the first time by the Company for the year fiscal year are:

- IFRS 10 “Consolidated Financial Statements”;
- IFRS 11 “Joint Arrangements”;
- IFRS 12 “Disclosure of Interests in Other Entities”;
- IAS 28 Revised “Interests in Associates and Joint Ventures”;
- Amendments to IFRS 10, 11 and 12, “Transition Guidance”;
- Amendments to IFRS 10, IFRS 12 and IAS 27 “Investment Entities”;
- Amendments to IAS 32 “Financial Instruments: Presentation - Offsetting Financial Assets and Financial Liabilities”;
- Amendments to IAS 36 “Recoverable Amount Disclosures for Non-Financial Assets”;
- Amendments to IAS 39 “Novation of Derivatives and Continuation of Hedge Accounting”.

The application of these standards did not have a significant impact on the consolidated financial statements.

Furthermore, the Company has not early adopted other standards, amendments, revisions or interpretations which will become compulsory for fiscal years beginning after January 1, 2015. These are the following standards, amendments, revisions and interpretations of the following standards:

- IFRIC 21 “Levies” applicable to periods open from June 17, 2014 forward;
- Annual improvements to IFRS: 2010 - 2012 cycle, effective for financial years beginning on or after February 1, 2015
- Annual improvements to IFRS: 2011 - 2013 cycle, effective for financial years beginning on or after January 1, 2015

The Company has not early adopted any standards, amendments, revisions or interpretations not yet adopted for use in the European Union:

- IFRS 9 and its amendments on “Financial Instruments”;
- IFRS 15 “Revenue from Contracts with Customers”;
- Amendments to IAS 19 “Defined Benefit Plans: Employee Contributions”;

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

- Amendments to IAS 16 and IAS 38 "Clarification of Acceptable Methods of Depreciation and Amortization";
- Amendments to IFRS 11 "Accounting for Acquisitions of Interests in Joint Operations".
- Amendments to IAS 1 relative to "disclosures"
- Annual improvements to IFRS: 2012 – 2014 cycle.

The impacts of the application of these standards on the consolidated financial statements are currently being analyzed.

### ***1.2. Consolidation methods***

The subsidiaries are all the entities for which the Company exercises control, with that control being accompanied generally by the ownership of more than half of the voting rights. The subsidiaries are consolidated by the full consolidation method beginning on the date on which the Company acquires the control of them. They are deconsolidated beginning on the date on which the controls cease to be exercised.

The intra-group transactions and balances are eliminated. The accounting methods of the subsidiaries have been aligned with those of the Company.

### ***1.3 Net investments abroad***

In compliance with the IAS 21 §15 standard, the foreign exchange translation gains and losses on long-term accounts receivable from his subsidiary in US dollars were recognized in equity. Indeed, these accounts receivables are considered as net investments in currencies within consolidated foreign subsidiaries, considering the unforeseeable nature of the payment of these receivables.

### ***1.4 Intangible assets***

In application of the criteria in the IAS 38 standard, the intangible assets acquired are recognized as assets in the balance sheet at their acquisition or production cost. The subsidies received and related the capitalized expenses are recognized as a reduction of cost.

#### ***Research and development expenses***

The research expenses are consistently recognized as expenses.

In accordance with IAS 38, the research costs are recognized as intangible assets only if all the following criteria are met:

- (a) Technical ability to complete the development project;
- (b) Intention on the part of the Company to complete the project and to utilize it;
- (c) Capacity to utilize the long-term intangible asset;
- (d) Proof of the probability of future economic benefits associated with the asset;
- (e) Availability of the technical, financial, and other resources for completing the project; and
- (f) Reliable measurement of the development expenses.

In application of this standard, the Company recognized all its R&D costs as expenses, until the first prototypes of Cellvizio were refined.

Development expenditures related to the refinement of new products were then recognized as assets, with those related to research and the improvements of existing products remaining as expenses for the fiscal year.

The development costs recognized as assets are amortized using the straight-line method, on their useful lifetime, over seven years for the projects put into service before December 31, 2013 and over five year for the projects put into service later on. The latter is treated as the period that runs until the obsolescence of the products recognized as assets.

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

*Patents*

The costs related to the filing of patents incurred by Mauna Kea Technologies until the latter were obtained are recognized as intangible assets because of the compliance with the criteria for the capitalization of said costs stipulated by IAS 38.

They are amortized on the basis of the straight line method over the term of protection granted.

*Software*

The costs related to the acquisition of the licenses to software packages are recognized as assets on the basis of the costs incurred to acquire and to implement the software packages in question.

They are amortized using the straight-line method over a period of 1 to 3 years.

**1.5 Property, plant, and equipment**

Property, plant, and equipment are recognized at their acquisition or production cost. The renovations and major improvements are capitalized, and the repair and maintenance expenses and the costs of the other renovation work are expensed as incurred. The subsidies received and related the capitalized expenses are recognized as a reduction of cost.

Property, plant, and equipment are depreciated on the basis of the straight-line method over the estimated lifetime of the property. The fixtures of property rented are depreciated over the term of their own lifetime or over the term of the rental agreement, whichever is shorter.

The Cellvizio at disposal in our partnership hospitals (Reference Centers), the Cellvizio at disposal in hospitals and having concluded a fee-for-service billing or a sale of consumables or the Cellvizio permanently used as demo equipment or replacement material are capitalized.

The depreciation periods used are the following:

Fixtures and improvements in structures.....	7 years,
Research and development tools.....	2 to 5 years,
Production tools.....	3 to 7 years,
Cellvizio at disposal in hospitals.....	5 years
Research equipment and Technical facilities.....	7 years,
Office equipment and furniture.....	5 years,
Computer equipment.....	3 years.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

### ***1.6 Recoverable amount of the non-current tangible and intangible assets***

Intangible assets and property, plant, and equipment are tested for impairment if the recovery of their book value is uncertain. With respect to the intangible assets in progress, even in the absence of indicators of impairment, an impairment test is conducted annually. An impairment loss is recognized to the extent of the excess of the carrying value over the recoverable value of the asset. The recoverable value of an asset corresponds to its fair value minus the costs of sale or its value in use, if the latter is higher.

With respect to the intangible assets of the Company, there do not exist any market data that allow the net fair value of the sale expenses to be determined other than by an estimation of the future cash flows. Consequently, the recoverable amount is, in substance, equal to the value in use.

The value in use is determined each year in accordance with IAS 36: It corresponds to the discounted value of the estimated future cash flows expected from the continuous use of the assets and from the derecognition of them at the end of the use expected by the Company. It does not take into account the impact of the financial structure, the tax effects, or restructuring efforts not undertaken.

### ***1.7 Financial assets***

The Company's financial assets include loans and receivables, and the cash and cash equivalents.

The valuation and the accounting treatment of the financial assets and liabilities are defined by the IAS 39 standard "Financial Instruments: Recognition and Measurement".

#### *Loans and receivables*

This category includes trade receivables, the other loans and receivables, and deposits and guarantees, which are classified under Non-current financial Assets on the balance sheet.

These instruments are initially recognized to the accounts at their fair value and then at the amortized cost calculated with the EIR method. The short-term receivables without an interest rate are measured at the amount of the original invoice unless the application of an implicit interest rate has a significant effect.

The company analyzes each of its trade receivables past due to determine whether an impairment loss should be recognized.

The loans and receivables are the object of a tracking of any objective indication of impairment. A financial asset is impaired if its book value is greater than its recoverable amount as estimated during impairment tests. The impairment is recognized in the income statement.

#### *Assets at fair value through profit or loss*

The assets considered to be held for trading purposes include the assets that the Company intends to resell in the near future in order to realize a capital gain, which is part of a portfolio of financial instruments managed together for which there exists a practice of selling in the short term.

### ***1.8 Inventories and work in progress***

The inventories are valued at their cost or at their net realizable value (NRV), if the latter is lower. In the latter case, the impairment loss is recognized in expenses. The inventories are measured according to the FIFO method.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

The demonstration equipment intended for sale in the short term is recognized in inventories.

### **1.9 Cash and cash equivalents**

The cash equivalents are owned for the purpose of meeting short-term cash commitments rather than for the objective of investment or for other purposes. They are readily convertible, into a known amount of cash, and are subject to a negligible risk of change in value. The cash and cash equivalents are constituted by liquid assets that are available immediately, long-term investments that can be liquidated immediately, and short-term investment securities. They are evaluated on the basis of the IAS 39 according to the categories they belong to.

The short-term investment securities are readily convertible into a known amount of cash and are subject to a negligible risk of change in value. They are measured at fair value, and changes in value are recorded in the financial gains or losses.

### **1.10 Issued capital**

The costs of share capital transactions that are directly attributable to the issue of new shares or options are recognized in equity as a deduction from the revenue from the issue, net of tax.

### **1.11 Liquidity contract**

Following its listing on the NYSE Euronext Paris regulated market, the Company signed a liquidity contract with a specialized institution in order to limit the intraday volatility of the Mauna Kea Technologies stock.

The portion of the contract that is invested in own shares of the Company by this service provider is posted to the accounts as a deduction from the consolidated shareholders' equity of the Company at the end of each fiscal year. The balance of "liquidity" is recorded as current financial assets.

### **1.12 Share-based payments**

Since its formation, the Company has established several plans for compensation paid in equity instruments in the form of "stock subscription warrants for business creator shares" [*bons de souscription de parts de créateur d'entreprise*, (BSPCEs)] awarded to employees and/or executives until the end of the Company's eligibility to this system in July 2014 and in the form of "stock subscription warrants" [*bons de souscription d'actions*, (BSAs)] awarded to non-employee members of the Board of Directors or of the Supervisory Board and in the form of stock subscription options granted to employees not entitled for BSPCEs (employees of the subsidiary Mauna Kea Technologies Inc, employees of the Company for the instruments awarded after July 2014).

In application of the IFRS 2 standard, the cost of the transactions paid with equity instruments is posted to the accounts as an expense in exchange for an increase in the shareholders' equity for the period during the course of which the rights to be enjoyed from the equity instruments are acquired.

The Company has applied the IFRS 2 standard to all the equity instruments granted, since 2002, to employees, members of the Board of Directors or of the Supervisory Board, natural persons, or to companies.

The fair value of the stock share subscription options granted to the employees is determined by application of the Black-Scholes option valuation model. The same is the case for the options granted to other natural persons who provide similar services, with the market value of the latter not being ascertainable.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

The determination of the fair value of the options includes the conditions governing the acquisition of the rights as described in Note 17: Share-based payments. The other factors taken into consideration are also presented in Note 17: Share-based payments.

### ***1.13 Measurement and recognition of financial liabilities***

#### *Financial liabilities at the amortized cost*

The borrowings and other financial liabilities are valued initially at their fair value and then at the amortized cost, calculated on the basis of the effective interest rate ("EIR") method.

The transaction expenses that are directly attributable to the acquisition or to the issue of a financial liability reduce that financial liability. These expenses are then amortized actuarially over the lifetime of the liability, on the basis of the EIR.

The EIR is the rate that equalizes the anticipated flow of future cash outflows with the current net book value of the financial liability in order to deduct from it its amortized cost.

#### *Liabilities at fair value through profit and loss*

The liabilities at fair value through profit and loss are measured at their fair value.

### ***1.14 Measurement and recognition of derivatives***

#### *Financial instruments used to hedge future cash flows*

The Company uses derivatives to manage and reduce its exposure to the risk of exchange rate fluctuations relating to its operating activities. Hedging exchange rate fluctuations only involves future cash flows on recorded assets or liabilities or a highly probable forecast transaction (e.g. expected purchase) that would impact the income statement.

Derivatives are measured at their fair value and recognized in the statement of financial position based on their maturity date. The Company applies hedge accounting by providing supporting documentation on the hedge relationship at the inception of each hedge and by assessing the effectiveness of the hedge relationship over the duration of the hedge. Fair value is based on quotations from third-party financial institutions.

The effective portion of derivative's gain or loss in fair value is recognized against equity and subsequently reclassified under operating profit/loss when the hedged transaction impacts profit/loss. The ineffective portion is reported under foreign exchange gains or losses.

### ***1.15 Conditional advances***

The Company receives a certain number of forms of assistance, in the form of subsidies or conditional advances. The details concerning this assistance are provided in Note 11: Borrowings and financial debts.

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A refundable loan under conditions is treated as a public subsidy if there exists reasonable assurance that the Company will fulfill the conditions related to the waiver of the repayment of the loan. If the contrary is the case, it is classified under debts.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

The amount resulting from the benefit of the rate obtained at the time of the granting of repayable advances does not bear interest and is considered a subsidy. This benefit is determined by applying a discount rate equal to the rate of 10-year fungible Treasury (10-year *Obligations Assimilables du Trésor*, "OAT") bonds.

### **1.16 Provisions**

#### *Provisions for risks and expenses*

The provisions for risks and expenses correspond to the commitments resulting from lawsuits and miscellaneous risks, the due dates and amounts of which are uncertain, with which the Company may be faced during its business activities.

A provision is recognized when the company has a legal or implicit obligation to a third party resulting from a past event, with respect to which it is likely or certain that it will cause an outflow of resources to that third party, without consideration that is anticipated to be at least equivalent to the latter, and for which the future outflows of liquid assets can be estimated reliably.

The amount recognized as a provision is the best estimate of the expenditure necessary to extinguish the obligation, updated if necessary, on the closing date.

#### *Retirement pension and post-employment benefits*

The employees of the Company receive the retirement benefits stipulated by law in France:

- obtaining compensation paid by the Company to employees upon their retirement (defined benefit plan);
- payment of retirement pensions by the Social Security agencies, which are financed by the contributions made by companies and employees (defined contribution government plans).

For the defined benefit plans, the costs of the retirement benefits are estimated by using the projected credit unit method. According to this method, the cost of the retirement pensions is recognized in the income statement in such a manner as to distribute it uniformly over the term of the services of the employees. The retirement benefits commitments are valued at the current value of the future payments estimated using the market rate based on the long-term obligations of the first-category companies with a term that corresponds to that estimated for the plan.

The company relies on actuaries qualified to conduct an annual review of the valuation of these plans.

In application to IAS 19 revised "Employee benefits", the service cost and net interest are recorded in operational result, and other remeasurements are included in other comprehensive income.

The Company's payments for the defined contribution plans are recognized as expenses on the income statement of the period with which they are associated.

### **1.17 Revenue from the ordinary business activities**

The sales revenue of the company is primarily the result of the sale of innovative medical imaging devices for medical diagnostics, research, and related services.

The revenue from the ordinary business activities comprises the fair value of the consideration received or receivable for the sale of goods in the ordinary course of the

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Company's activities. The revenue from the ordinary business activities appears net of the value added tax, product returns, rebates, and discounts, and after deduction of the intra-group sales

The Company posts revenue to the accounts when the amount can be valued reliably, when it is likely that the future economic advantages will benefit the Company. For sales of products, the sales revenue is recognized either at the time the products are made available or at or upon delivery depending on the terms and conditions of the order. The sales revenue related to the warranty is posted on the basis of the straight-line method over the lifetime of the warranty. When it is a matter of making Cellvizio available to a customer, Cellvizio remain as assets of the Company, and the sales revenue is recognized as the sale of consumables in the act performed by the health care professional.

### ***1.18 Other income***

#### *Subsidies*

Since it was created, because of its innovative character, the Company has received a certain number of sources of assistance or subsidies from the central Government or from local public authorities, intended to finance its operation or the recruitment of specific personnel.

The subsidies are recorded when there is a reasonable assurance that:

- the Company will comply with the conditions attached to the subsidies and ;
- the subsidies will be received.

A public subsidy that is to be received either as compensation for expenses or for losses already incurred, or for immediate financial support of the Company without associated future costs, is posted to the accounts as revenue for the fiscal year during the course of which the debt becomes owned as a receivable. Otherwise, the subsidy is posted in the accounts under "Other income" for the fiscal year to which the corresponding charges or expenses are posted.

