



Mauna Kea Technologies

A French Public Limited Society (*société anonyme*) with share capital of 766,273.52 euros
Registered office: 9 rue d'Enghien
75010 Paris, France
431 268 028 in the Paris Trade and Companies Register

2016 Registration Document



This Registration Document was filed with the *Autorité des marchés financiers* (AMF, French Financial Markets Authority) on May 31, 2017 in accordance with Article 212-13 of the AMF General Regulations. 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.

This document is available free of charge from the Company's registered office. It is also available in electronic format on the AMF website (www.amf-france.org) and on the Company's website (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 SA;
- > the term "Mauna Kea Technologies Inc." or the "Subsidiary" refers to the American subsidiary Mauna Kea Technologies Inc., wholly owned by Mauna Kea Technologies SA;
- > the term "Group" refers to Mauna Kea Technologies SA 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.

May 31, 2017

Alexandre Loiseau
Chief Executive Officer

Incorporation by reference

Pursuant to Article 28 of European Regulation No. 809/2004 of April 29, 2004, the following information is incorporated by reference in this Registration Document:

1. Regarding the 2015 financial year:

- the management report of the Board of Directors on the consolidated financial statements, the consolidated financial statements and the statutory auditors' report are presented in Sections 9 and 20 of the Registration Document filed with the AMF under No. R. 16-054 on June 13, 2016;
- the statutory auditors' special report on related party agreements is provided in Section 19.3 of said Registration Document.

2. Regarding the 2014 financial year:

- the management report of the Board of Directors on the consolidated financial statements, the consolidated financial statements and the statutory auditors' report are presented in Sections 9 and 20 of the Registration Document filed with the AMF under No. R. 15-056 on June 24, 2015;
- the statutory auditors' special report on related party agreements is provided in Section 19.3 of said Registration Document.

1.3. Persons responsible for the financial information



Alexandre Loiseau

Chief Executive Officer

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France

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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. Olivier Robinault
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.

Expiration date of the current term of office: at the close of the Annual 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, France.

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

Duration of the current term of office: six financial years from May 3, 2017.

Expiration date of the current term of office: at the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2023.

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.

Expiration date of the current term of office: at the close of the Annual 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, France.

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.

Expiration date of the current term of office: at the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016.

The office held by Auditex was not renewed at the general meeting of May 3, 2017, since the appointment of an alternate statutory auditor is not required when the principal statutory auditor is not a natural person or a single-person legal entity.

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 "Examination of earnings and financial position", 10 "Cash and capital", and 20 "Financial information concerning the issuer's assets and liabilities, financial position and profits and losses".

Simplified consolidated balance sheet

Consolidated data audited in €K	At December 31		
	2016	2015	2014
Non-current assets	3,625	3,893	4,440
Including intangible assets	2,565	3,135	3,542
Including property, plant and equipment	898	625	794
Including non-current financial assets	162	133	105
Current assets	16,349	18,610	23,098
Including cash and cash equivalents	9,053	10,620	15,018
TOTAL OF ASSETS	19,974	22,503	27,538
Equity	11,157	14,091	18,168
Non-current liabilities	2,900	2,428	3,124
Including long-term debt	2,640	2,182	2,606
Current liabilities	5,917	5,984	6,264
Including short-term borrowings and debts	404	719	638
TOTAL OF EQUITY AND LIABILITIES	19,974	22,503	27,538

Simplified consolidated income statement

Consolidated data audited in €K	At December 31		
	2016	2015	2014
Total sales of "equipment"	4,217	5,190	7,175
Total sales of "consumables" (probes)	2,941	2,473	2,958
Total sales of "services"	1,629	884	882
Total sales	8,787	8,547	11,016
Other income	883	1,434	1,267
Total of revenue	9,670	9,981	12,282
Cost of sales	(2,720)	(2,534)	(3,675)
Gross margin	69%	70%	67%
Total operating expenses	(19,660)	(22,939)	(26,088)
Other operating income and expenses	-	232	-
Operating profit (loss)	(9,990)	(12,726)	(13,805)
Profit before tax	(9,744)	(12,643)	(13,973)
Profit/(loss)	(9,744)	(12,643)	(13,973)
Other comprehensive income	26	200	99
Comprehensive income	(9,718)	(12,443)	(13,874)

Simplified consolidated cash-flow statements

Consolidated data audited in €K	At December 31		
	2016	2015	2014
Net cash flows from operating activities	(7,836)	(11,729)	(12,731)
Of which self-financing capacity	(8,635)	(11,284)	(11,733)
Of which change in WCR related to business activities	799	(446)	(998)
Net cash flows from investing activities	(573)	(326)	(567)
Net cash flows from financing activities	6,826	7,618	483
Change in cash	(1,567)	(4,398)	(12,774)

Net cash position

Consolidated data audited in €K	2016	of which < 1 year	of which > 1 year
Financial debts	(3,044)	(404)	(2,640)
Of which BPI-Coface advances	(3,038)	(404)	(2,634)
Cash and cash equivalents	9,053	9,053	-
Net cash balances	6,009	8,649	(2,640)

Q1 2017 sales:

The Company reported its quarterly sales for 2017:

Consolidated data in €K	At March 31		
	2017	2016	Change
Total sales of "equipment"	684	920	-26%
Total sales of "consumables" (probes)	535	682	-22%
Total sales of "services"	380	353	+7%
Total sales	1,599	1,954	-18%

In the first quarter, the Company sold 6 Cellvizio systems (one system was a conversion to sale of a consignment system placed in 2016) and secured contracts for 6 new systems under consignment in the U.S, compared to 9 systems sold and 1 consignment system shipped in the first quarter of 2016. Consumable probes unit volume was 125 units, compared to 197 probes in the first quarter 2016. The number of probe reorders (probes sold to existing customers) was 115 units in the first quarter 2017, compared to 167 in the first quarter 2016, reflecting relatively stable volume in the U.S. and lower volume in other markets.

SECTION 4

RISK FACTORS

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

Of the risks presented below, the Company would like to draw investors' attention to the risks related to the Group's commercial expansion, as well as the liquidity risk:

- the Group's development will depend in part on the pace at which healthcare professionals endorse its breakthrough technology; without this endorsement, the large-scale marketing of the Cellvizio may be compromised;
- the Group's development depends on its ability to market its products on new indications in the medical or research domains; this involves retaining the reimbursements already granted by some payers in the United States and securing new reimbursements for new indications and in new countries;
- the Group believes that balancing its yearly operating accounts will take several years and it considers that it will need to secure new financing, with equity and/or debt, to finance its operations within that time frame.

Summary table of risks

Section	Type of risk	Risk summary
4.1	Risks related to the markets in which the Group operates	
a	Technology risk	There are alternative technologies and the appearance of new competing technologies cannot be ruled out.
b	External growth risk	The Group might be unable to carry out the necessary growth transactions, or said transactions 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.
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's development is also conditional on its capacity to commercialize its products for new indications in the medical and research fields.
		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.
		Marketing of Cellvizio LAB relies on a distribution network and a limited direct sales force.
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.
		In the future, some of the Company's business could depend on technologies belonging to third parties.
4.2.3	Risks relating to the manufacturing process	The Company depends on a single partner for the supply of an important component.
		The Company depends on third parties for the manufacture of its products.

4.2.4	Risks relating to clients	The Company does not believe that it is exposed to any client risk.
4.2.5	Risks relating to potential product liability	The Company may be exposed to risks involving its being held liable during clinical development or the commercial exploitation of its products.
		The Company cannot ensure that its current insurance coverage is sufficient to respond to liability actions that may be brought against it.
4.2.6	Risks relating to the warranty granted on the products sold by the Company	The Company cannot guarantee that its estimation of the financial consequences of the risk of its contractual warranty being enforced is sufficient to satisfy the enforcement of the contractual warranty by all of its clients.
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.
4.4	Financial risks	
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.
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.
4.4.3	Risks related to the research tax credit	The method used by the Company to calculate its research and development expenses may be challenged, or it may lose its research tax credit (CIR) in the event of a regulatory change or due to a challenge by the tax authorities.
4.4.4	Risks relating to access to public advances	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 Group is exposed to changes in the EUR/USD exchange rate through its US subsidiary.
4.4.6	Interest rate, credit and cash management risks	
a	Interest rate risk	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.
b	Credit and cash management risk	The Group has established policies that insure it that its customers have an appropriate credit risk history.
4.4.7	Risk of dilution	Any additional award or issuance will result in a potentially significant additional dilution for the Company's shareholders.
4.5	Legal risks	
4.5.1	Risks relating to regulations applicable to the medical devices developed by the Group and possible changes in regulations	New regulatory constraints may prevent the marketing of the Company's products in the event of withdrawal or suspension of marketing authorizations, or they may slow it down by making the manufacture of said products more costly.
4.5.2	Risks relating to authorizations already obtained or ongoing processes	
a	Risks relating to the regulatory environment in Europe	The Company may not be able to renew the certificates necessary for the CE marking of its existing products within the required time frames.

b	Risks related to the regulatory environment in the United States	The Company would not be able to market its products on the US market if the FDA authorizations relating to the Group's existing products were to be challenged, or if the authorization requests for the Group's new products were rejected by the FDA.
c	Risks related to the regulatory environment in other countries	The Company's inability to obtain or maintain the necessary authorizations for its products could have a material adverse effect on its business, financial situation, earnings, growth and prospects.
4.5.3	Risks related to failures in industrial processes	The suspension, total stoppage, or total or partial prohibition of the activities of the Company's suppliers might materially affect the Group's financial situation, earnings and reputation.
4.5.4	Environmental risks	The nature of the Group's operations does not pose any major environmental risk.

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 Miniproboscopes, 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.

These technologies could acquire significant market share and limit the Group's ability to successfully market its products. Thus, they could prevent the technology integrated by the Company in Cellvizio (optical laser scanning) from becoming the standard 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") and to protect itself from this risk, the Group is constantly monitoring technology, patents and products so as to understand and anticipate change in its technological and business ecosystem. Thus, the Group continuously strives to improve its existing products and develop new products to provide solutions adapted to new areas of medicine and new pathologies, without compromising its technological progress.