#### *Research Tax Credit*

Research tax credits are granted to companies by the French government in order to encourage them to conduct technical and scientific research. Companies that prove that they have expenditures that meet the required criteria (research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause) receive a tax credit that can be used for the payment of the corporate tax due for the fiscal year in which the expenditures were made and the next three fiscal years, or, as applicable, be reimbursed for the excess portion.

The part of the tax credit used to finance research expenses is recognized under "Other income" of the year to which the eligible research expenses are related. The part used to finance eligible development expenses is deducted from costs related to assets.

### ***1.19 Cost of sales***

The cost of sales is made up of raw material consumption, labor costs, amortizations, inventory allowance and overheads relating to the production.

### ***1.20 Rental agreements***

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

The Group does not have any finance leases pursuant to the IAS 17 standard.

The rental agreements for which a significant portion of the risks and advantages is preserved by the lessor are classified as ordinary rental agreements. The payments made for these ordinary rental agreements, net of any incentive measures, are recognized as expenses on the income statement in a linear manner over the term of the agreement.

### ***1.21 Taxes***

#### ***Income tax***

The deferred income taxes are recognized on the basis of the broad conception and on the basis of the liability method, for all the temporary differences between the value for tax purposes and the stated book value of the assets and liabilities that appear within the financial statements. The primary temporary differences are related to the tax losses that can be carried forward or backward. The tax rates that have been ratified by a legal text as of the closing date are utilized to determine the differed taxes.

The deferred tax assets are posted to the accounts only to the extent that it is likely that the future profits will be sufficient to absorb the losses that can be carried forward. Considering its stage of development, the Company does not post assets net of deferred taxes to the accounts.

### ***1.22 Segment information***

The Company has not, as of this date, identified separate sectors of business activity. The Company operates within a single operating segment: endomicroscopy.

### ***1.23 Other comprehensive income***

The revenue and expense items for the period recognized directly in equity are presented, as applicable, under the rubric "Other comprehensive income". These are principally:

- EUR/USD currency translation differences of the subsidiary Mauna Kea Technologies, Inc;
- Changes in pension plan provisions arising from changes in the actuarial assumptions;
- The effective portion of the change in cash flow hedging instruments.

### ***1.24 Decisive accounting estimates and judgments***

The estimates and judgments made by the management while implementing the accounting methods described above are based on the historical information and on other factors, in particular, on the anticipation of future events judged to be reasonable in light of the circumstances. These estimates and judgments are primarily the following:

#### ***Valuation of the stock subscription warrants and stock subscription options***

The valuation of the fair value of the stock warrants and stock subscription options granted to employees or to service providers is made on the basis of actuarial models. These models require the use by the Company of certain calculation assumptions such as the expected volatility of the security.

**SECTION 20** - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

*Valuation of the long-term intangible assets*

The measurement of the use value of the long-term intangible assets is based on an assumption of growth in sales and a discount rate that reflects the best estimates of the management.

**1.25 Events after the closure of accounts**

The balance sheet and the income statement of the Company are adjusted to reflect the subsequent events that alter the amounts related to the situations that exist as of the closing date. The adjustments are made until the date the financial statements are approved by the Board of Directors.

The other events following the closing date that have not resulted in adjustments are presented in Note 25: Subsequent events.

Note 2: Company and scope

Founded in May 2000, Mauna Kea Technologies S.A. ("the Company") develops, produces and markets microendoscopes and probes and provides the related services.

To enhance its development in the United States, the Company founded the distribution subsidiary Mauna Kea Technologies, Inc., on January 3, 2005.

Companies	As of 31 December				Consolidation method
	2014		2013		
	% of	% of control	% of	% of control	
Mauna Kea Technologies SA (1)	100%	100%	100%	100%	Full consolidation
Mauna Kea Technologies Inc	100%	100%	100%	100%	Full consolidation

(1) Parent company of the Group

No change in scope took place during the period.

Note 3: Long-term intangible assets

The intangible assets are broken down as follows:

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

**INTANGIBLE ASSETS**

(Amounts in thousands of euros)

	<u>12/31/2012</u>	<u>Increase</u>	<u>Decrease</u>	<u>Reclassification</u>	<u>12/31/2013</u>
Development costs	2,313			35	2,348
Patents, licenses and trademarks	1,046	53		101	1,200
Software packages	204	50	(11)	114	357
Development costs in progress	390	713		(35)	1,069
Patents, licenses and trademarks in progress	539	141		(101)	579
Other intangible assets in progress	114	16		(114)	16
<b>Total gross of intangible assets</b>	<b>4,607</b>	<b>973</b>	<b>(11)</b>		<b>5,568</b>
Amort. / dép. of development costs	(1,052)	(283)			(1,335)
Amort. / dép. of patents, licenses and trademarks	(292)	(78)			(369)
Amort. / dép. of software packages	(100)	(63)	11		(151)
<b>Total amort. / dép. of intangible assets</b>	<b>(1,444)</b>	<b>(423)</b>	<b>11</b>		<b>(1,856)</b>
<b>Total net of intangible assets</b>	<b>3,163</b>	<b>550</b>			<b>3,713</b>

**INTANGIBLE ASSETS**

(Amounts in thousands of euros)

	<u>12/31/2013</u>	<u>Increase</u>	<u>Decrease</u>	<u>Reclassification</u>	<u>12/31/2014</u>
Development costs	2,348			1,275	3,623
Patents, licenses and trademarks	1,200	32		107	1,340
Software packages	357	39		16	413
Development costs in progress	1,069	207		(1,275)	
Patents, licenses and trademarks in progress	579	124		(107)	596
Other intangible assets in progress	16			(16)	
<b>Total gross of intangible assets</b>	<b>5,568</b>	<b>403</b>			<b>5,972</b>
Amort. / dép. of development costs	(1,335)	(406)			(1,741)
Amort. / dép. of patents, licenses and trademarks	(369)	(84)			(454)
Amort. / dép. of software packages	(151)	(84)			(236)
<b>Total amort. / dép. of intangible assets</b>	<b>(1,856)</b>	<b>(574)</b>			<b>(2,431)</b>
<b>Total net of intangible assets</b>	<b>3,713</b>	<b>(171)</b>			<b>3,542</b>

The period was marked by the launch of the marketing of the second generation Cellvizio Dual Band and the new 2.2 version of the Cellvizio software, which led to the start of amortization of the development costs relating to these projects.

**ANNUAL CHANGE IN DEVELOPMENT COSTS  
(CAPITALISED PORTION)**

(Amounts in thousands of euros)

	<u>As of 31 December</u>	
	<u>2014</u>	<u>2013</u>
External costs		90
Wages and salaries, social security costs	242	842
Research Tax Credit	(73)	(253)
Share-based payment transaction expense	38	34
<b>Gross change in development costs</b>	<b>207</b>	<b>713</b>
Amortisation of development costs	(406)	(283)
<b>Net change in development costs</b>	<b>(199)</b>	<b>431</b>

The intangibles assets are subject to an impairment test to determine their value in use, which is based on the discounted cash flows method and determined as follows:

- cash flow projections are determined for the years 2015 to 2019 based on future sales forecasts which correspond to the best estimates made by the management.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

For the tests conducted on patents, a final value calculated by taking into account a discounted normalized flow with a growth rate to infinity of 2% integrated into the measurement to the extent that the residual period of protection is greater than 5 years;

- the discounting rate used is the weighted average cost of the share capital of the Group of 12%. This is the rate used by financial analysts in the business sector who cover value.

These tests did not reveal any impairment of the assets tested.

A sensitivity test was conducted based on the following key assumptions used by management:

- Reduction in the sales growth rate by 5 points per year over the forecast period.
- Change in the EBITDA margin over sales ratio of  $\pm 1$  point of the normalized flow.
- Increase in the weighted average cost of the share capital of 1 point.

No impairment should be recognized as a result of the sensitivity tests conducted.

### NOTE 4: PROPERTY, PLANT, AND EQUIPMENT

The assets under property, plant, and equipment are broken down as follows:

PROPERTY, PLANT AND EQUIPMENT (Amounts in thousands of euros)						
	12/31/2012	Increase	Decrease / Scrapping	Exchange differences	Reclassification	12/31/2013
Industrial equipment	1,032	54	(189)	2	(24)	874
Fixture in buildings	50	1				51
Other tangible assets	636	153	(36)	(4)	(1)	747
<b>Total gross of property, plant and equipment</b>	<b>1,718</b>	<b>208</b>	<b>(226)</b>	<b>(2)</b>	<b>(25)</b>	<b>1,673</b>
Amort. / dép. of industrial equipment	(754)	(132)	189		17	(681)
Amort. / dép. of fixture in buildings	(18)	(7)				(24)
Dep other tang assets	(375)	(114)	36	2	1	(449)
<b>Total amort. / dép. of property, plant and equipment</b>	<b>(1,147)</b>	<b>(253)</b>	<b>226</b>	<b>2</b>	<b>17</b>	<b>(1,154)</b>
<b>Total net of property, plant and equipment</b>	<b>571</b>	<b>(45)</b>			<b>(7)</b>	<b>519</b>

PROPERTY, PLANT AND EQUIPMENT (Amounts in thousands of euros)						
	12/31/2013	Increase	Decrease / Scrapping	Exchange differences	Reclassification	12/31/2014
Industrial equipment	874	53		19	347	1,293
Fixture in buildings	51					51
Other tangible assets	747	199	(1)	12	(43)	914
<b>Total gross of property, plant and equipment</b>	<b>1,673</b>	<b>253</b>	<b>(1)</b>	<b>31</b>	<b>304</b>	<b>2,259</b>
Amort. / dép. of industrial equipment	(681)	(217)		(5)	39	(864)
Amort. / dép. of fixture in buildings	(24)	(7)				(31)
Dep other tang assets	(449)	(127)	1	(8)	13	(570)
<b>Total amort. / dép. of property, plant and equipment</b>	<b>(1,154)</b>	<b>(351)</b>	<b>1</b>	<b>(13)</b>	<b>52</b>	<b>(1,465)</b>
<b>Total net of property, plant and equipment</b>	<b>519</b>	<b>(98)</b>		<b>17</b>	<b>356</b>	<b>794</b>

Reclassifications refer to movements from one item to another, and the reclassification from inventory to non-current assets of equipment permanently used as demonstration or replacement equipment and equipment at disposal to clients of the Group.

In the absence of impairment indicators, no impairment tests were conducted to property, plant, and equipment.

### Note 5: Non-current financial assets

The non-current financial assets include only the security deposits paid according to ordinary rental agreements.

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 6: Inventories and work in progress

Inventories and work in progress are broken down as follows:

**INVENTORIES & WORK IN PROGRESS**

(Amounts in thousands of euros)

	As of 31 December	
	2014	2013
Inventories of raw materials	816	920
Inventories & work in progress of finished goods	1,216	1,414
<b>Total gross of inventories &amp; work in progress</b>	<b>2,032</b>	<b>2,334</b>
Dep. of inventories of raw materials	(74)	(59)
Dep. of inventories & work in progress of finished goods	(45)	(13)
<b>Total dep. of inventories &amp; work in progress</b>	<b>(120)</b>	<b>(72)</b>
<b>Total net of inventories &amp; work in progress</b>	<b>1,912</b>	<b>2,263</b>

At the end of each period, inventories and work in progress of finished goods include certain assets related to goods that no longer appear in our catalogue. These identified assets are kept by the Company so that After-Sales Customer Service can use them. They are impaired by 80%.

Note 7: Trade receivables and other current assets

**7.1 Trade and accounts payable**

The trade receivables are broken down as follows:

**TRADE RECEIVABLES**

(Amounts in thousands of euros)

	As of 31 December	
	2014	2013
Trade receivables	3,948	3,151
Dep. of trade receivables	(73)	(37)
<b>Total net of trade receivables</b>	<b>3,874</b>	<b>3,114</b>

Trade receivables past due and not impaired amounted to €928 thousand at December 31, 2014. The increase in trade receivables was due largely to larger outstandings at certain distributors.

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7.2 Other current assets

The other current assets are broken down as follows:

	<b>OTHER CURRENT ASSETS</b>	
	(Amounts in thousands of euros)	
	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Personnel and related accounts	50	28
Research Tax Credit	1,251	984
Other tax receivables	328	279
Other receivables	208	318
Prepaid expenses	328	250
<b>Total gross of other current assets</b>	<b>2,165</b>	<b>1,859</b>
Dep. of other current assets		
<b>Total net of other current assets</b>	<b>2,165</b>	<b>1,859</b>

Other taxes receivable are related to deductible VAT and reimbursement of VAT requested.

Other receivables mainly include advances to suppliers, amounting to €165 thousand in 2014 and € 282 thousand in 2013.

The prepaid expenses correspond, in 2014, mostly to insurance, rent, design, communication expenses and travel expenses.

Research Tax Credit

The changes in the Research Tax Credit were as follows:

	<b>CHANGES IN THE RESEARCH TAX CREDIT RECEIVABLE</b>				
	(Amounts in thousands of euros)				
	<b>12/31/2012</b>	<b>Operating revenue</b>	<b>Payment received</b>	<b>Capitalised portion</b>	<b>12/31/2013</b>
Research Tax Credit	1,100	732	(1,100)	253	984

	<b>CHANGES IN THE RESEARCH TAX CREDIT RECEIVABLE</b>				
	(Amounts in thousands of euros)				
	<b>12/31/2013</b>	<b>Operating revenue</b>	<b>Payment received</b>	<b>Capitalised portion</b>	<b>12/31/2014</b>
Research Tax Credit	984	1,178	(984)	73	1,251

The Company requested the reimbursement of the 2014 Research Tax Credit under the regime for EU SMEs, in accordance with current regulations. This reimbursement will be made in 2015.

**SECTION 20** - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 8: Current financial assets

The current financial assets item corresponds to the cash balance of the securities account opened under the Company's liquidity contract domiciled with Gilbert Dupont, i.e. €128 thousand at December 31, 2014 compared with €207 thousand at December 31, 2013.

Note 9: Cash and cash equivalents

Cash and cash equivalents are broken down as follows:

**CASH AND CASH EQUIVALENTS**  
(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Short-term bank deposits	14,375	3,287
Money market funds	643	24,505
<b>Total of cash and cash equivalents</b>	<b>15,018</b>	<b>27,792</b>

The amount of unrealized capital gains on cash equivalents was recorded under financial gains or losses.

The money market funds are broken down as follows:

**MONEY MARKET FUNDS**

	<b>Quantity</b>	<b>Price as of 12.31.2012 (in €)</b>	<b>Valuation (in K€)</b>	<b>Cost price (in K€)</b>
Actions BNP Paribas deposit P	629	1,022	643	643
<b>Total of money market funds</b>	<b>629</b>		<b>643</b>	<b>643</b>

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 10: Share capital

**10.1 Share capital issued**

The share capital is set at five hundred fifty-nine thousand seven hundred euros and seventy-six cents (€559,700.76). It is divided into 13,992,519 ordinary shares, fully subscribed and paid up, each with a par value of €0.04.

This figure does not include stock subscription warrants (BSAs), stock warrants for business creator shares (BSPCEs) and stock options granted to certain investors and natural persons, who may or may not be employees of the Company.