As of end of December 2016, the R&D department had 27 associates and the budget devoted to R&D in 2016 came to more than €4.4 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, and until its products are better covered (in full or in part) by the public or private healthcare insurance systems, depending on the geographic region.

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, new operating procedures and the interpretation and integration of resulting new information (mainly *in vivo* microscopic images);
- limitations on reimbursements by public or private health insurance plans or collective entities.

Without the endorsement of healthcare professionals, the widespread commercial adoption of the Cellvizio could be more or less compromised, 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.

At the date of this Registration Document, the Group markets Cellvizio and its miniproboscopes in two markets: "Cellvizio LAB" is a specific version of the product targeted at research laboratories, while Cellvizio is sold to healthcare facilities (hospitals and clinics) in the areas of gastroenterology, pneumology and urology. Miniproboscopes used in clinical practice have a limited number of usages and thus generate recurring income.

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;
- the ability of its distributors to create a market in a wide range of application fields; and/or
- the results from current and future clinical trials.

The Company plans to continue its research and development efforts to perfect its existing products and develop new products and services. It believes that there are numerous other medical applications that could benefit from data obtained in examinations using the Cellvizio.

The Group's commercial development depends on its ability to preserve the reimbursements already granted by certain payers (private and public health insurers) and to extend reimbursements to other indications and 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 area, however, the Company reached a first milestone in March 2012, when the American Medical Association created three new, category I reimbursement codes for endomicroscopy (CPT codes) 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. The rates of the code for upper tracts were revised in late 2016 following a reclassification of the innovative aspect of endomicroscopy, and increased from 80 to 130% for the main code depending on the conditions of the patient's stay (out-patient or in-patient)¹. The third code concerns histopathologists.

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 February 2016, the American scientific societies in gastroenterology specified that needle-based endomicroscopy for pancreatic cysts was covered by the upper-tract CPT code.

At the date of this Registration Document, the United States is still 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. Please refer to Section 6.3.4 of this Registration Document.

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.

Cellvizio is marketed to healthcare facilities (hospitals and clinical practices) by a combination of three sales forces. In France and in the United States, it is marketed by a direct sales force for gastroenterology and pneumology applications. In other geographical areas instead, and in particular in Asia, certain South American countries and European countries other than France, the Company wants to adopt an indirect approach through a network of independent distributors who are granted

¹ Source: CMS 2017, @www.cms.gov

exclusivity by region and industry and market the technology under the Cellvizio brand. In addition, at the start of 2015 an industrial alliance known as Cook Medical was established for the exclusive global distribution of Cellvizio for urology applications.

Successful marketing of its products in France and in the United States relies, in particular, on the Group's ability to recruit, train and retain an in-house sales force.

On the other hand, the successful marketing of the Group's products on international markets through partners and distributors depends on its financial resources, its expertise and the clientele of its business partners. The Group cannot ensure that it will be able to retain its existing distributors or enter into new distribution agreements/partnerships to reach all the countries with sales potential, or that these distributors/partners 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 is even more significant given that in general these medical supplies and devices distributors have to promote and market several products, including some of their own manufacture. Consequently, they have limited time to devote to each product.

As of late December 2016, almost 40 exclusive distribution agreements had been signed not counting the one granted to the Company's United States subsidiary. In addition, an industrial and marketing agreement has been signed with Cook Medical Inc. For more information, refer to Section 6.5 "Marketing strategy: refocusing on indirect sales" 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 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.

Principaux Partenariats sur les territoires commerciaux prioritaires

Partenariats	Siemens	Siemens	Cook Medical	Fujifilm	AMCO	Edinburgh Molecular Imaging
Indication	CLE en radiologie interventionnelle	CLE en neurochirurgie	CLE en urologie	CLE en gastroentérologie et pneumologie	CLE en gastroentérologie et pneumologie	Imagerie biomoléculaire
Produits	AQ-Flex (IR)	modèle expérimental	CystoFlex/UroFlex	toute la gamme autorisée en Chine	toute la gamme autorisée au Japon	AveoFlex
Type de contrat	Partenariat de recherche clinique	Partenariat de recherche clinique	Partenariat de commercialisation	Partenariat de commercialisation	Partenariat de commercialisation	Partenariat de recherche clinique
Zone géographique	Strasbourg NHC et Hôpital Européen Georges Pompidou de Paris	Essai clinique en Cologne, 150 cas déjà publiés	Worldwide	China	Japon	Essai clinique auprès de Cleveland Clinic (Etats-Unis), UMCG (Netherlands) et Royal infirmary Edinburgh

*CLE : Confocal laser endomicroscopy

SECTION 4 - RISK FACTORS

		Geographical regions - Partnerships and distributors								
		Interventions	Products	EMEA Direct sales: France, UK, Germany, Netherlands, Belgium, Switzerland	Indirect sales: EMEA	China	Japan	APAC excluding China	United States	Americas excluding United States
Endoscopy	Biliopancreatic interventions	AQ-Flex/CholangioFlex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Endoluminal interventions	Gastro/Coloflex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Pneumological interventions	AlveoFlex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Urology interventions	UroFlex	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	
Surgery	Anti-reflux surgery	GastroFlex	-	-	-	-	-	Direct	-	
	Oncological surgery	CelioFlex	Direct					Direct		
	Urology surgery	CelioFlex								
	Other surgery	CelioFlex	Direct					Direct		
	Neurosurgery	In progress		Siemens (clinical investigation)						
Other approaches	Interventional radiology	In progress	Siemens (clinical investigation)/Direct							
	Biomolecular imaging	In progress		Clinical trial with Cleveland Clinic (US), UMCG (Netherlands) and Royal Infirmary of Edinburgh						