The table below shows the history of the Company's share capital since December 31, 2013:

Date	Type of transaction		Issued capital (en K€)	Share premium (en K€)	Number of shares comprising the issued capital
<b>12/31/2013</b>	<b>Total</b>		<b>552</b>	<b>57,501</b>	<b>13,803</b>
2/6/2014	Exercice of BSPCE		1	104	26
3/7/2014	Exercice of stock options		0	19	5
4/3/2014	Exercice of BSPCE		2	155	44
6/2/2014	Exercice of BSPCE		3	215	80
8/4/2014	Exercice of BSPCE		1	62	20
9/1/2014	Exercice of BSPCE		0	28	7
10/1/2014	Exercice of BSPCE		0	17	8
11/14/2014	Souscription of BSA			18	
12/22/2014	Souscription of BSA			24	
12/24/2014	Souscription of BSA			18	
<b>12/31/2014</b>	<b>Total</b>		<b>560</b>	<b>58,162</b>	<b>13,993</b>

**10.2 Stock warrants and options**

The Company issued stock subscription warrants (BSAs) representing compensation, stock warrants for employees (BSPCEs and BCEs) and stock options (SO) for which the changes since December 31, 2013 are presented below:

Type	Date of granting	Exercise price	Price	Outstanding as of 12.31.2012	Granted	Exercised	Cancelled	Outstanding as of 12.31.2013	Potential number of shares
Options granted before the 1st january 2014				<b>4,033,660</b>		<b>754,373</b>	<b>90,881</b>	<b>3,188,406</b>	<b>1,289,664</b>
BSPCE 2014	2/12/14	10.56			281,000		5,000	276,000	276,000
SO 2014	2/12/14	10.56			10,000		2,000	8,000	8,000
SO	9/1/14	6.02			100,000		100,000		
BSA	9/1/14	6.12			100,000			100,000	100,000
				<b>4,033,660</b>	<b>491,000</b>	<b>754,373</b>	<b>197,881</b>	<b>3,572,406</b>	<b>1,673,664</b>

Following the consolidation of shares (4 old shares for 1 new one) on May 25, 2011, four BSAs, BSPCEs, or stock options are needed to subscribe to one share for warrants with grant dates prior to that date. For warrants and options granted subsequent to that date, the rate is one warrant per share.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

### 10.3 Acquisition by the Company of its own shares

The Company's combined general meeting of June 11, 2014 authorized the Board of Directors, for a period of 18 months from the date of the meeting, to implement a share repurchase program, on one or more occasions, in accordance with the provisions of Article L. 225-209 and following of the French Commercial Code and in accordance with the General Regulations of the *Autorité des Marchés Financiers* (AMF) under the conditions described below:

#### Objectives of the share repurchase program :

- to ensure the liquidity of the Company's shares under the terms of a liquidity contract to be concluded with an investment services provider, in accordance with a Code of Conduct approved by the AMF;
- to meet the obligations related to stock option, free stock award, or employee savings plans, or other awards of shares to the employees and executives of the Company or the company associated with it;
- to tender shares on exercise of the rights attached to securities giving access to the share capital;
- to purchase shares to hold for their subsequent exchange or use as consideration in potential acquisitions; or
- to cancel some or all of the shares of stock thereby bought back.

**Maximum purchase price:** €30 per share excluding fees and commissions, with a total limit of €5,000,000.

**Maximum number of shares that may be purchased:** 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

It is specified that the number of shares acquired by the Company to be retained and subsequently delivered in payment or in an exchange for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of its share capital.

#### Summary of the shares purchased and sold over the year:

	2014				
	1st	2nd	3rd	4th	Total
Securities purchased	172,060	161,310	179,026	221,820	734,216
Price	11.50	11.11	6.61	5.95	8.54
Total amount	1,979	1,792	1,183	1,319	6,273
Securities sold	176,578	146,421	180,318	226,843	730,160
Price	11.50	11.12	6.64	5.91	8.48
Total amount	2,030	1,628	1,197	1,340	6,194

As at December 31, 2014, the Company held 17,537 Mauna Kea Technologies shares, purchased at an average price of €5.99 and valued at €5.75, resulting in a loss of €4 thousand.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 11: Borrowings and financial debts

### *11.1 Advances from BPI (formerly OSEO)*

Conditional advances from public authorities were made subject to a contract with "OSEO Innovation".

The Company has received three advance contracts of this type. The changes in their status are summarized below. These advances are 100% repayable (at their nominal value) in the event of technical and/or commercial success.

The reimbursable portion of the advances received with repayment terms of more than one year is posted as "Long-term debt", while the portion with repayment terms of less than one year is posted as "Short-term borrowings and financial debt".

#### *First advance*

On August 5, 2004, OSEO granted Mauna Kea Technologies interest-free aid in the amount of €400 thousand for the development of an industrial prototype of a multi-wavelength fiber confocal microscopy system to be used for in vivo molecular imaging. The entire amount of this aid had been reimbursed.

#### *Second advance*

On October 10, 2006, Mauna Kea Technologies obtained an interest-free repayable innovation aid in the amount of €620 thousand from OSEO for the development of a multi-modal endoscopic device to be used for medical diagnostics. The OSEO payments have been paid in installments between the date the agreement was signed and the end of the project as follows:

- First payment of €300 thousand after the agreement was signed (on October 30, 2006);
- Second payment of €180 thousand on May 14, 2010;
- Last payment of €140 thousand on June 10, 2013.

Repayment of this aid to support innovation began following the technical and commercial success of the project in accordance with the following terms:

- |                                    |               |
|------------------------------------|---------------|
| - September 30, 2012               | €150 thousand |
| - September 20, 2013               | €170 thousand |
| - No later than September 30, 2015 | €300 thousand |

#### *Third advance*

On May 31, 2010, Mauna Kea Technologies obtained repayable innovation aid of in the amount of €3,416 thousand from OSEO as part of the PERSEE project. It is the ambition of this project to develop, validate, and then market a device capable of improving diagnostic and pre-operative assessment techniques for cancer patients. The first payments on this advance are as follows:

- First payment of €454 thousand on May 31, 2010;
- Second payment of €1,138 thousand on December 21, 2011;
- Third payment of €685 thousand on May 29, 2013.

The OSEO grant stipulates two further payments totaling €1,139 thousand.

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Based on the initial contract, the Company is required to reimburse OSEO a total of €3,996 thousand including 2.45% interest once total sales of €2,500 thousand is reached. This amount will be updated according to the amounts actually received.

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**11.2 COFACE advances**

The Company received interest-free repayable advances from COFACE for its development in the USA and Canada, in accordance with the following terms:

- First payment of €212 thousand on February 29, 2008;
- Second payment of €652 thousand on December 23, 2008;
- Third payment of €560 thousand on January 26, 2010;
- Fourth payment of €280 thousand on December 27, 2010.

Repayment will be made with payments determined on the basis of projections of sales revenue in the USA and Canada, from the use of products and services generated by the project up to the following limits:

- 14% of sales revenue related to services provided;
- 7% of the sales revenue in the case of sales of goods.

In the event that revenue is inadequate for the expected repayments, no additional repayments will be made to COFACE.

From 2011 to 2014, the Company made repayments to COFACE amounting to €986 thousand. On the basis of the most recent commercial forecasts, the repayment of the remaining €718 thousand should occur no later than August 31, 2018.

**CHANGES IN REPAYABLE ADVANCES**

(Amounts in thousands of euros)

	<u>12/31/2012</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Others</u>	<u>12/31/2013</u>
OSEO Funding (1st advance)	120		(120)		
OSEO Funding (2nd advance)	324	140	(170)	4	297
OSEO Funding (3rd advance)	1,433	685		(42)	2,075
COFACE	1,212		(324)	6	894
<b>Total of repayable advances</b>	<b><u>3,088</u></b>	<b><u>825</u></b>	<b><u>(614)</u></b>	<b><u>(32)</u></b>	<b><u>3,266</u></b>

	<u>12/31/2013</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Others</u>	<u>12/31/2014</u>
OSEO Funding (1st advance)					
OSEO Funding (2nd advance)	297			3	300
OSEO Funding (3rd advance)	2,075			126	2,201
COFACE	894		(203)	24	715
<b>Total of repayable advances</b>	<b><u>3,266</u></b>		<b><u>(203)</u></b>	<b><u>153</u></b>	<b><u>3,216</u></b>

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**11.3 Long-term loans and borrowings**

Long-term debt is broken down as follows:

<b>LONG-TERM LOANS AND BORROWINGS</b>						
(Amounts in thousands of euros)						
	<u>12/31/2012</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Reclassification</u>	<u>Others</u>	<u>12/31/2013</u>
Shareholders' accounts	5					5
Repayable advances OSEO Funding	1,586	685		(180)	(15)	2,075
Repayable advances COFACE	771			(214)	6	563
<b>Total of long-term loans and borrowings</b>	<b>2,362</b>	<b>685</b>		<b>(394)</b>	<b>(10)</b>	<b>2,643</b>

	<u>12/31/2013</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Reclassification</u>	<u>Others</u>	<u>12/31/2014</u>
Shareholders' accounts	5					5
Repayable advances OSEO Funding	2,075				149	2,224
Repayable advances COFACE	563			(209)	23	377
<b>Total of long-term loans and borrowings</b>	<b>2,643</b>			<b>(209)</b>	<b>172</b>	<b>2,606</b>

For 2014, the amounts under reclassifications include the reclassification from short-term financial debt of the undiscounted portion of repayable advances in the amount of €203 thousand due in 2015.

The changes listed under "Others" involve the discounting of the long-term conditional advances.

**11.4 Cash flow hedges**

To hedge its exposure to exchange rate risk for a portion of its cash flows from operating activities in foreign currencies, the Group had initiated a hedging program for the yen and subscribed a forward contract agreement of JPY 50 millions, with a maturity date in October 2014.

For 2014 the required criteria of hedge effectiveness are not sufficient to sustain the hedging relationship, the €(30) thousand registered in equity in 2013 had been recycled in financial result in 2014.

**11.5 Repayment terms of financial liabilities**

The repayment terms of financial liabilities as of December 31, 2014 are broken down as follows:

<b>REPAYMENT TERMS OF LIABILITIES</b>				
(Amounts in thousands of euros)				
	<u>Gross amount</u>	<u>Less than one year</u>	<u>One to three years</u>	<u>Three to five years</u>
Long-term loans and borrowings	2,606		1,122	1,484
Short-term loans and borrowings	638	638		
Trade payables	2,238	2,238		
Other current liabilities	3,388	3,388		
<b>Total of liabilities</b>	<b>8,870</b>	<b>6,264</b>	<b>1,122</b>	<b>1,484</b>

The repayment terms of long-term loans and borrowings and short-term loans and borrowings relating to repayable advances are determined based on the planned repayment estimates as at December 31, 2014.

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Note 12: Non-current provisions

Non-current provisions are broken down as follows:

**NON-CURRENT PROVISIONS**

(Amounts in thousands of euros)

	<u>12/31/2012</u>	<u>Allowance</u>	<u>Unused reversals</u>	<u>Used reversals</u>	<u>Others</u>	<u>12/31/2013</u>
Pension plan provision	174	27	(14)		(6)	181
Provisions for personnel disputes	244				(11)	233
Provision for software update	23		(8)			15
Others provisions for expenses	40	10	(15)			36
<b>Total of non-current provisions</b>	<b>481</b>	<b>37</b>	<b>(36)</b>		<b>(17)</b>	<b>465</b>

**NON-CURRENT PROVISIONS**

(Amounts in thousands of euros)

	<u>12/31/2013</u>	<u>Allowance</u>	<u>Unused reversals</u>	<u>Used reversals</u>	<u>Others</u>	<u>12/31/2014</u>
Pension plan provision	181	55	(28)		79	287
Provisions for personnel disputes	233	91	(242)		9	91
Provision for software update	15					15
Others provisions for expenses	36	82			7	125
<b>Total of non-current provisions</b>	<b>465</b>	<b>228</b>	<b>(270)</b>		<b>95</b>	<b>518</b>

The changes listed under "Others" related first to actuarial differences in valuation of pension obligations of €79 thousand in 2014 against €6 thousand in 2013; and secondly, currency exchange adjustments of €16 thousand in 2014 versus €11 thousand in 2013.

**12.1 Commitments related to lump-sum compensation paid upon retirement**

For estimated retirement commitments, the following assumptions were used for all categories of employees (employees, ETAM [Employees, Technicians, and Supervisors], and managers):

**PENSION PLAN PROVISION**

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
% social security expenses	48%	47%
Salary increases	2%	2%
Discount rate	1.89%	3.50%

- Retirement age: 65;
- Terms of retirement: voluntary retirement;
- Mortality table: INSEE 2014 in 2014 and INSEE 2013 in 2013;
- Collective agreement: metal industries;
- Digressive employee turnover based on age.

The Company does not finance its pension plan provision. No retirements took place over the last 2 fiscal years.

The discount rate comes from iBoxx Corporate AA10+ references adjusted for the term of the Company's plan estimated at 23 years.

**12.2 Provisions for employee litigation**

In May 2014 an employee lawsuit in the United States was resolved in our favor, without any monetary cost to the Group. Since the provision was no longer called for, it was completely reversed.

**12.3 Other provision for risks and expenses**

The provisions for updating of software packages were recognized in order to cover the costs of updating Cellvizio products from version 1.0 to version 1.5.

On December 31, 2014 the Group recognized a provision of €82 thousand for a commercial lawsuit in the United States.

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 13: Trade payable and other current liabilities

No discounts were made on trade payables and other current liabilities because they matured within one year at the end of each fiscal year in question.

**13.1 Trade payables**

Trade payables were broken down as follows:

	<b>TRADE PAYABLES</b>	
	<i>(Amounts in thousands of euros)</i>	
	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Trade payables	<u>2,238</u>	<u>2,439</u>

**13.2 Other current liabilities**

The other current liabilities are broken down as follows:

	<b>OTHER CURRENT LIABILITIES</b>	
	<i>(Amounts in thousands of euros)</i>	
	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Taxes payable	202	132
Staff and social security payable	2,466	2,174
Other payable	53	243
Deferred revenue	667	630
<b>Total of other current liabilities</b>	<b><u>3,388</u></b>	<b><u>3,178</u></b>

Tax liabilities mainly concern taxes on payroll, turnover and value added tax.

The social debts are related to social contribution expenses, annual bonuses, and vacation compensation payable.

Deferred income essentially comprises maintenance contracts on systems sold (maintenance periods of one to three years), as well as a one-year warranty on Cellvizio.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 14: Financial assets and liabilities on balance sheet and their impact on the profit

### FINANCIAL INSTRUMENTS ON BALANCE SHEET AND THEIR IMPACT ON THE PROFIT (OR LOSS)

(Amounts in thousands of euros)

As of 31 December 2013	Value on the balance sheet	Fair value through profit or loss	Fair value through equity	Loans and receivables	Debt at amortised cost
<b>Assets</b>					
Non-current financial assets	77			77	
Trade receivables	3,114			3,114	
Other current assets (2)	1,327			1,327	
Current financial assets	207			207	
Cash equivalents (1)	24,505	24,505			
Cash	3,287			3,287	
<b>Total of assets</b>	<b>32,518</b>	<b>24,505</b>		<b>8,013</b>	
<b>Liabilities</b>					
Long-term loans and borrowings	2,643				2,643
Short-term loans and borrowings	659		30		629
Trade payables	2,439				2,439
Other current liabilities	2,548				2,548
<b>Total of liabilities</b>	<b>8,289</b>		<b>30</b>		<b>8,259</b>
As of 31 December 2014	Value on the balance sheet	Fair value through profit or loss	Fair value through equity	Loans and receivables	Debt at amortised cost
<b>Assets</b>					
Non-current financial assets	105			105	
Trade receivables	3,874			3,874	
Other current assets (2)	1,672			1,672	
Current financial assets	128			128	
Cash equivalents (1)	643	643			
Cash	14,375			14,375	
<b>Total of assets</b>	<b>20,797</b>	<b>643</b>		<b>20,154</b>	
<b>Liabilities</b>					
Long-term loans and borrowings	2,606				2,606
Short-term loans and borrowings	638				638
Trade payables	2,238				2,238
Other current liabilities	2,721				2,721
<b>Total of liabilities</b>	<b>8,203</b>				<b>8,203</b>

(1) The assessment of the fair value of financial assets at fair value on profit refers to an active market (Level 1 category according to IFRS 7).

(2) Advances paid and received that are not repaid in cash, deferred income and prepaid expenses that are not defined as financial liabilities are not included here.

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Note 15: Sales revenue and operating revenue

Sales and operating revenue consist of the following:

**SALES AND OPERATING REVENUE**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Sales	11,016	9,977
Subsidies	4	13
Research Tax Credit and other tax credits	1,239	826
Discounted portion of repayable advances	23	78
Other income	1	22
<b>Total of revenue</b>	<b>12,282</b>	<b>10,915</b>

The Group's sales comprise the sale of Cellvizio products and accessories (probes, software and others) as well as services.

The other tax credits cover the amount of the competitiveness and employment tax credit.

**SALES BY TYPE**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Total sales of "equipements"	7,175	6,835
Total sales of "consumables" (probes)	2,958	2,603
Total sales of "services"	882	538
<b>Total sales by type</b>	<b>11,016</b>	<b>9,977</b>

Sales revenue by geographical area is as follows:

**SALES BY GEOGRAPHICAL AREA**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
EMEA (Europe, Middle-east, Africa)	3,197	2,973
<i>including France</i>	<i>1,047</i>	<i>1,073</i>
America	4,013	4,502
<i>including USA</i>	<i>2,810</i>	<i>3,536</i>
Asia	3,806	2,502
<i>including China</i>	<i>995</i>	<i>1,136</i>
<i>including Japan</i>	<i>1,446</i>	<i>587</i>
<b>Total sales by geographical area</b>	<b>11,016</b>	<b>9,977</b>

For the purposes of the geographical analysis, the management of the Group allocates the sales revenue on the basis of the place where the products are delivered or, if services are provided, on the basis of the location of the corporate headquarters of the customer.

At December 31, 2013 one customer represented more than 10% of sales revenue.

At December 31, 2014 none of the Group's customers' accounts represented more than 10% of sales revenue.

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 16: Staff costs

The Group employed 120 persons as of December 31, 2014 as against 112 persons as of December 31, 2013.

Employee expense was as follows:

**EMPLOYEE BENEFITS EXPENSE**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Wages and salaries, social security costs	12,364	10,739
Pension costs	27	13
Share-based payment transaction expenses	1,257	851
<b>Total of employee benefits expense</b>	<b>13,648</b>	<b>11,603</b>

Note 17: Share-based payments

The share-based payments include all warrants (BSAs/BSPCEs/Stock Options) awarded to employees, to non-employee members of the Board of Directors or of the Supervisory Board or service providers.

They were recognized as expenses beginning in the year they were awarded, with the exception of the BCE-A of August 4, 2008 and of the 100 000 2014-BSPCEs with immediate vesting, the terms of acquisition of the BSPCEs and the stock options are as follows:

- 25% of the BSPCEs/Stock Options are vested, assuming beneficiaries remain within the Group on or after the first anniversary of the day they were awarded;
- 25% of the BSPCEs/Stock Options are vested, assuming beneficiaries remain within the Group on or after the second anniversary of the day they were awarded;
- 25% of the BSPCEs/Stock Options are vested, assuming beneficiaries remain within the Group on or after the third anniversary of the day they were awarded;
- The remainder (25% of the BSPCEs/Stock Options) are vested, assuming beneficiaries remain within the Group on or after the fourth anniversary of the day they were awarded;

The terms and conditions governing the acquisition of the stock warrants granted during the 2011 and 2014 fiscal years are the following:

- 33.3% of the stock warrants are vested, assuming beneficiaries remain within the Group beginning on the first anniversary of the date on which they were granted;
  - 33.3% of the stock warrants are vested, assuming beneficiaries remain within the Group beginning on the second anniversary of the date on which they were granted;
- The remaining balance, that is, 33.3% of the stock warrants, may be exercised beginning on the third anniversary of the date they were granted;

With exception of the SO awarded in 2011, exercisable no later than 7 years of the date of their issuance, the warrants (BSAs/BSPCEs/Stock Options) are exercisable no later than ten 10 years of the date of their issuance. It being specified that the stock warrants that have not yet been exercised upon the expiration of this period of ten years would be null and void by operation of law.

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All outstanding warrants as of December 31, 2014 break down as follows:

SHARE-BASED PAYMENTS									
Type	Date of granting	Exercise price	Expiration date	Number of warrants	Cancelled	Exercised	Outstanding warrants at 12/31/2014	Equivalent in shares at 12/31/2014	Equivalent in shares vestable at 12/31/2014
BSPCE 4	7/11/05	0.5671	7/11/15	80,000	0	0	80,000	20,000	20,000
BSPCE 5	3/10/06	0.916	3/10/16	310,950	17,500	158,450	135,000	33,750	33,750
BSPCE 5	8/10/06	0.916	8/10/16	100,000	20,000	45,000	35,000	8,750	8,750
BSPCE 5	9/13/06	0.916	9/13/16	20,000	10,000	0	10,000	2,500	2,500
BSPCE 5	10/9/06	0.916	10/9/16	25,000	0	0	25,000	6,250	6,250
SO 2008	6/2/08	1.00	6/2/15	670,000	230,000	188,592	251,408	62,852	62,852
BSPCE 6	8/4/08	1.00	8/4/18	1,225,000	570,008	337,492	317,500	79,375	79,375
BCE-A	8/4/08	1.00	8/4/18	500,000	0	4	499,996	124,999	124,999
BSPCE 6	12/8/08	1.00	12/8/18	35,000	0	0	35,000	8,750	8,750
SO 2008	1/30/09	1.00	1/30/16	40,000	0	4,000	36,000	9,000	9,000
BSPCE 6	11/24/09	1.00	11/24/19	637,500	273,756	192,492	171,252	42,813	42,813
SO 2008	3/1/10	1.00	3/1/17	250,000	100,000	10,000	140,000	35,000	35,000
SO 2010	1/31/10	1.00	1/31/21	245,000	88,750	56,250	100,000	25,000	18,750
BSPCE 2010	2/15/11	1.00	2/15/21	915,000	120,000	259,500	535,500	133,875	89,813
SO 2010	2/15/11	1.00	2/15/21	50,000	40,000	0	10,000	2,500	1,875
BSPCE 2010	3/1/11	1.00	3/1/21	200,000	0	150,000	50,000	12,500	0
SO 2010	4/1/11	1.00	4/1/21	100,000	0	0	100,000	25,000	18,750
BSA	7/5/11	13.00	7/5/21	80,000	0	0	80,000	80,000	80,000
BSPCE 2011	12/5/11	13.00	12/5/21	129,500	68,250	0	61,250	61,250	54,375
SO 2011	12/5/11	11.44	12/5/21	288,153	268,153	0	20,000	20,000	15,000
BSPCE 2012	12/4/12	10.79	12/4/22	239,500	21,625	625	217,250	217,250	107,900
SO 2012	12/4/12	10.79	12/4/22	161,000	31,000	0	130,000	130,000	65,000
BSPCE 2013	5/7/13	10.28	5/7/23	63,000	15,750	0	47,250	47,250	13,500
SO 2013	12/9/13	10.05	12/9/23	101,000	0	0	101,000	101,000	25,250
BSPCE 2014	2/12/14	10.56	2/12/24	281,000	5,000	0	276,000	276,000	0
SO 2014	2/12/14	10.56	2/12/24	10,000	2,000	0	8,000	8,000	0
BSA 2014	9/1/14	6.12	9/1/24	100,000	0	0	100,000	100,000	0
BSPCE 2014	9/1/14	6.02	9/1/24	100,000	100,000	0	0	0	0
				<b>6,956,603</b>	<b>1,981,792</b>	<b>1,402,405</b>	<b>3,572,406</b>	<b>1,673,664</b>	<b>924,252</b>

The other primary assumptions used to determine share-based payments expense by applying the Black-Scholes valuation model for options were as follows:

- Risk-free interest rate: rate of government borrowings (GFRN index) ;
- Dividend: none;
- Turnover: 15%;
- Volatility: 60% for the BSAs, BSPCEs and stock options granted before December 31, 2011, 35% for the BSPCEs and stock options granted in 2012, 34% for the BSPCEs and stock options granted in 2013 and 33% for plans granted in 2014.
- As of 2012, the volatility applied corresponds to the average historic volatility of a basket of stocks of listed companies in the sector of industry in which the Company operates and/or have a market capitalization and traded share volume comparable with those of the Company. Listed companies whose shares were traded for less than 1 euro were excluded from the panel.

The exercise price, estimated lifespan, and fair value of underlying shares as of the grant date of the warrants were used for the valuation of each category of share-based compensation.

The expense of share-based payments during the period breaks down as follows:

SHARE-BASED PAYMENTS		
(Amounts in thousands of euros)		
	As of 31 December	
	2014	2013
BSPCE	905	685
Stock Options	327	83
BSA	63	117
<b>Total share-based payments</b>	<b>1,295</b>	<b>885</b>
Capitalised part on R&D	-38	-34
<b>Expense IFRS 2 of the period</b>	<b>1,257</b>	<b>851</b>

SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 18: External expenses

**18.1 Research & Development Department**

**RESEARCH & DEVELOPMENT**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Purchases consumed	59	26
Employee benefits expenses	2,607	2,135
External expenses	1,259	1,015
Net change in amortisation and depreciation	658	435
<b>Total of Research &amp; Development</b>	<b>4,583</b>	<b>3,611</b>

**18.2 Sales & Marketing Department**

**SALES & MARKETING**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Purchases consumed	89	70
Employee benefits expenses	7,516	6,263
External expenses	5,085	4,735
Net change in amortisation and depreciation	62	106
<b>Total of Sales &amp; Marketing</b>	<b>12,753</b>	<b>11,174</b>

**18.3 Overhead**

**ADMINISTRATIVE EXPENSES**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Purchases consumed	56	59
Employee benefits expenses	1,752	1,893
External expenses	1,739	1,594
Taxes	130	85
Net change in amortisation and depreciation	159	128
<b>Total of Administrative expenses</b>	<b>3,837</b>	<b>3,759</b>

Note 19: Financial income and expenses

Financial income and expenses are broken down as follows:

**FINANCIAL REVENUE AND EXPENSES**

(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Foreign exchange gains	124	97
Gains on cash equivalents	123	110
Other financial incomes	4	
<b>Total of financial revenue</b>	<b>251</b>	<b>207</b>
Foreign exchange losses	(218)	(56)
Losses on cash equivalents	(25)	(100)
Discounting expenses	(176)	(44)
<b>Total of financial expenses</b>	<b>(419)</b>	<b>(202)</b>
<b>Total of financial revenue and expenses</b>	<b>(168)</b>	<b>5</b>

**SECTION 20** - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Note 20: Income tax expense

According to the legislation in force, the Group has tax losses that may be carried forward indefinitely in France in the total amount of €59,963 thousand and tax losses that may be carried forward for 20 years in the United States in the total amount of €25,113 thousand, that is, a total of €85,076 thousand as of December 31, 2014. The deferred tax asset base net of temporary passive differences was not capitalized in order to be conservative, pursuant to the principles described in Note 1: Accounting principles.

The tax rate applicable to the Company is the rate in effect in France (33.33%). By convention, the deferred income tax rate used is 34.43%.

**TAX RECONCILIATION**  
(Amounts in thousands of euros)

	As of 31 December	
	2014	2013
Profit / (loss)	(13,991)	(11,516)
Income tax expense		
<b>Profit before tax</b>	<b>(13,991)</b>	<b>(11,516)</b>
<b>Theoretical tax expense - 34.43%</b>	<b>(4,817)</b>	<b>(3,965)</b>
Other non-deductible expenses and tax-exempt income	28	27
Effect of tax rate differences	(34)	(22)
Deferred tax assets not recognised	4,824	3,960
<b>Actual income tax expense</b>		

Note 21: Commitments

*Obligations pursuant to ordinary rental agreements*

A new commercial lease was signed by Capkey Gates at Sugarloaf Partners LLC and Mauna Kea Technologies Inc. to rent the offices located at 1325 Satellite Boulevard, Unit 108, Suwanee, GA, 333024 United States from February 1, 2013 to February 28, 2017.

In addition, the Company has entered into leases on vehicles and office equipment.

The firm and unconditional commitments under ordinary rental agreements are broken down as follows as of December 31, 2014:

**OBLIGATIONS PURSUANT TO  
ORDINARY RENTAL AGREEMENTS**  
(Amounts in thousands of euros)

	As of 31 December	
	2014	2013
Portion with terms of less than 1 year	224	211
Portion with terms of between 1 and 5 years	448	429
Portion with terms of more than 5 years	89	119
<b>Total of commitments pursuant to ordinary rental agreements</b>	<b>761</b>	<b>759</b>

**SECTION 20** - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

*Commitments under other contracts*

The Company subcontracts the manufacturing of some of the sub-assemblies necessary for the manufacturing of its products with suppliers. In order to secure these operations, it has made commitments to purchase a certain quantity of sub-assemblies from those suppliers as described in the table below.

**OBLIGATIONS PURSUANT TO  
OTHER AGREEMENTS**  
(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Portion with terms of less than 1 year	1,526	1,558
Portion with terms of between 1 and 5 years	1,858	168
<b>Total of supplier commitments</b>	<b>3,384</b>	<b>1,726</b>

The increase in supplier liabilities was due to renegotiation of the contract with the Japanese supplier of fiber optics over the next three years.

There were no material changes to the Company's other commitments over the year.

Note 22: Transactions with related parties

The amounts of compensation presented below, which were granted to the members of the Company's executive staff and other related parties, were recognized as expenses during the periods presented:

**RELATED PARTY TRANSACTIONS**  
(Amounts in thousands of euros)

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
Wages and salaries - General direction	219	288
Wages and salaries other related party	86	105
Share-based payments - General direction (*)	333	
Share-based payments other related party	1	11
Fees	36	

The valuation method used for the benefits related to these share-based payments is presented in Note 17: Share-based payments.

(\*) Plan of 100,000 BPCEs was awarded on February, 12<sup>th</sup> 2014, with a subscription price at 10,56€ per share.

Note 23: Net earnings per share

*Basic earnings*

Basic earnings per share are calculated by dividing the net earnings attributable to the shareholders of the Company by the weighted average number of shares of ordinary and stock outstanding during the year.

**EARNINGS PER SHARE**

	<b>As of 31 December</b>	
	<b>2014</b>	<b>2013</b>
<b>Profit / (loss) (in K€)</b>	<b>(13,991)</b>	<b>(11,516)</b>
Weighted average number of shares outstanding (in thousands)	13,905	13,727
<b>Earnings per share (in €)</b>	<b>(1.01)</b>	<b>(0.84)</b>
Weighted average number of potential shares (in thousands)	15,588	15,317

**SECTION 20** - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

Instruments that grant rights to the share capital on a deferred basis (BSAs, BSPCEs or stock options) are considered anti-dilutive because they cause an increase in earnings per share. Thus, diluted earnings per share are identical to basic earnings per share.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

### Note 24: Management of financial risk

The main financial instruments used by the Group are financial assets, cash, and investment securities. The purpose of managing these instruments is to finance the Company's business activity. It is the Group's policy not to subscribe to financial instruments for speculative purposes. For the first time in 2013, the Company bought a derivative instrument to hedge future cash flows.

The primary risks to which the Group is exposed are interest rate risk and credit risk.

#### *Exchange rate risk*

The main currencies for which the Group is exposed to a significant exchange rate risk are the US dollar and the yen.

The purpose of the Mauna Kea Technologies Inc. subsidiary established in the State of Georgia is to distribute and market the Group's products in the United States. To this end, it is fully financed by the parent company, with which it has established three agreements:

- a cash management agreement for a current account in USD;
- a distribution agreement;
- a service agreement (Management fees).

The Group's major exchange rate risk is linked to the Euro/USD parity fluctuation. In fact, the Group markets the product and services in the USA through its subsidiary Mauna Kea Technologies Inc. Its revenues and expenses - including the purchases of Cellvizio and probes to Mauna Kea Technologies SA - are expressed in US dollars the operational currency of the subsidiary. As a result, the Group is exposed to changes in the EUR/USD exchange rate through that subsidiary.