No marketing or ongoing partnership

Marketing of Cellvizio LAB relies on a distribution network 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 this day, Cellvizio's clinical contributions have been reported in numerous publications. There are more than 900 clinical publications worldwide on endomicroscopy, including several randomized, multicenter clinical trials, including some, of key gastroenterology applications, funded by the Group. In spite of the tangible evidence already obtained and disclosed, the Group continues its efforts and will continue to organize this type of trial, in particular with a view to clinically validating Cellvizio's contribution to new medical fields (urology, pneumology, surgery, interventional radiology, neurosurgery and biomarkers, etc.).

The quality and interest of these multicenter clinical trials are linked to the Group's ability to select its partner healthcare facilities and to recruit sufficient numbers of patients in relatively short periods of time to be able to quickly publish the results. The distance or geographical distribution of the trial sites may also give rise to operational and logistical challenges which may generate additional costs and delays. This is rationalized to mitigate these risks.

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.

Outside gastroenterology, the number of confocal endomicroscopy clinical trials is continuing to increase. They concern medical indications in the fields of urology, pneumology, surgery, interventional radiology, neurosurgery and biomarkers. These are not always identified by the Company as Sponsor, but can result from Investigator-Initiated Clinical Trials. 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 6.5.2.

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 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, the costs of which 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 proceeds from the sale of these 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 does not believe the loss of these exclusive licenses will have a material 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 identify 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. In November 2006, the latter then became a shareholder in Mauna Kea Technologies as part of a capital increase and held 1.1% of its capital at December 31, 2016.

Following an initial contract signed in December 2010, a collaborative cost-reduction project was carried out over a period of almost five years, during which both the Company and Fujikura performed an in-depth joint analysis of their mutual industrial restrictions and reached the following outcomes:

- in March 2011, validation of a type of fiber optics offering both the potential for significant cost reductions by increasing product volumes, and improved technical performance of the Company's products. The supplies requirements under the contract were fulfilled in March 2013;
- transfer to Fujikura and assembly of a miniprobe model in accordance with procedures validated by the Company, completed in June 2013. This enables the Company to forecast an increase in miniprobe production. The relevant supplies were provided as planned in the two years following completion of the transfer, at the price and in the quantities set out in the contract, which expired in May 2015.

Since then, the Company has continued to transfer certain manufacturing stages of its Confocal Miniprobes to Fujikura, further strengthening its relationship with this key supplier.

The Company and Fujikura signed a new framework agreement effective from January 1, 2015 for a term of three years (duration amended to four years in May 2016), tacitly renewable.

It sets a minimum purchase volume for the Company over four 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.

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). These choices are in line with the Company's wish to focus its manufacturing efforts on high value added tasks and to take advantage of the industrial know-how of savvy suppliers.

In light of its dependence on third parties to manufacture its products, the Company's business success is partly based on its ability to secure products manufactured externally in accordance with the required performance standards, in the quantities and within the timeframes requested and in a profitable manner. 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, opto-electronic components) of its equipment and consumables, it would have to revalidate 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 Company 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 and partners.

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 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 2016 was Cook Medical, Inc., the exclusive partner in urology. 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 of €529 thousand, still outstanding today.

The aggregate weight of the Group's three largest client balances accounts for 38% and 41% of trade receivables as of December 31, 2016 and 2015 respectively.

In 2016, one distributor in the APAC region accounted for more than 10.38% 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 Group 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, 2016, 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 €(92,456) thousand, including a net loss of €(9,744) thousand for the financial year ended December 31, 2016. 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.
- and more recently in its new business strategy, the increase of its fixed base of systems made available in its consignment model on its American market.

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 (all of which were converted by the end of 2007).

On February 9, 2017, the Company contracted funding through a bond issue of €7 million with IPF Partners, a fund specialized in alternative financing for European growth companies in the healthcare sector. This funding is made up of two bond portions: the first, which amounts to €4.0 million, has been issued to date; the second, for the remaining €3.0 million, will be available over the coming 12 months, subject to the achievement of pre-determined targets.

This funding is made up of 7,000,000 secured bonds for a total value of €7 million. The annual interest rate on these bonds is set at three-month EURIBOR + 8.5%. The term of the first portion is set at five years (of which 18 months without repayment of principal) and the second at four years (of which 12 months without repayment of principal). The terms and conditions of the bonds impose certain financial commitments.

The Company's financial commitments to benefit from the second tranche mainly concern the achievement of sales targets and targets relating to the level of capital-based financing. The Company is not exposed to any risks in the event that these targets are not met.

The Company is not exposed to liquidity risk resulting from the potential enforcement of prepayment clauses in bank loans.