A change in exchange rates has an impact on Group earnings and shareholders' equity in the same manner, as follows:

- A variation in the EUR/USD exchange rate of +10% would have generated an improvement in earnings of €527 thousand as of December 31, 2014;
- A variation in the EUR/USD exchange rate of -10% would have generated a drop in earnings of €(644) thousand as of December 31, 2014.

In 2013, the Company entered into a yen forward contract to reduce its exposure to exchange rate risk on future purchases. It expired in 2014. There are no other contracts covering this risk.

#### *Liquidity risk*

See Note 1.9: Cash and cash equivalents

#### *Interest Rate Risk*

The Company's exposure to interest rate risk primarily involves cash equivalents and investment securities. These are comprised of money market funds and term deposit accounts. Changes in interest rates have a direct impact on the rate of return for these investments and the cash flows generated.

As of December 31, 2014, the Company's financial debt was not subject to interest rate risk because it primarily involved interest-free repayable advances or preferred-interest rate in a total non-discounted amount of €3,296 thousand as described in Note 11: Borrowings and financial debt

As of this date, the Company has not taken out any loans with credit institutions and therefore has only a very low exposure to interest rate risk.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

### *Credit Risk*

In the Company's experience, the payment of certain public financing of research expenditures is subject to credit risk.

The Company manages its available cash in a prudent manner. Cash and cash equivalents include available cash and current financial instruments owned by the Company (mostly money market funds). As of December 31, 2014, the available cash and investment securities owned by the Company were for the most part invested in products with a maturity of less than 12 months.

Credit risk related to cash, cash equivalents, and current financial instruments is insignificant in light of the quality of the co-contracting financial institutions.

With regard to its trade receivables, the Company has no significant concentration of credit risk.

### *Fair value*

The fair value of financial instruments traded on an active market is based on the market price at the balance sheet date. The market prices used for the financial assets held by the Company are the purchase prices in effect on the market as of the valuation date.

The nominal value, minus provisions for impairment, of other payables and receivables is assumed to approach the fair value of those items.

### Note 25: Subsequent events

On March 11, 2015 the Company established a line of equity financing with Société Générale based on the 20th resolution of the General Meeting of Shareholders on June 11, 2014.

At the share price on that date, the total use of this financing line would bring the Company additional financing of €7 million.

As part of this financing line, and subject to compliance with certain conditions (floor price subscription and minimum average daily volume traded), Société Générale agreed to subscribe 1,390,000 new shares, representing 9.9% of the current capital stock by January 11, 2016, with at least half by July 11, 2015, what times and in what fractions Société Générale may choose.

For each tranche, the issue price will bear a 5% discount off the average price, weighted by the volumes traded in the preceding three sessions. In March 2015, first month of the implementation of this line of equity financing, 140,000 stock subscription warrants have been subscribed in an amount of €704,900.

## **20.2. Pro forma financial information**

Not applicable.

## **20.3. Historical financial statements of Mauna Kea Technologies**

Because the Company has prepared consolidated financial statements for the reference period, the Company's individual historical financial statements for the period are not included in this Registration Document.

## 20.4. Verification of historical annual financial information

COFIDEC  
155, boulevard Haussmann  
75008 Paris  
S.A.R.L. au capital de € 32.800

ERNST & YOUNG et Autres  
1/2, place des Saisons  
92400 Courbevoie - Paris-La Défense 1  
S.A.S. à capital variable

Commissaire aux Comptes  
Membre de la compagnie  
régionale de Paris

Commissaire aux Comptes  
Membre de la compagnie  
régionale de Versailles

Mauna Kea Technologies  
Year ended December 31, 2014

Statutory auditors' report on the consolidated financial statements

To the Shareholders,

In compliance with the assignment entrusted to us by your annual general meetings, we hereby report to you, for the year ended December 31, 2014, on:

- the audit of the accompanying consolidated financial statements of Mauna Kea Technologies;
- the justification of our assessments;
- the specific verification required by law.

These consolidated financial statements have been approved by the board of directors. Our role is to express an opinion on these consolidated financial statements based on our audit.

### I. Opinion on the consolidated financial statements

We conducted our audit in accordance with professional standards applicable in France; those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit involves performing procedures, using sampling techniques or other methods of selection, to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made, as well as the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

In our opinion, the consolidated financial statements give a true and fair view of the assets and liabilities and of the financial position of the group as at December 31, 2014 and of the results of its operations for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union.

### II. Justification of our assessments

In accordance with the requirements of article L. 823-9 of the French commercial code (*Code de commerce*) relating to the justification of our assessments, we bring to your attention the following matters:

- As part of our assessment of the accounting policies used by your group, we examined the methods used to capitalize, depreciate and impair intangible assets. We ensured that the information provided in notes "1.4: Intangible assets" and "1.6: Recoverable amount of the non-current tangible and intangible assets" to the consolidated financial statements provide appropriate information on the methods used by your group.

## SECTION 20 - Financial information concerning the issuer's assets and liabilities, financial position and profits and losses

- Intangible assets have also been subject to an impairment test according to policies described in note "3: Intangible assets" to the consolidated financial statements. As part of our work, we have reviewed the methodology and assumptions used by your group to determine the recoverable amount of these assets. On this basis, we have assessed the reasonableness of these estimates.
- Since its creation, your group has set up compensation plans settled in equity instruments whose methods of recognition and measurement are described in notes "1.12: Share-based Payments" and "17: Share-based Payments" to the consolidated financial statements. As part of our work, we appreciated the relevance of the valuation model used and reviewed the assumptions used by your group to measure the fair value of these instruments. On this basis, we have assessed the reasonableness of these estimates.

These assessments were made as part of our audit of the consolidated financial statements taken as a whole, and therefore contributed to the opinion we formed which is expressed in the first part of this report.

### III. Specific verification

As required by law we have also verified, in accordance with professional standards applicable in France, the information presented in the group's management report.

We have no matters to report as to its fair presentation and its consistency with the consolidated financial statements.

Paris and Paris-La Défense, April 21, 2015

The statutory auditors  
*French original signed by*

COFIDEC  
Thibault Faure

ERNST & YOUNG et Autres  
Cédric Garcia

### 20.5. Date of most recent financial information

December 31, 2014.

### 20.6. Consolidated interim financial information

Not applicable.

## **20.7. Dividend distribution policy**

### **20.7.1. Dividends paid during the last three financial years**

None.

### **20.7.2. Dividend distribution policy**

There are no plans to initiate a dividend payment policy in the near term in view of the Company's stage of development.

## **20.8. Legal and arbitration proceedings**

As of the filing date of the Registration Document, there are no government, legal or arbitration proceedings to the Company's knowledge that are pending or threatened and likely to have a material impact on the financial position, operations or earnings of the Company and/or its subsidiary in the last 12 months.

The Group was subpoenaed by a customer in the United States over a trade dispute. The dispute was settled amicably in January 2015. The provision recognized in the financial statements to December 31, 2014 covered the amount paid by the Group. (see Note 12.3 to the consolidated financial statements presented in Section 20.1 of this Registration Document).

No unfunded litigation currently exists.

In addition, provisions were set aside at 12/31/14 for two labor disputes, still ongoing to this day.

## **20.9. Significant change to financial or commercial position**

As far as the Company is aware, there has been no significant change in the Group's financial or commercial position since December 31, 2014.

## SECTION 21

### ADDITIONAL INFORMATION

#### 21.1. Share capital

##### 21.1.1. Amount of share capital

At December 31, 2014, the Company's share capital totaled €559,700.76, divided into 13,992,519 shares with a par value of €0.04 each, fully paid up.

##### 21.1.2. Securities not representing capital

None.

##### 21.1.3. Company's buyback of its own shares

On May 24, 2012, the Company signed a liquidity contract in accordance with AMAFI guidelines with GILBERT DUPONT, which took effect on May 25, 2012. This followed a similar contract signed on September 2, 2011 with Société Générale Securities.

The contract was endowed with:

- 7,558 securities transferred from the old liquidity contract;
- €127,913.78 in cash from the old liquidity contract;
- €150,000.00 in cash as an additional contribution from the Company.

At December 31, 2014, under this contract, the Company held 17,537 of its shares and €128,251.92 in the cash account.

These shares, valued based on the FIFO method, were acquired based on a carrying amount of €105,037.65.

#### Summary of corporate actions performed by the Company between January 1, 2013 and December 31, 2014

	2014				TOTAL
	1st quarter	2nd quarter	3rd quarter	4th quarter	
Securities purchased	172,060	161,310	179,026	221,820	734,216
Price (in €)	11.50	11.11	6.61	5.95	8.54
Total amount (in €K)	1,979	1,792	1,183	1,319	6,273
Securities sold	176,578	146,421	180,318	226,843	730,160
Price (in €)	11.50	11.12	6.64	5.91	8.48
Total amount (in €K)	2,030	1,628	1,197	1,340	6,197

Features of the Company's share buyback program:

The Combined General Meeting of June 11, 2014 authorized the Board of Directors, for a period of 18 months from the date of the meeting, to implement a share buyback program, on one or more occasions, in accordance with the provisions of Article L. 225-209 et seq. of the French Commercial Code and in accordance with the General Regulation of the *Autorité des Marchés Financiers* (AMF) under the conditions described below:

#### Objectives of the share buyback program:

- to ensure the liquidity of the Company's shares under the terms of a liquidity contract to be entered into with an independent investment service provider, in compliance with the code of professional conduct approved by the AMF;

## SECTION 21 - Additional information

- to honor obligations linked to stock option and bonus share plans;
- company savings schemes or other share awards to employees and executives of the Company or its associates;
- to deliver shares when the rights attached to securities giving access to the share capital are exercised;
- to purchase shares to be held for their subsequent exchange or use as consideration in potential acquisitions;
- or to cancel some or all of the shares thus repurchased.

**Maximum purchase price:** €30 per share excluding fees and commissions, with a total limit of €5,000,000.

**Maximum number of shares that may be purchased:** 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

It is specified that the number of shares acquired by the Company to be retained and subsequently delivered in payment or in an exchange for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of its share capital.

The shares purchased in this way may be canceled.

The Combined General Meeting of June 11, 2014 granted authorization for a capital increase for a period of 18 months to the Board of Directors with a view to the purchase by the Company of its own shares subject to a limit of 10% of the total number of shares comprising the capital. The maximum unit purchase price per share (excluding fees and commission) is set at €30 and the overall limit at €5,000,000.

### 21.1.4. Financial instruments giving access to the capital

Three different types of securities give access to the capital:

- Founders' warrants (BSPCE);
- Stock options (SO);
- Share warrants (BSA).

### Summary of dilutive instruments

On the filing date of the Registration Document and after taking into account the 4-for-1 reverse stock split, the total number of ordinary shares that could be created by fully exercising all financial instruments giving access to the share capital and issued to date, is 1,599,289, i.e. a maximum dilution of 10.35% based on existing capital and 9.38% based on diluted capital. The dilution in voting rights is 8.92% based on voting rights existing to date and 8.19% based on diluted voting rights.

### Founders' warrants (BSPCE)

See following pages

## SECTION 21 - Additional information

Plan no.	BSPCE 06					BSPCE 08			BSPCE 08A	BSPCE 10		BSPCE 11	BSPCE 12		BSPCE 13
Date(s) of Shareholders' Meeting(s)	07 26 04 and 04 27 07 and 06 16 09	March 7, 2006 and April 27, 2007 and June 16, 2009	March 7, 2006 and April 27, 2007 and June 16, 2009	March 7, 2006 and April 27, 2007 and June 16, 2009	March 7, 2006 and April 27, 2007 and June 16, 2009	May 27, 2008 and June 16, 2009	May 27, 2008 and June 16, 2009	May 27, 2008 and June 16, 2009	May 27, 2008 and June 16, 2009	30 juin 2010		May 25, 2011	15 juin 2012		June 19, 2013
Date of Chairman's decision	July 11, 2005	March 10, 2006	August 10, 2006	September 13, 2006	October 9, 2006	August 4, 2008	December 8, 2008	November 24, 2009	August 4, 2008	February 15, 2011	March 1, 2011	December 5, 2011	December 4, 2012	May 7, 2013	February 12, 2014
Number of authorized BSPCE <sup>(1)</sup>	551,216	700,000	700,000	700,000	700,000	1,900,000	1,900,000	1,900,000	500,000	1,250,000	1,250,000	800,000	800,000	800,000	800,000
Total number of allocated BSPCE <sup>(1)</sup>	80,000	415,000	120,000	20,000	25,000	1,225,000	35,000	637,500	500,000	915,000	200,000	129,500	239,500	63,000	281,000
Number of shares that may initially be subscribed for <sup>(2)</sup>	80,000	415,000	120,000	20,000	25,000	1,225,000	35,000	637,500	500,000	915,000	200,000	129,500	239,500	63,000	281,000
of which the number that may be subscribed for by corporate officers:															
of which Alexandre Loiseau		0	0	0	0	0	0	0	500,000	0	0	0	0	0	100,000
Number of beneficiaries who are not corporate officers	1	29	6	2	1	45	3	21	0	27	1	13	46	7	42
Start date for exercise of the BSPCE	July 11, 2006	March 10, 2007	August 10, 2007	September 13, 2007	October 9, 2007	August 4, 2009	December 8, 2009	November 24, 2010	August 4, 2009	February 15, 2013	March 1, 2012	December 5, 2012	December 4, 2013	May 7, 2014	February 12, 2015
BSPCE expiration date	July 11, 2015	March 10, 2016	August 10, 2016	September 13, 2016	October 9, 2016	August 4, 2018	December 8, 2018	November 24, 2019	August 4, 2018	February 15, 2021	March 1, 2021	December 5, 2021	December 4, 2022	May 7, 2023	February 12, 2024
BSPCE exercise price <sup>(3)</sup>	2.2684 €	3.664 €	3.664 €	3.664 €	3.664 €	4.00 €	4.00 €	4.00 €	4.00 €	4.00 €	4.00 €	13.00 €	10.79 €	10.28 €	10.56 €
Exercise procedures	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(5)	(5)	(5)	(6)
Number of subscribed shares as of May 31, 2015 <sup>(3)</sup>	0	44,613	11,250	0	0	83,123	0	38,748	1	79,562	37,500	0	625	0	0
Cumulative number of BCE canceled or invalid as of May 31, 2015 <sup>(1)</sup>	0	121,550	40,000	10,000	0	620,008	0	311,256	3	138,752	0	69,500	22,875	18,000	5,000
BSPCE remaining as of May 31, 2015 <sup>(1)</sup>	80,000	115,000	35,000	10,000	25,000	272,500	35,000	171,252	499,996	458,000	50,000	60,000	216,000	45,000	276,000
<sup>(3)</sup>	20,000	28,750	8,750	2,500	6,250	68,125	8,750	42,813	124,999	114,500	12,500	45,000	107,988	22,500	69,000

(1) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 has no impact on the number of BSPCE allocated, canceled, void or remaining. Only their exercise conditions are adjusted (price and parity). It should be noted that the last column of the table specifies a BSPCE plan itself allocated after the 4-for-1 reverse stock split decision. The initial characteristics mentioned in the table therefore already take the 4-for-1 reverse stock split into account;

(2) The conditions for exercising the BSPCE have been adjusted to take into account the 4-for-1 reverse stock split approved by the General Meeting convened on May 25, 2011. This line corresponds to a figure that is pre-incorporation of said reverse stock split, i.e. an exercise parity of one new share per exercise of one BSPCE. Plans since May 25, 2011 have a parity of one new share for every BSPCE.

(3) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 has the consequence of adjusting only the exercise price and parity of the BSPCE and therefore, of the number of shares that can result from said exercise. These figures take the adjustment into account, except for those in the last column, since the detailed plan was allocated after the 4-for-1 reverse stock split decision. Hence, the exercise price corresponds to the subscription price per share after taking the 4-for-1 reverse stock split into account.

(4) Given that the conditions provided for during the allocation are waived, all the stock options can be exercised.

(5) The conditions for exercising the BSPCE are as follows:

- 25% of the BSPCE may be exercised starting on the first anniversary of their allocation;
- 25% of the BSPCE may be exercised starting on the second anniversary of their allocation;
- 25% of the BSPCE may be exercised starting on the third anniversary of their allocation;
- The remaining balance, i.e. 25% of the warrants, may be exercised starting on the fourth anniversary of their allocation.
- 

(6) The procedures for exercising these BSPCE are identical to point (5), except for the 100,000 BSPCE vesting immediately.

As of May 31, 2015, the exercise of all BSPCE could lead to the creation of 1,034,937 new ordinary shares following the 4-for-1 reverse stock split, of which 682,425 shares could potentially be exercised as of the date of this report, in view of the vesting under the conditions set out in point (5).

## Stock Option Plans

Information on Stock Options Plans										
Date of Shareholders' Meeting	May 27, 2008	May 27, 2008	May 27, 2008	June 30, 2010	June 30, 2010	June 30, 2010	May 25, 2011	June 15, 2012	June 19, 2013	June 19, 2013
Date of Chairman's decisions	June 2, 2008	January 30, 2009	March 1, 2010	January 31, 2011	February 15, 2011	April 1, 2011	December 5, 2011	December 4, 2012	December 9, 2013	February 12, 2014
Total number of options authorized	960,000	960,000	960,000	750,000	750,000	750,000	800,000	800,000	800,000	800,000
Total number of options granted <sup>(1)</sup>	670,000	40,000	250,000	245,000	50,000	100,000	288,153	161,000	101,000	10,000
Total number of shares that may initially be subscribed for <sup>(2)</sup>	670,000	40,000	250,000	245,000	50,000	100,000	288,153	161,000	101,000	10,000
<i>Of which number that may be subscribed for by</i>										
<i>corporate officers</i>	0	0	0	0	0	0	0	0	0	0
<i>Number of beneficiaries who are not corporate officers</i>	5	1	3	5	2	1	10	11	8	4
Start date for exercise of the options	June 2, 2009	January 30, 2010	March 1, 2011	January 31, 2012	February 15, 2012	April 1, 2012	December 5, 2012	December 4, 2013	December 9, 2014	February 12, 2015
Option expiration date	June 2, 2019	January 30, 2016	March 1, 2021	January 31, 2021	February 15, 2021	April 1, 2021	December 5, 2021	December 4, 2022	December 9, 2023	February 12, 2024
Subscription price <sup>(3)</sup>	4.00 €	4.00 €	4.00 €	4.00 €	13.00 €	4.00 €	11.44 €	10.79 €	10.05 €	10.56 €
Exercise procedures	(4)	(4)	(4)	(4)	(4)	(4)	(5)	(5)	(5)	(5)
Number of subscribed shares as of May 31, 2015 <sup>(3)</sup>	47,148	10,000	2,500	14,062	0	25,000	0	0	0	0
Cumulative number of stock options canceled or invalid <sup>(1)</sup>	230,000	0	100,000	88,752	40,000	0	268,153	31,000	0	2,000
Stock options remaining as of May 31, 2015 <sup>(1)</sup>	(251,408)	(0)	(140,000)	100,000	10,000	0	20,000	130,000	101,000	8,000
Total number of shares that may be subscribed for as of May 31, 2015 <sup>(3)</sup>	(62,852)	(0)	(35,000)	25,000	2,500	0	15,000	65,000	25,250	2,000

(1) The 4-for-1 reverse stock split approved by the General Meeting held on May 25, 2011 has no impact on the number of stock options allocated, cancelled, void or remaining. Only their exercise conditions are adjusted (price and parity).

(2) The conditions for exercising the stock options have been adjusted to take into account the 4-for-1 reverse stock split approved by the General Meeting on May 25, 2011. This line corresponds to a figure calculated before taking said reverse stock split into account, i.e. an exercise parity of one new share for every stock option exercised.

(3) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 has the consequence of adjusting only the exercise price and parity of the stock options and therefore, of the number of shares that can result from said exercise. These figures take the adjustment into account. Hence, the exercise price corresponds to the subscription price per share after taking the 4-for-1 reverse stock split into account.

(4) Given that the conditions provided for during the allocation are waived, all stock options may be exercised.

(5) The conditions for exercising stock options are as follows:

- 25% of the S.O. may be exercised starting on the first anniversary of their allocation;
- 25% of additional S.O. may be exercised starting on the second anniversary of their allocation;
- 25% of additional S.O. may be exercised starting on the third anniversary of their allocation;
- The remaining balance, i.e. 25% of the S.O., may be exercised starting on the fourth anniversary of their allocation.

As of May 31, 2015, the exercise of all stock options granted could lead to the creation of 384,352 new ordinary shares, of which 232,602 shares could potentially be exercised as of the date of this report under the conditions set forth in point (5).

## Share Warrant (BSA) Plan

	BSA 11 No. 3	BSA 2014	BSA 2015
Date of Shareholders' Meeting	May 25, 2011	June 11, 2014	June 11, 2014
Date of Chairman's decisions	July 5, 2011	September 1, 2014	March 6, 2015
Number of authorized share warrants (BSA)	800,000	400,000	1,390,000
Total number of issues share warrants (BSA) <sup>(1)</sup>	80,000	100,000	1,390,000
Total number of shares that may initially be subscribed for <sup>(2)</sup>	80,000	100,000	1,390,000
<i>of which number that may be subscribed for by corporate officers</i>	1	2	0
<i>of which André-Michel Ballester</i>	40,000		
<i>of which Christopher McFadden</i>		30,000	
<i>of which Jean-Luc Boulnois</i>		30,000	
Number of beneficiaries who are not corporate officers	1	1	1
Start date for exercise of the BSA	July 5, 2012	September 1, 2015	March 11, 2015
BSA expiration date	July 5, 2021	September 1, 2024	January 11, 2016
BSA issue price	1.30 €	0.61 €	0.0001 €
BSA exercise price <sup>(3)</sup>	13.00 €	6.120 €	(5)
Exercise procedures	(4)	(4)	(5)
Number of subscribed shares as of May 31, 2015 <sup>(3)</sup>	0	0	210,000
Cumulative number of BSA canceled or invalid as of May 31, 2015 <sup>(1)</sup>	0	0	1,180,000
BSA remaining as of May 31, 2015 <sup>(1)</sup>	80,000	100,000	0
Total number of shares that may be subscribed for as of May 31, 2015 <sup>(3)</sup>	80,000	0	0

(1) The 4-for-1 reverse stock split approved by the General Meeting held on May 25, 2011 has no impact on the number of BSA authorized, issued, void, cancelled or remaining. Only their exercise conditions are adjusted (price and parity).

(2) The conditions for exercising the share warrants have been adjusted to take into account the 4-for-1 reverse stock split approved by the General Meeting convened on May 25, 2011. This line corresponds to a figure calculated before taking said reverse stock split into account, i.e. an exercise parity of one new share for every share warrant exercised.

(3) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 has the consequence of adjusting only the exercise price and parity of the BSA and therefore, of the number of shares that can result from said exercise. These figures take the adjustment into account. Hence, the exercise price corresponds to the subscription price per share after taking the 4-for-1 reverse stock split into account.

(4) One-third of share warrants could be exercised after a period of 12 months, and then in additional one-third tranches at the end of each year for two years, subject to a 75% attendance rate at board meetings held in each of the three years.

(5) These share warrants relate to the equity financing facility arranged with Société Générale. As part of this financing facility and subject to certain terms and conditions (subscription floor price and minimum average daily volumes), Société Générale committed to subscribe 1,390,000 new shares (representing 9.9% of the current share capital) by January 11, 2016, at least half of which by July 11, 2015, at the times and at the pace it shall deem appropriate. For each tranche, the issue price will be discounted by 5% based on the volume-weighted average price of the previous three trading sessions. The Company bought back and canceled 1,180,000 share warrants issued for Société Générale for a total amount of €118 and unsubscribed as at May 31, 2015.

As of May 31, 2015, the exercise of all share warrants granted could lead to the creation of 180,000 new ordinary shares following the 4-for-1 reverse stock split. Of these, 80,000 shares could potentially be exercised as of the date of this report, considering the vesting conditions previously mentioned.



## 21.1.5. Authorized Share Capital

The resolutions approved by the Extraordinary General Meetings of May 25, 2011, June 15, 2012, June 19, 2013, June 11, 2014 and May 27, 2015 are summarized below:

Summary of authorization granted to the Board of Directors to increase the share capital

<u>Date of the Annual General Meeting</u>	<u>Purpose of the authorization</u>	<u>Expiration date</u>	<u>Issue pricing methods</u>
June 11, 2014 (18 <sup>th</sup> resolution)	<p><i>Delegation of authority granted to the Board to increase the capital by issuing ordinary shares or any securities giving access to the capital with preferential subscription rights for shareholders - Maximum nominal amount: €184,000*</i></p> <p><i>(Articles L. 225-129 to L. 225-129-6, L. 228-91 and L. 228-92 of the French Commercial Code)</i></p>	August 11, 2016 (26 months)	N/A
June 11, 2014 (19 <sup>th</sup> resolution)	<p><i>Delegation of authority granted to the Board to increase the capital by issuing ordinary shares or any securities giving access to the capital without preferential subscription rights for shareholders and a public offering - Maximum nominal amount: €184,000*</i></p> <p><i>(Articles L. 225-129 to L. 225-129-6, L. 225-135, L. 225-135-1, L. 225-136, L. 228-91 and L. 228-92 of the French Commercial Code)</i></p>	August 11, 2016 (26 months)	the issue price of the shares, likely to be issued pursuant to this delegation of authority will be set by the Board and will at least be equal to the weighted average price quoted on the previous three trading days, less any discount permitted by law (currently 5%) and adjusted in the event of a difference in the vesting date. It is specified that the issue price of securities giving access to the share capital will be equal to the amount received immediately by the Company plus any amount it might receive subsequently, that is, for each share issued as a result of the issuance of such securities, at least equal to the issue price defined above.
June 11, 2014 (20 <sup>th</sup> resolution)	<p><i>Delegation of authority granted to the Board to increase the share capital by issuing ordinary shares or any securities giving access to the share capital without preferential subscription rights for shareholders, as part of an offering for qualified investors or a limited circle of investors as referred to in Section II of Article L. 411-2 of the French Monetary and Financial Code - Maximum nominal amount: €184,000*</i></p> <p><i>(Articles L. 225-129 to L. 225-129-6, L. 225-135, L. 225-135-1, L. 225-136, L. 228-91 and L. 228-92 of the French Commercial Code)</i></p>	August 11, 2016 (26 months)	see 19 <sup>th</sup> resolution above
June 11, 2014 (21 <sup>st</sup> resolution)	<p><i>Authorization for the Board, in the event of the issue of shares or any security giving access to the capital without preferential subscription rights for shareholders, to set the issue price, subject to a maximum of 10% of the share capital and within the limits set by the Annual General Meeting</i></p> <p><i>(Article L. 225-136-1 of the French Commercial Code)</i></p>	August 11, 2016 (26 months)	The issue price of ordinary shares will at least be equal to the weighted average price of the previous five trading sessions, less a maximum discount of 15% where applicable. It is specified that the issue price of securities giving access to the capital will be such that the amount received immediately by the Company, plus any amount it might receive subsequently, is, for each share issued as a result of the issuance of such securities, at least

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<u>Date of the Annual General Meeting</u>	<u>Purpose of the authorization</u>	<u>Expiration date</u>	<u>Issue pricing methods</u>
			equal to the issue price defined above.
<b>June 11, 2014</b> (22 <sup>nd</sup> resolution)	<i>Delegation of authority for the Board to increase the number of securities to be issued in the event of a capital increase with or without preferential subscription rights in accordance with the authority delegated above*</i>  (Articles L. 225-129, L. 225-129-2, L. 225-135, L. 225-135-1 et seq., L. 228-91 and L. 228-92 of the French Commercial Code)	<b>August 11, 2016</b> (26 months)	Same price as the initial issue price subject to a maximum of 15% of the initial issue
<b>June 11, 2014</b> (23 <sup>rd</sup> resolution)	<i>Delegation of authority granted to the Board to issue ordinary shares and securities giving access to the Company's capital, in the event of a public offering involving an exchange component instigated by the Company - Maximum nominal amount: €184,000*</i>  (Articles L. 225-129 to L. 225-129-6, L. 225-148, L. 228-91 and L. 228-92 of the French Commercial Code)	<b>August 11, 2016</b> (26 months)	N/A
<b>June 11, 2014</b> (24 <sup>th</sup> resolution)	<i>Delegation of authority granted to the Board to increase the share capital, within a limit of 10% of the capital, as consideration for contributions in kind of equity instruments or securities giving access to the capital of other companies and not part of a public exchange offering - Maximum nominal amount: €184,000*</i>	<b>August 11, 2016</b> (26 months)	N/A
<b>June 11, 2014</b> (26 <sup>th</sup> resolution)	<i>Delegation of authority granted to the Board to increase the capital by the incorporation of premiums, reserves, profits or other items - Maximum nominal amount: €16,000</i>	<b>August 11, 2016</b> (26 months)	N/A
<b>May 27, 2015</b> (7 <sup>th</sup> resolution)	<i>Authorization to be given to the Board of Directors to allow the Company to purchase its own shares, within a limit of 10% of the total number of shares comprising the capital</i>	<b>November 27, 2016</b> (18 months)	Maximum unit purchase price per share (excluding fees and commission): €30  Overall limit: €5,000,000
<b>May 27, 2015</b> (8 <sup>th</sup> resolution)	<i>Authorization to be given to the Board to reduce the share capital by canceling shares under the share buyback authorization, within a limit of 10% of the amount of share capital in each 24-month period</i>	<b>November 27, 2016</b> (18 months)	N/A
<b>May 27, 2015</b> (10 <sup>th</sup> resolution)	<i>Authorization given to the Board to grant options to subscribe for or buy Company shares - Maximum number of options: 400,000**</i>	<b>July 27, 2018</b> (38 months)	the purchase or subscription price per share will be set by the Board of Directors when the options are granted, subject to the limits imposed by law and by this resolution; the price may not be less than ninety-five percent (95%) of the average price quoted during the 20 trading sessions preceding the date of the Board's decision to grant the options, rounded down to the nearest euro, or for purchase options, 80% of the average purchase price of treasury shares held by the Company, rounded down to the nearest euro

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<u>Date of the Annual General Meeting</u>	<u>Purpose of the authorization</u>	<u>Expiration date</u>	<u>Issue pricing methods</u>
<p><b>May 27, 2015</b> (12<sup>th</sup> resolution)</p>	<p><i>Delegation of authority granted to the Board of Directors to issue and allocate share warrants to (i) members and non-voting members of the Board of Directors of the Company in office at the warrant allocation date and who are not employees or executives of the Company or of one of its subsidiaries, (ii) a service provider or consultant under contract to the Company or to one of its subsidiaries, or (iii) members of any committee that the Board of Directors should establish who are not employees or executives of the Company or of one of its subsidiaries</i> Maximum number of share warrants: 400,000**</p>	<p><b>November 27, 2016</b> (18 months)</p>	<p>The BSA issue price will be determined by the Board of Directors on the warrant issue date, depending on the features of the warrant, and will be at least equal to 5% of the average volume-weighted average price of the five (5) previous trading sessions on the Euronext Paris regulated market, prior to the date of allocation of said warrant by the Board</p> <p>The subscription price of a share following the exercise of a share warrant will be at least equal to the weighted average price quoted during the last 20 trading sessions prior to the date of allocation of said warrant by the Board.</p>
<p><b>May 27, 2015</b> (14<sup>th</sup> resolution)</p>	<p><i>Delegation of authority granted to the Board to increase the share capital by issuing ordinary shares or any securities giving access to the share capital without preferential subscription rights for shareholders, for the benefit of a certain category of persons under an equity financing facility - Maximum nominal amount: €84,000</i></p> <p><i>(Articles L. 225-129, L. 225-129-2, L-225-129-4, L. 225-135, L-225-138 and L. 228-91 et seq .of the French Commercial Code)</i></p>	<p><b>November 27, 2016</b> (18 months)</p>	<p>the issue price of the shares issued pursuant to this delegation of authority will be set by the Board of Directors and will be at least equal to the average of the volume-weighted average prices of the previous three trading sessions, less a maximum discount of 15%, where applicable, taking account of their vesting date if necessary; it is specified that (i) in the event of the issuance of securities giving access to the share capital, the issue price of the shares likely to result from their exercise, conversion or exchange may, where appropriate, be set, at the discretion of the Board of Directors, based on a calculation formula defined by the Board and applied subsequent to the issuance of such securities (e.g. upon their exercise, conversion or exchange), in which case the aforementioned maximum discount may be assessed, if the Board deems it appropriate, on the date of application of said formula (and not on the date on which the issue price is set), and (ii) the issue price of the securities giving access to the share capital, if any, issued under this resolution, will be such that any amount received immediately by the Company, plus the amount likely to be received by it upon exercise or conversion of such securities is, for each share issued as a consequence of the issuance of such securities, at least equal to the aforementioned minimum amount</p>

\* Limit common to all capital increases likely to be made pursuant to the authority delegated under the 18<sup>th</sup> to 20<sup>th</sup> and the 22<sup>nd</sup> to 24<sup>th</sup> resolutions above (AGM of June 11, 2014)

\*\* the total amount (i) of shares likely to be issued or acquired upon exercise of the options granted under the 10<sup>th</sup> resolution of the General Meeting of May 27, 2015, (ii) of any bonus shares awarded under the 11<sup>th</sup> resolution of that General Meeting, and (iii) of shares likely to be issued upon exercise of the share warrants allocated under the 12<sup>th</sup> resolution of the same General Meeting, may not exceed 400,000 shares

**21.1.6. Information on the capital of any member of the Group subject to an option or a conditional or unconditional agreement to be put under option**

To the knowledge of the Company, no call or put options or other obligations exist in favor of the Company's shareholders or are approved by the latter with respect to the Company's shares.