At December 31, 2016, the Group's cash and cash equivalents came to €9.1 million. The Board of Directors worked on the assumption of a going concern, taking into account the cash position at the end of December 2016, sales prospects (including from partnership agreements), receipt of the 2015 research tax credit, the bond issue in February 2017, and provisional cash flows. Following a specific review of its liquidity risk, the Company considers that it is able to meet its scheduled repayments until December 31, 2017.

As at the date of this Registration Document, the Group has no liquidity risk since its cash flow at the date of this Registration Document covers its funding requirements until May 31, 2018.

Over the first quarter 2017, the Company continued to strengthen its equity through the PACEO financing line, through the receipt of its research tax credit for 2015, and by borrowing through the debt raised with IPF Partners. As at April 30, 2017, considering its cash position of €10.0 million and its forecast cash flows, the Company considers that it will be able to meet its future maturity schedules until May 31, 2018.

The Group is examining various sources of financing—with equity, debt or other non-dilutive solutions—to ensure continuity of operations in that time frame and beyond. More generally, the Group believes that balancing its yearly operating accounts will take several years. Therefore, it considers that it will need to secure new financing, with equity and/or debt, to finance its operations within that time frame.

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 €(7,836) thousand and €(11,729) thousand for the financial years closed on December 31, 2016 and 2015.

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 areas;

- 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 faces a liquidity risk and will not be able to honor its obligations and its cash resource requirements without implementing new equity financing, through loans or other non-dilutive sources of financing.

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 2014-2016 financial years:

(in €k)	12/31/2016	12/31/2015	12/31/2014
Research Tax Credit	828	1,201	1,251

4.4.4. Risks relating to access to public advances

At December 31, 2016, the Company enjoyed the following aid:

At Dec. 31, 2016 (in €k)	Amount granted	Amount received	Amount reimbursed	Discount effects	Amount still to be reimbursed
OSEO sub-total	4,436	3,923	1,020	-269	2,635
Total COFACE advances	1,704	1,704	1,295	-5	404
Total aid	6,140	5,627	2,315	274	3,038

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 to the consolidated financial statements closed on December 31, 2016 presented in Section 20.1 "Consolidated financial statements prepared under IFRS for the year ended December 31, 2016" 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.

Nevertheless, the Company considers that this risk is low for both the advance it received from the COFACE and for the advance it received from OSEO (BPI France):

COFACE advance

On December 12, 2006, the Company entered into a prospection insurance contract covering Canada and the United States. The cover period is from 09/01/2006 to 08/31/2010.

The initial amortization period was from 09/01/2010 to 08/31/2015 and has been extended until 08/31/2018 via a rider signed on January 12, 2010.

The contract can be annulled if:

- the Company does not make at least one trip into the prospected area during the coverage period;
- the Company's equity falls below 2 million euros at some point during the lifetime of the contract.

The "amortizations" are for repayment of the COFACE advances, which are made every year in line with the following conditions:

- 7% of the invoice value of goods;
- 14% of the value of services;
- 30% of the proceeds from the sale of the Company's goods.

At the end of December 2016, a €404,000 debt remained for the last scheduled amortization, which will be readjusted for sales for the period from 09/01/2015 to 08/31/2016.

OSEO advance (PERSEE project)

Article 2.13 of the Framework Agreement for the PERSEE project provides for early repayments of two kinds:

1/ Immediate repayment by operation of law in the event of judicial liquidation/business shutdown/dissolution/amicable liquidation.

2/ Repayment by operation of law and on the sole initiative of Oseo in the event of:

- failure by the Company to meet one of its obligations (*) [...];
- irregular situation with regard to its tax and social security obligations;
- inaccurate or dishonest declarations.

(*) Article 2.1.2 of the Framework Agreement outlines the Company's obligations:

- use the aid received for research;
- do everything within its power to carry out the work planned;
- document and give reasons for the work performed.

Article 4.3 of the Beneficiary Contract governing the PERSEE project stipulates that early repayment may be demanded by OSEO in the event of a contribution/merger/split/change in control of the Company or disposal of its assets.

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 Massachusetts 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 EUR/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 €267 thousand as of December 31, 2016;
- a variation in the EUR/USD exchange rate of -10% would have generated a drop in earnings of €(326) thousand as of December 31, 2016.

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	66%
EUR	15%
Other	19%
Total	100%

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, 2016, 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 €3,038 thousand as described in Note 11 "Borrowings and financial debt" of the consolidated notes included in Section 20.1 of this Registration Document.

To date, the Company has secured a non-dilutive, €7.0 million senior debt financing with IPF Partners, a leading provider of alternative financing solutions for emerging, commercial-stage European healthcare companies. This debt financing is comprised of two bond tranches of bonds: the first tranche of €4.0 million issued to date; the second for the remaining €3.0 million available in the next 12 months, subject to preset closing conditions.

This financing consists of 7,000,000 secured bonds for a total value of €7 million. The interest on the bonds will bear interest at an annual rate equal to the 3-month EURIBOR +8.5%. The term of the first portion is set at five years (of which eighteen months without repayment of capital) and the second at four years (of which twelve months without repayment of capital).

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 cash on hand only.

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 it was founded, regularly issued or allocated stock options, share warrants (BSA), founders' warrants (BSPCE) and, in 2016, preferred shares. 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 as of December 31, 2016, would enable the subscription of 1,754,830 new shares, thus generating a dilution equal to 8.77% on the basis of the capital existing to date and 8.07% on the basis of the diluted capital. The dilution in voting rights would come to 8.14% on the basis of the voting rights existing to date and 7.53% 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. The Company's products are subject to strict regulations which are continually changing as a result of global harmonization. In particular, the European Directive that has been revised as the "RECAST" regulation² was approved by the European Parliament in early April 2017 and is due to be published in May 2017, with a compliance deadline of May 2020.

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

² Regulation (EU) 2017 of the European Parliament on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

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. Replacement of this Directive by the new "RECAST" regulation will lead to stricter requirements which are harder to implement.

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 PreMarket 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 resort to the “510k” procedure to submit a file to the FDA for review. After being approved, the medical device is registered in a file kept up to date by the FDA.

The Company has already secured FDA approval for 12 applications of existing products in gastroenterology, pneumology, urology and laparoscopy (authorizations K051585, K061666, K111047, K120208, K122042, K123676, K132389, K133466, K141358, K150831, K151593 and K160416).

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, Israel, Saudi Arabia, Colombia, and more recently in Japan (April 2014).

In 2015, the Company obtained marketing authorization in Mexico and extended the range of existing marketed products in China (Cellvizio 100 Series with the new miniprobe designed to observe pancreatic cysts and for urology) and in Japan (miniprobe to observe pancreatic cysts). In 2016, new authorizations were obtained in Latin America and Asia.

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.

All marketing and reimbursement authorizations can be found in Section 6.3.4 of this Registration Document.

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

While the Company has put in place a supplier selection and monitoring system, it cannot guarantee that its suppliers or subcontractors comply or will comply at all times with the applicable regulations. 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
Comprehensive corporate insurance	AXA	
Fire and secondary risks		Ceiling €8.8 million
Broken glass		€15,000
Operating losses		€5,241,000
Broken machinery	AXA	
Cellvizio loaned or leased to a healthcare facility		€350,000
Investment guarantee		€100,000
		Equipment shown at trade shows (one per month)
Civil operating liability	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
Criminal defense – Appeal		€30,000
Civil liability/products		
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

Assistance to persons travelling	AXA	
All travelers (Company and Subsidiary)		
Personal accident insurance		€50,000
Civil liability insurance		€4,500,000
Key persons accident	CHUBB	€150,000/person
Risks covered:		€450,000/event
- accidental death		
- total irreversible loss of autonomy		
Three persons concerned: Chief Executive Officer, VP Finance and Scientific Director		
Employer's liability	Chartis Insurance	€500,000 Per year
Civil liability following a breach of employment law		
Defense		
Legal advice		
Liability of corporate officers	AIG	€5,000,000
All de jure and de facto senior managers (Company and Subsidiary)		
Transported merchandise	AGCS	Sales price Max: €1.5 million/claim

4.7. Legal and arbitration proceedings

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, France. The contact information for the Company is as follows:

Telephone: +33 (0)1 48 24 03 45

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

E-mail: investor@maunakeatech.com

Website: 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, Genset), Jean-Luc Nahon (Softway, 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 pneumology.

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 pneumology.

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 ever ICCU (International Conference of Cellvizio Users), a conference for the

community of Cellvizio users held in Miami Beach, Florida and attended by 45 physicians.

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

Seventh annual ICCU conference with more than 300 participants, including 85 experts, in Lisbon.

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.

Publication of two studies showing that endomicroscopy provides real time identification of healthy and cancerous tissue during breast-conserving surgery. Publication of results of a clinical study on the use of CLE with Cellvizio in the

scientific journal Breast Cancer Research and Treatment.	510(k) clearance obtained from the FDA for the use of Cellvizio® in surgery, allowing identification of cancerous tissue and effective guidance of treatment during surgery.	Endorsement of Cellvizio® by the American Society of General Surgeons (ASGS)
Obtaining a CPT reimbursement code in the United States for a Cellvizio biliary application.	Regulatory approval obtained in China to market the latest generation of Cellvizio 100s as well as probes specific to pancreatic (needle-based confocal laser endomicroscopy or nCLE) and urological applications.	Increase in reimbursement rates at hospitals and ambulatory surgical centers in the United States
Marketing authorization for Cellvizio received from the Mexican Health Authority.	Signed a master agreement with Cook Medical for urological applications.	Completion of the recruitment of 200 patients for the Contact II study on the diagnosis of pancreatic cysts using needle-based confocal laser endoscopy (nCLE)
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.	2016 Listed on the OTCQX market in the USA.	The first study on the contribution of Cellvizio to pediatric heart surgery is launched
Obtained CE marking in indications of minimally invasive laparoscopic surgery.	Extension of strategic partnership with Fujifilm China.	The CONTACT clinical study confirms the clinical effectiveness of Cellvizio needle-based endomicroscopy in the diagnosis of pancreatic cysts
CE marking obtained for interventional radiology.	Exclusive urology partnership with Cook Medical FDA authorization for the marketing of miniprobes	Publication of the results of the PERSEE study in "Surgical Endoscopy" and the "European Journal of Gastroenterology & Hepatology"
CE marking obtained for the new perioperative platform Cellvizio 800.	Collaboration with Edinburgh Molecular Imaging.	
Regulatory approval obtained in Japan for the confocal endomicroscopy miniprobe AQ-FLEX 19.		