## 21.1.7. Historical of Share Capital

## Changes in Share Capital since the creation of the Company

This table retraces changes in the Company's share capital since its creation. This is historical data, taking into account the 4-for-1 reverse stock split authorized by the general meeting on May 25, 2011.

Date	Type of transaction	Number of shares created	Number of shares comprising the capital	Nominal amount (€)	Share capital (€)
04/21/2000	Constitution	62,000	62,000	1.00	62,000.00
07/04/2000	100-for-1 share split	6,138,000	6,200,000	0.01	62,000.00
09/21/2000	Cash issue of O shares	3,233,100	9,433,100	0.01	94,331.00
2003	Cash issue of O shares	3,820,400	13,253,500	0.01	132,535.00
2004	Cash issue of O shares	3,062,234	16,315,734	0.01	163,157.34
2006	Cash issue of O shares	1,926,978	18,242,712	0.01	182,427.12
2007	Exercise of BSPCE	20,950	18,263,662	0.01	182,636.62
2007	Cash issue of P Shares	8,447,419	26,711,081	0.01	267,110.81
2007	Bond conversions	1,869,477	28,580,558	0.01	285,805.58
2008	Exercise of BSPCE	529,500	29,110,058	0.01	291,100.58
2008	Cash issue of P Shares	6,082,345	35,192,403	0.01	351,924.03
2010	Exercise of BSPCE	5,000	35,197,403	0.01	351,974.03
2010	Exercise of BSA	530,376	35,727,779	0.01	357,277.79
05/02/2011	Exercise of BSPCE	1	35,727,780	0.01	357,277.80
05/25/2011	4-for-1 reverse stock split	(26,795,835)	8,931,945	0.04	357,277.80
07/11/2011	Capital increase	4,346,243	13,278,188	0.04	531,127.52
2011	Exercise of Stock Options	1,000	13,279,188	0.04	531,167.52
2011	Exercise of BSPCE	124,028	13,403,216	0.04	536,128.64
2012	Exercise of BSPCE	100,093	13,503,309	0.04	540,132.36
2012	Exercise of BSA	51,250	13,554,559	0.04	542,182.36
2012	Exercise of Stock Options	7,187	13,561,746	0.04	542,469.84
2013	Exercise of BSPCE	189,875	13,751,621	0.04	550,064.84
2013	Exercise of Stock Options	51,836	13,803,457	0.04	552,138.28
2014	Exercise of BSPCE	184,375	13,987,832	0.04	559,513.28
2014	Exercise of Stock Options	4,687	13,992,519	0.04	559,700.76
2015	Exercise of BSPCE	30,937	14,023,456	0.04	560,938.24
2015	Exercise of Stock Options	34,000	14,057,456	0.04	562,298.24
2015	Exercise of BSA	210,000	14,267,456	0.04	570,698.24
05/12/2015	Capital increase	1,189,251	15,456,707	0.04	618,268.28

## 21.2. Memorandum and bylaws

### 21.2.1. Company purpose

The Company aims to do the following in France and abroad:

- Design, develop and market scientific instruments, in particular optical medical imaging instruments, using all existing or future technological resources;
- All research activities in order to develop, register and use all process patents and industrial or intellectual property rights as well as all transactions relating to these patents and these rights;
- All of which directly or indirectly on its behalf or on behalf of third parties, whether alone or with third parties, through the creation of new companies, partnership contributions, mergers, partnerships, joint ventures or transfers instead of payments by means of renting or leasing any assets, claims or otherwise;
- And generally, any financial, commercial, industrial, moveable, real estate and financial transactions, that might relate directly or indirectly to any of the stated purposes or any other similar purpose designed to develop the Company's assets.

### 21.2.2. Provisions of the bylaws or other provisions concerning the members of the administrative and governing bodies.

#### Board of Directors

(a) Composition of the Board of Directors (Articles 11.1 and 11.2 of the bylaws)

The Company is managed by a Board consisting of natural and legal persons whose number is set by the Ordinary General Meeting within the limits set out by law.

Any legal person must, upon its appointment, designate a natural person as a permanent representative on the Board of Directors. The permanent representative's term of office shall be the same as that of the legal person director he or she represents. When the legal person dismisses its permanent representative, it must immediately find a replacement. The same provisions shall apply in case of the permanent representative's death or resignation.

The term of office of the Directors shall be three years. The term of office of a Director shall end after the Ordinary Annual General Meeting deciding on the past financial year's accounts held in the year in which the term of office of said Director expires.

The Directors may always be reelected; they may be dismissed at any time by a decision of the Annual General Meeting.

If one or more Board of Directors' seats become vacant because of death or resignation, the Board of Directors may, between two General Meetings, make appointments ad interim.

The appointments made by the Board, in line with the paragraph above, shall be subject to ratification by the next Ordinary Annual General Meeting.

If there is no ratification, the decisions made and the procedural measures carried out earlier by the Board shall remain in effect.

When the number of Directors falls below the legal minimum, the remaining Directors must immediately convene an Ordinary General Meeting in order to complete the Board's membership.

A Company employee may be appointed as a Director. His or her employment contract must, however, correspond to actual employment. Said employee will not, in that case, lose the benefit of his or her employment contract.

The number of Directors who are linked to the Company through an employment contract may not exceed one-third of the Directors in office.

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The number of Directors who are more than 70 years of age may not be greater than one-third of the Directors in office. When this limit is exceeded during a term of office, the oldest Director shall automatically be deemed to have resigned following the next Annual General Meeting.

The Board of Directors shall elect from among its members a Chairman who must be a natural person. It shall determine the term of the Chairman's duties, which term may not be greater than his or her term of office as a Director, and the Board may dismiss the Chairman at any time. The Board will set the Chairman's compensation.

The Chairman organizes and conducts the activities of the Board, and reports these to the General Meeting. The Chairman shall monitor the efficient working of the Company's bodies and shall ensure, in particular, that the Directors are able to carry out their duties.

The Chairman of the Board may not be older than 75 years of age. If the Chairman reaches that age limit during his or her term of office as Chairman, he or she shall be deemed to have resigned. The Chairman's term of office shall continue, however, until the next meeting of the Board of Directors during which the Chairman's successor will be appointed. Subject to this provision, the Chairman of the Board may always be reelected.

### (b) Non-voting Board members (Article 15 of the bylaws)

The Ordinary General Meeting may, at the recommendation of the Board of Directors, appoint non-voting Board members. The Board of Directors may also appoint non-voting Board members directly, subject to ratification by the next General Meeting.

The non-voting Board members, whose number may not be greater than five, shall constitute a panel. They are selected freely on the basis of their qualifications.

They are appointed for a three-year term that ends following the Ordinary Annual General Meeting that has ruled on the accounts of the past financial year.

The panel of non-voting Board members shall examine the questions that the Board of Directors or its Chairman submits, for opinion, to its review. The non-voting Board members shall attend the Board of Directors' meetings and shall participate in the deliberations in an advisory capacity only, without their absence affecting the validity of the deliberations.

They are convened to the Board's meetings under the same conditions as the Directors.

The Board of Directors may pay the non-voting Board members by deducting an amount from the attendance fees allocated by the General Meeting to the Directors.

### (c) Meeting of the Board of Directors (Article 12 of the bylaws)

The Board of Directors shall meet as often as the Company's interest requires.

The Directors shall be convened by the Chairman to attend the Board's meetings. Meeting notices may be given in writing or orally.

The CEO may also ask the Chairman to convene the Board of Directors on a specific agenda.

Moreover, the Directors representing at least one-third of the Board members may validly convene the Board. In this case, they must specify the agenda of the meeting.

When a Works Council is established, this Council's representatives, appointed in accordance with the provisions of the French Labor Code, must be convened to all Board of Directors' meetings.

The Board meetings shall take place either at the registered office or any other venue in France or outside France.

In order for the Board's decisions to be valid, the number of members present must at least be equal to half of the members.

## SECTION 21 - Additional information

The decisions of the Board of Directors shall be taken by a majority vote; in case of a tie, the Chairman at the meeting will have the casting vote.

The internal rules that the Board of Directors may adopt, could provide in particular that the Directors who take part in the Board's meeting through videoconferencing or other telecommunications means compliance with applicable regulations shall be deemed present for calculation of the quorum and majority. This provision shall not apply for the adoption of the decisions referred to in Articles L. 232-1 and L. 233-16 of the French Commercial Code.

Each Director shall receive the information necessary to fulfill his or her mandate and term of office, and may obtain all documents that he or she deems useful.

Every Director may give power of attorney, including by letter, telegram, telex, fax, email or any other means of electronic communication, to another Director in order to represent him or her at a Board meeting. However, no Director may have more than one power of attorney at any one meeting.

Copies of, or excerpts from, the Board of Directors' decisions shall be validly certified by the Chairman of the Board of Directors, the Chief Executive Officer, the Director who is temporarily assigned the duties of Chairman, or an agent empowered for that purpose.

### (d) Powers of the Board of Directors (Article 13 of the bylaws)

The Board of Directors shall determine the general direction of the Company's business and shall ensure its implementation. Subject to the powers expressly granted to the Shareholders' Meetings, and within the limit of the Company purpose, the Board will deal with any question pertaining to the smooth running of the Company and will settle the business that concerns the Company in its deliberations.

In its relations with third parties, the Company is bound even by the actions of the Board of Directors that do not fall under the Company purpose, unless it establishes that the third party knew that the action was beyond said purpose or that it could not fail to know under the circumstances, it being excluded that the publication of the bylaws alone is sufficient to constitute this evidence.

The Board of Directors shall carry out the verifications and inspections that it deems advisable. Moreover, the Board of Directors shall have the special powers conferred to it by law.

## General Management

The Company's general management will be handled, under his or her responsibility, either by the Chairman of the Board or by another individual appointed by the Board of Directors holding the title of Chief Executive Officer (CEO).

The CEO shall be vested with the most extensive powers to act in all circumstances on behalf of the Company. Said CEO shall exercise his or her powers within the limit of the Company purpose and subject to the powers that the law expressly confers on General Meetings of Shareholders and the Board of Directors.

The CEO shall represent the Company in its relations with third parties. The Company shall be bound even by the actions of the CEO that do not fall under the Company purpose, unless it proves that the third party knew that the action was beyond said purpose or that it could not fail to know under the circumstances, it being excluded that the publication of the bylaws alone is sufficient to constitute this evidence.

The CEO may not be older than 65 years of age. If the CEO reaches this age limit, he or she will be deemed to have resigned. The CEO's term of office will however continue until the next meeting of the Board of Directors during which the new CEO would be appointed.

When the CEO exercises the duties of a Director, the duration of his or her term of office may not exceed his or her term of office as Director.

The Board of Directors may dismiss the CEO at any time. If the dismissal is decided without due cause, it may lead to damages, except when the CEO assumes the functions of Chairman of the Board of Directors.

Following a resolution taken by a majority vote of the Directors present or represented, the Board of Directors shall choose between the two modes for assuming general management referred to in the first item of paragraph [sic].

Shareholders and third parties shall be informed of that choice under the legal and regulatory conditions.

The choice thus made by the Board of Directors shall remain in effect until the Board decides otherwise or, at the discretion of the Board, for the duration of the CEO's term of office.

When the Company's general management is assumed by the Chairman of the Board of Directors, the provisions that apply to the CEO shall apply to it.

In accordance with the provisions of Article 706-43 of the French Code of Criminal Procedure, the CEO may validly delegate authority to any person of his or her choice to represent the Company in regard to any prosecution that might be instituted against it.

Upon the recommendation of the CEO, the Board of Directors may instruct one or more individuals to assist the CEO as Deputy CEO.

By agreement with the CEO, the Board of Directors shall determine the scope and term of the powers conferred on the Deputy CEOs. The Board of Directors shall establish their remuneration. When a Deputy CEO holds the title of Director, his or her term of office may not exceed his or her term of office as Director.

With regard to third parties, the Deputy CEOs shall have the same powers as the CEO; the Deputy CEOs shall have in particular powers to take part in court proceedings.

The number of Deputy CEOs may not exceed five.

The Deputy CEO(s) may be dismissed at any time by the Board of Directors upon the recommendation of the CEO. If the dismissal is resolved without due cause, it may lead to damages.

A Deputy CEO may not be older than 65 years of age. If a Deputy CEO reaches that age limit during his or her term of office, he or she shall be deemed to have resigned. The Deputy CEO's term of office shall continue, however, until the next meeting of the Board of Directors during which a new Deputy CEO could possibly be appointed.

When the CEO ceases to exercise his or her duties or is prevented from doing so, the Deputy CEO(s) shall keep their duties and responsibilities until the appointment of the new CEO unless otherwise decided by the Board of Directors.

### **21.2.3. Rights, privileges and restrictions attached to the Company's shares**

#### **Type of securities (Article 7 of the bylaws)**

Fully paid-up shares are in registered or bearer form, as the shareholder so chooses, subject, however, to the application of legal provisions relating to the form of shares held by certain individuals or legal persons. Shares that have not been fully paid up must be in registered form.

Shares are registered in an account subject to the conditions and according to the procedures laid down by the applicable legal and regulatory provisions.

Ownership of shares issued in registered form is evidenced by their entry in the registered share account.

**Voting rights (Extract from Article 9 of the bylaws)**

The rights and obligations attached to a share are transferred therewith, and the transfer includes all dividends accruing, due and not paid and, where applicable, the share of any reserves and provisions.

Share ownership automatically implies approval by the shareholder of these bylaws and of the resolutions of annual general meetings of the shareholders.

Unless otherwise provided by law, and without prejudice to the double voting right provided for below, each shareholder has as many voting rights and may cast as many votes at general meetings as the paid-up shares held. For the same par value, and without prejudice to the double voting right provided for below, each capital or dividend share carries the right to one vote.

A double voting right to that carried by other shares, in view of the percentage of the share capital they represent, is assigned to all fully paid-up shares (of any category) which can be shown to have been registered for at least three years in the name of the same shareholder. It is stipulated that the conversion of preferred shares into ordinary shares will not affect the calculation of the holding period. This right is also conferred, from issue, in the event of a capital increase by incorporation of reserves, profits or share premiums on bonus registered shares awarded to shareholders based on their existing shares by virtue of which they already enjoy such a right.