5.2. Investments

5.2.1. Principal investments made since 2013

Gross Investments (IFRS, in €K)	FY 2016 12 months Consolidated	FY 2015 12 months Consolidated	FY 2014 12 months Consolidated
Intangible assets	89	255	403
Property, plant, and equipment	427	107	253
Non-current financial assets	29	28	28
TOTAL	545	380	684

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 2016, no development expenses were capitalized since the expenses were not eligible under IAS 38.

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, 2016, the investments made have been of the same kind and order of magnitude as those mentioned above during the 2011-2015 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 global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer thanks to real time *in vivo* microscopic visualization. The Company's flagship product, Cellvizio, has received clearance to sell a wide range of applications in more than 40 countries including the United States, Europe, Japan, China, Canada, Brazil and Mexico.

The Group has designed, developed and marketed an innovative imaging platform used to view tissues at cellular level, in real time, during standard procedures. Through this set of new technologies, the microscope can be positioned in the patient's body instead of having to remove an often random fragment of tissue or organ from the patient which is then placed under a microscope.

The technological platform, called Cellvizio, thus positions the Group as a key player in the digital transformation of medicine and surgery. The Group's objective is therefore to develop further, from diagnostic methods of an analog paradigm, which is costly and not very efficient, to a completely digital, instant paradigm which can provide doctors and surgeons with all the power of real-time cellular visualization with the best machine learning algorithms.

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

The Company is mainly focusing its efforts on the American market, where conditions have improved significantly.

Furthermore, the implementation of the "Vision 2020" strategic plan, which is set to make Mauna Kea Technologies a leading player in the digital transformation of medicine and surgery, is now well under way. After successfully bringing microscopes into the patient's body, the Company is now on the verge of bringing *in vivo* the connected laboratory of the future, harnessing the full power of the latest artificial intelligence techniques now available in the Cloud and the advent of next-generation molecular markers.

A summary is given below of the indications we cover, the Miniprobes suitable for these indications, the geographic areas in which we can market them and where we have secured repayment codes.

Route of access	Indications	Interventions	Products	Geographic marketing areas (1) (2)	Geographic areas where repayment rights have been secured
Endoscopy	Digestive endoscopy	Biliopancreatic interventions	AQ-Flex	All countries except South Korea, Australia & Canada	USA: Upper digestive tract including needle-based access to the pancreas
			CholangioFlex	All countries	-
		Endoluminal interventions	ColoFlex	All countries	France: pending HAS (France health regulatory body)
			GastroFlex	All countries	USA: Upper digestive tract France: pending UNCAM
	Pneumology	Pneumological interventions	AlveoFlex	All countries	-
	Cystoscopy, ureteroscopy	Interventions Urology interventions	CystoFlex F/UHDR	All countries except Israel & Singapore in progress	-
			UroFlex B	All countries except Singapore in progress	-
	Surgery	Digestive surgery	Anti-reflux surgery	GastroFlex	All countries
Laparoscopic surgery		Oncological surgery	CelioFlex UHD5	Bangladesh + Chile + Europe + HK + India + USA	-
			CelioFlex UHD5	Bangladesh + Chile + Europe + HK + India + USA	-
			CelioFlex UHD5	Bangladesh + Chile + Europe + HK + India + USA	-
		Robotic surgery	CelioFlex UHD5	In progress	-
Neurosurgery		Neurosurgery	In progress	In progress	-
Other approaches	Interventional radiology	Radiology Interventional radiology	AQ-Flex IR	Bangladesh + Chile + Europe + HK + India	-
		Biomolecular imaging	In progress	In progress	-

(1) Unless stated otherwise, the Company holds the marketing authorizations for its products in all of the following countries: Australia, Bangladesh, Belarus, Brazil, Canada, Chile, China, Colombia, Ecuador, Egypt, Europe (Bosnia, Bulgaria, Croatia, France, Greece, Italy, Baltic Countries, Poland, Czech Republic, Romania, Scandinavia, Serbia), Hong Kong, India, Iran, Israel, Japan, Mexico, Pakistan, Peru, Russia, Singapore, South Korea, Thailand, Turkey, USA, Yemen.

(2) Authorizations are in the process of being granted for all indications/products in Saudi Arabia.

> Cellvizio, a breakthrough technological innovation

Cellvizio is the smallest microscope in the world, 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 1,000 times more than a standard camera. They are obtained by pressure of the Cellvizio miniprobe on the wall of the mucosa or target organ. The process is therefore minimally invasive and perfectly repeatable.

The company has been awarded 206 patents to protect its technologies and processes. (See Section 11.2 of this Registration Document).