Shareholders may, by registered letter with return receipt requested sent to the Company, waive their double voting rights temporarily or permanently and in whole or in part. Said waiver shall take effect on the third business day after the Company receives the waiver notice.

Whenever several securities or shares, whether preferred or otherwise, need to be held in order to exercise a particular right, the shareholders or securities holders shall be responsible for acquiring the necessary number of shares or securities.

**Rights to dividends and profits (Extracts from Articles 9, 21 and 22 of the bylaws)**

Each share shall carry the right, in the ownership of the Company's assets and in the distribution of profits and the liquidation surplus, to a share proportional to the number and par value of the existing shares.

A deduction of at least five percent (5%) must be made from the profit of the financial year, minus previous losses, if any, which deduction will be allocated for the establishment of a reserve fund called "legal reserve". Said deduction will no longer be mandatory once the amount of legal reserve reaches one-tenth of the share capital.

The distributable profit shall comprise the profit of the financial year minus the previous losses and the deduction set forth in the paragraph above, plus the profit carried forward.

If the financial year's accounts, as approved by the General Meeting, result in distributable profit, the General Meeting will decide to record it under one or more reserve items for which it will decide the allocation or use, to carry it forward or to distribute it as dividends.

After recognizing the existence of reserves that are available, the General Meeting may resolve to distribute amounts deducted from these reserves. In that case, the resolution shall specify expressly the reserve items from which these deductions are made. However, the dividends are first deducted from the distributable profit of the financial year.

The terms for paying the dividends shall be established by the General Meeting or, otherwise, by the Board of Directors.

However, the dividend payment must be made no later than nine months after the end of the financial year.

The General Meeting ruling on the accounts of the financial year may give each shareholder, for all or part of the dividend distributed, a choice between paying the dividend in cash or in shares.

Likewise, the Ordinary General Meeting, ruling under the conditions provided for by Article L. 232-12 of the French Commercial Code, may in the event of payment to each shareholder of an interim dividend authorized by the Board of Directors, and for all or some of said interim dividend, allow the Board of Directors to offer a choice between payment of the interim dividend in cash or in shares.

The offer of payment in shares, the price and the conditions of issue of the shares, as well as the share payment request and the conditions of performance of the capital increase are governed by applicable law and regulations.

When financial statements prepared during or at the end of the financial year and certified by the statutory auditors indicates that the Company, since the previous year-end, after amortization, depreciation and provisions and less any prior losses, in addition to amounts to be allocated to reserves in pursuance of the law or these bylaws and taking into account retained earnings, has made a profit, the Board of Directors may decide to distribute an interim dividend before approval of the financial statements for the period and set the amount and date of distribution. The amount of such interim dividends may not exceed the amount of profit defined in this paragraph. Otherwise, the Board of Directors may not exercise the option described above.

### **Preferred subscription right**

The Company's shares give the right to a preferred subscription right with regard to increases in share capital under the conditions set forth by the French Commercial Code.

### **Limitation of voting rights**

No clause in the bylaws restricts the voting right attached to the shares.

### **Identifiable bearer securities**

Subject to applicable legal and regulatory conditions, the Company may also request at any time, at its own expense, from any qualified organization, the name, or, if it is a legal person, the company name, nationality and address of the holders of securities conferring immediate or future voting rights in its own Shareholders' Meetings, as well as the number of securities held by each and, as the case may be, the restrictions that may apply to these securities.

### **Company buyback of its own shares**

See Section 21.1.3.

#### **21.2.4. Amendment terms and conditions of shareholders' rights**

The shareholders' rights, as set out in the Company's bylaws, may only be amended by the Company's Extraordinary Annual General Meeting.

### 21.2.5. General Meetings of Shareholders

(a) Holding of general meetings (Article 19 of the bylaws)

General Meetings are convened and held under the conditions set forth by law.

When the Company wishes to convene the meeting through electronic communication instead of postal mail, it must first receive the approval of the shareholders concerned who will specify their electronic mail addresses.

Meetings shall be held at the registered office or any other venue specified in the meeting notice.

The right to participate in the Meetings shall be governed by applicable legal and regulatory provisions, and shall in particular be conditional on the accounting registration of the securities under the name of the shareholder or the proxy registered on the shareholder's behalf three business days prior to the Meeting at 12:00 a.m., Paris time, either in the accounts of registered securities held by the Company, or in the accounts of bearer securities held by the authorized proxy.

If the shareholder is unable to attend the Meeting in person, he or she may select one of the following three options:

- Grant a power of attorney under the conditions authorized by law and regulations;
- Vote by absentee ballot; or
- Send a power of attorney to the Company, without indicating a proxy,

under the conditions provided for by law and regulations.

The Board of Directors may organize, under the conditions provided for by applicable laws and regulations, the shareholders' participation and vote at meetings through videoconferencing or other telecommunications enabling them to be identified. If the Board of Directors decides to avail itself of this option for a specific meeting, this decision will be stated in the meeting notice. Shareholders taking part in meetings through videoconferencing or any of the other aforesaid telecommunications means, according to what the Board of Directors chooses, shall be deemed present for calculation of the quorum and majority.

Meetings shall be chaired by the Chairman of the Board of Directors or, if absent, by the CEO, a Deputy CEO if the latter is a Director, or a Director specifically appointed for this purpose by the Board. Otherwise, the meeting will elect its Chairman.

The duties of tellers shall be carried out by the two members attending the meeting who, accepting these duties, have the greatest number of votes. The bureau of the shareholders' meeting shall appoint the secretary, who need not be a shareholder.

An attendance sheet will be kept under the conditions laid down by law.

The Ordinary Annual General Meeting convened pursuant to the first meeting notice shall constitute a quorum when the present or represented shareholders have at least one-fifth of the shares with voting rights. The Ordinary Annual General Meeting convened pursuant to a second meeting notice shall constitute a quorum irrespective of the number of present or represented shareholders.

The decisions of the Ordinary Annual General Meeting shall be taken by a majority vote by the present or represented shareholders.

The Extraordinary Annual General Meeting convened pursuant to the first meeting notice shall constitute a quorum when the present or represented shareholders have at least one-fourth of the shares with voting rights. The Extraordinary Annual General Meeting convened pursuant to a second meeting notice shall constitute a quorum when the present or represented shareholders have at least one-fifth of the shares with voting rights.

The decisions of the Extraordinary Annual General Meeting shall be taken by a two-thirds majority of the shareholders present or represented.

Copies or extracts of the meeting's minutes shall be validly certified by the Chairman of the Board of Directors, a Director acting as CEO, or by the meeting secretary.

(b) Powers of meetings (Article 19 of the bylaws)

Ordinary and Extraordinary General Meetings of the Shareholders shall exercise their respective powers under the conditions laid down by law.

**21.2.6. Provisions that delay, postpone or prevent a change in control**

The Company's bylaws do not contain any provisions that enable delaying, postponing or preventing a change in control.

**21.2.7. Exceeding the statutory thresholds (Article 8.3 of the bylaws)**

Any natural or legal person, acting alone or in concert with others, who holds, in any manner whatsoever, as defined by Articles L. 233-7 et seq. of the French Commercial Code, directly or indirectly, a share equal to three percent (3%) of the Company's share capital or voting rights, must disclose to the Company the information referred to in Article L. 233-7-I of the French Commercial Code (in particular the total number of shares and voting rights said person holds), by registered letter with return receipt requested, or by any equivalent means for persons residing outside France, sent to the head office within four trading days of the date on which the threshold is crossed.

This obligation also applies, under the conditions above, each time a new 3% threshold of the Company's share capital or voting rights is reached or exceeded, whatever the reason therefore may be, including above the 5% legal threshold.

Any shareholder whose stake in the share capital or voting rights falls below one of the thresholds set forth above must also inform the Company thereof within the same period of four trading days and according to the same terms.

In the event of non-compliance with this provision and upon request by one or more shareholders holding at least five percent of the Company's share capital or voting rights, the shares that exceed the portion that should have been notified shall be deprived of voting rights at any shareholders' meeting to be held until expiry of a two-year period following the date when the notification was cured.

**21.2.8. Specific provisions governing changes to the share capital**

The Company's bylaws do not have any special provision governing changes to its share capital.

## SECTION 22

### MATERIAL CONTRACTS

With the exception of the licenses and research and development agreements described in Section 11 of this Registration Document, as well as the contracts described below, the Group has not entered into any significant agreements other than those entered into in the normal course of its business.

Following on from the initial contract signed in 2010, at the end of 2014 the Company renewed its agreement with Fujikura (a company under Japanese law) for the supply of laser fibers and assemblies, Fujikura being the only supplier of laser fibers to the Company.

The signing of this type of agreement between Fujikura and the Company ensures that the manufacture and marketing of its products are compliant with ISO 13485:2003 and ISO 9001:2000 standards, and that the products are compliant with the Company's technical specifications and other quality references provided for in the agreement. It also sets out the terms of the relationship with this key supplier. The Company is confident in its ability to renegotiate its contracts with Fujikura on terms that should not adversely impact its business.

**SECTION 23**  
**THIRD-PARTY INFORMATION, STATEMENTS BY**  
**EXPERTS AND LETTERS OF INTENT**

None.

## SECTION 24 DOCUMENTS ON DISPLAY

Copies of this Registration Document are available free of charge at the registered office of the Company, 9 rue d'Enghien, 75010 Paris, France. This Registration Document may also be viewed on the Company's website ([www.maunakeatech.com](http://www.maunakeatech.com)) and on the AMF website ([www.amf-france.org](http://www.amf-france.org)).

The bylaws, minutes from General Meetings and other corporate documents of the Company, as well as the historical financial information and any evaluation or representation drawn up by an expert at the Company's request that must be made available to the shareholders, in accordance with applicable legislation, may be consulted, free of charge, at the registered office of the Company.

Regulated information within the meaning of the AMF General Regulation is also available on the Company's website ([www.maunakeatech.com](http://www.maunakeatech.com)).

## SECTION 25 DISCLOSURES ON EQUITY INVESTMENTS

The information concerning the subsidiary Mauna Kea Technologies Inc. is included in Sections 7 and 8 of this Registration Document.

## GLOSSARY

**Histopathology:** technical medical specialty, human and veterinary, comprising the study of macroscopic and microscopic lesions in pathological tissues sampled from a living or deceased subject;

**Autofluorescence:** light generated naturally by biological tissues, for example, under the action of illumination. Endoscopic imaging through autofluorescence therefore consists in analyzing this light in order to enhance, for instance, the detection of precancerous lesions;

**Biopsy:** mechanism that consists of taking a sample from the organism in order to carry out a microscopic examination;

**Optical biopsy:** see endomicroscopy;

**Bronchoscopy:** endoscopic examination enabling the visual exploration of the trachea and the bronchi and taking samples for analysis;

**Catheter:** medical device consisting of a tube designed to be inserted into the lumen of a body cavity or blood vessel, enabling drainage or infusion of liquids, or access for other medical devices;

**Cholangiocarcinoma:** biliary tract tumor;

**Colonoscopy:** specific case of endoscopy consisting of an exploratory examination of the colon (from the rectum to the small intestine);

**Cystoscopy (or Endourology):** endoscopic medical examination to examine the inner wall (mucosa) of the bladder via the urethra and possibly the ureters. This examination also enables therapeutic intervention;

**Dysplasia:** cellular/architectural modifications, the intensity of which defines the grade of dysplasia (Low grade = benign tumor, High grade = malignant tumor in situ = not crossing the basal membrane).

**Echoendoscopy:** exploration of the tracheobronchial tree combining endoscopy and ultrasonography. It is used to identify and take biopsies of structures situated behind walls and not visible with conventional endoscopy (essentially nodes, tumors and cysts).

At the end of the bronchoscope, an ultrasound probe is used to capture images in mode B and Doppler.

**Distal tip:** The farthest tip of a mini-probe, for instance. The distal tip of the confocal mini-probes contains optical micro-lenses;

**Endo-brachy-esophagus (EBO or Barrett's esophagus):** complication of gastro-esophageal reflux which, if it is not treated, can develop into esophageal cancer;

**Endomicroscopy:** endoscopic procedure with a device providing a microscopic image of the tissues;

**Endoscopic confocal microscopy via a miniprobe (ECM):** endomicroscopic procedure using a miniprobe compatible with standard endoscopes. The only ECM system available is the Cellvizio;

**White light endoscopy:** traditional endoscopy.

**EGD (Esophageal-Gastro-duodenoscopy):** upper endoscopy used to examine the esophagus, stomach and duodenum;

**Multicenter clinical trials:** clinical trials which take place simultaneously in several different places;

**Randomized clinical trial:** see "Randomized Clinical Trial";

**Randomized clinical trial:** clinical trial of a new treatment, during which the participants are allocated at random to the control group or the experimental group;

**Histology:** a branch of biology and medicine that studies biological tissues;

**Narrow Band Imaging (NBI):** NBI is a technology developed by Olympus based on an optical filter which can be used to improve visibility and contrast between capillaries, veins and other microstructures;

**Distal lesion:** lesions situated at the farthest tip of a given organ (esophagus, biliary tract, etc.);

**Dysplastic lesion:** precancerous lesion;

**Barrett's Esophagus:** see Endo-brachy-esophagus (EBO);

**Metaplasia:** transformation of a cellular tissue. Reversible phenomenon not disturbing the tissue's functions.

**Advanced mosaic:** optimized treatment of a succession of adjacent images used to reconstruct wide-angle maps of a mucosa;

**Mucosectomy:** endoscopic treatment of a precancerous lesion consisting of a resection of the mucosa and possibly of the sub-mucosa in a hollow organ, such as the colon, esophagus or stomach;

**Confocal miniprobes:** invention of Mauna Kea Technologies. They are made up of a bundle of several tens of thousands of optical fibers sequentially scanned by a laser beam emitted by the scanning unit. They carry the laser beam towards the area to be observed, inside the human anatomical tracts, through other standard endoscopic devices (colonoscope, gastroscope, bronchoscope, cholangioscope, etc.), a catheter or even a needle;

**Nodules:** abnormal, rounded, and palpable formations on or under the skin, which can be benign or malignant. Some nodules can be cancerous tumors;

**Optoelectronics:** combination of optical and electronic technologies;

**Polyp:** growth of the mucosa (typically in the colon) that can be benign or malignant. Some polyps can be flat and very hard to detect;

**Resection:** surgical ablation of part of an organ or a pathological tissue such as a tumor;

**Transurethral resection:** This procedure takes place via natural pathways without opening the abdomen. The surgeon inserts a device called a resector into the urethral channel. The operation takes place under visual control. The resector is used to remove the lesion and coagulate the various vessels which are likely to bleed. The tissues removed are sent to the laboratory for analysis. This procedure is used for both biopsies and the resection of bladder tumors.

**Learned society:** society or organization which groups experts who, through their work and thought processes, help knowledge to progress in their respective fields;

**Biliary and/or pancreatic duct strictures:** shrinkage of the natural pathways, whether pancreatic or biliary;

**System of spectroscopic interrogation of colorectal polyps:** optical technology which could, theoretically, be used to investigate the nature of a polyp by analyzing the light it reflects;

**Tomography:** Imaging technique enabling a virtual cutting of the human body. The scanner is an example of a tomographic technique. Endomicroscopy is also a tomographic technique that makes virtual cuts of the tissues;

**Tract:** set of organs constituting a system (digestive tract, genital tract, etc.);

**Ureter:** the ureters are muscular channels which carry urine from the kidneys to the bladder. In adults, the ureters are generally 25 to 30 cm long.

**Transpleural route:** invasive access route across the pleura, i.e. the space between the lungs and the thoracic wall.

## LIST OF CLINICAL PUBLICATIONS

The clinical publications are available on the Company's website; via the following link:  
<http://www.maunakeatech.com/en/content/clinical-evidence>