> **Cellvizio, a benefit for patients, physicians and health systems**

Cellvizio is designed to help physicians reduce uncertainty in 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 design was focused on requiring minimal changes to existing practices. With this in mind, a range of probes has been developed that are compatible with existing practices. For example, in the digestive endoscopy field, Miniprobos for this type of application are compatible with almost all endoscopes on the market, and integrate naturally as an endoscopic tool. Cellvizio makes it possible to improve practices without radically changing them.

Cellvizio's medical benefit has been proven by many clinical trials concerning each of the indications in which it is routinely used today.

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%³, Barrett's esophagus: 58%⁴ 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 6.3.3 "Products and clinical validation").

> **Cellvizio, a multiple-indication platform**

Cellvizio is designed to be a platform potentially capable of application in all medical and surgical sectors in which tissue characterization is required. These include gastroenterology, urology, pneumology as well as gynecology, ENT, surgery, and interventional radiology. 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 that has not yet been evaluated.

Cellvizio can be used in gastroenterology, pneumology or urology, where only miniprobos are specific to each indication. There is a miniprobe for every indication, which, depending on the model, can be reused 10 or 20 times. (See Section 6.3.3 "Products and clinical validation").

> **A protected ownership innovation**

As of December 31, 2016, the Mauna Kea Technologies patents portfolio included 206 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, pneumology 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.

³ "Presence Of High-risk Prostate Cancer Can Be Predicted Without A Biopsy, New Study Says." ScienceDaily. ScienceDaily, May 22, 2005.

⁴ Bertani H. et al. Improved Detection of Incident Dysplasia by pCLE in a BE Surveillance Program. Dig Dis Sci, 2013.

There are more than 900 published references for endomicroscopy in the PubMed database, based on the key word “endomicroscopy”.

The results of the Company’s clinical studies program are outlined in Section 6.3.3 of this Registration Document.

For example, in October 2016, Dr. Bertand Napoléon presented the results of the second phase of the CONTACT study at the United European Gastroenterology Week (UEGW) in Vienna. The study, involving 209 patients in five French centers, showed that needle-based endomicroscopy successfully confirmed the benign nature of undetermined pancreatic cysts with 100% specificity by confirming a superficial vascular network found only in this type of cyst and invisible to traditional imaging, identified in the first phase of this study published in 2015 in *Endoscopy* and in *Surgical Endoscopy*. 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. Other characteristic signs of malignant lesions that are equally specific were presented at UEGW in 2016 (mucinous cysts and intraductal papillary mucinous tumors of the pancreas).

> **Marketing authorization obtained**

The Group has obtained twelve 510(k) regulatory authorizations from the United States Food & Drug Administration (FDA) as well as CE marking for its use in digestive, pulmonary and urological tracts using endoscopy. In 2015 Mauna Kea Technologies also obtained CE marking for two new miniprbes for laparoscopic surgery and interventional radiology, and in October 2015, FDA regulatory authorization in laparoscopic surgery.

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 were obtained in China (renewed at the end of 2015 for the new version of the Cellvizio 100 Series with AQ-Flex miniprbes and extension to urology), in Brazil, Russia and Mexico in 2015, and in Venezuela, Uruguay and Taiwan in 2016.

The Company has obtained dual authorization in Japan: a class 1 authorization for the use of Cellvizio technology, and a class 2 (NINSHO) authorization for the endoscopic use of Cellvizio miniprbes. They both concern all the current clinical indications covered by Cellvizio, except laparoscopy and interventional radiology: gastroenterology, including the AQ-Flex Miniprobe for pancreatic cysts, urology and pneumology.

Summary of the marketing authorizations for all of the Company's products

	Cellvizio systems (1)		Pneumology	Digestive endoscopy				Urology			Interventional radiology	Laparoscopic surgery
	-		Pneumo. int.	Endoluminal interventions		Biliopancreatic interventions		Interventions Urology interventions			Radio. int.	Laparoscopic surgery
	F400	F800	AlveoFlex	GastroFlex	ColoFlex	CholangioFlex	AQ-Flex	UroFlex B	CystoFlex F	CystoFlex UHDR	AQ-Flex IR	CelioFlex UHD5
Europe												
Israel									In progress	In progress		
Russia												
Belarus												
Saudi Arabia	In progress		In progress	In progress	In progress	In progress	In progress	In progress	In progress	In progress		
Turkey												
Yemen												
Iran												
Pakistan												
Egypt												
Australia							In progress					
China												
Hong Kong												
India												
Japan												
South Korea										In progress		
Singapore								In progress	In progress	In progress		
Taiwan												
Thailand												
Bangladesh												
Canada							In progress					
USA												
Brazil												
Mexico												
Colombia												
Chile												
Venezuela												
Ecuador												
Peru												
Uruguay												

(1) The Cellvizio F400 and F800 are differentiated by the wavelengths they use; the F800 is only marketed in the EU and USA

Key	
	Marketing authorization applied for and obtained
In progress	Marketing authorization applied for and currently being processed
	Marketing authorization not applied for

> Repayment

In the United States, in March 2012, the Group obtained the creation of three new category 1 CPT® codes for the upper digestive tract and histopathology review. 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, 2017, the Medicare/Medicaid tariff linked to these first two codes has been approximately \$2,500 per procedure. In early 2016, the American Medical Association (AMA) defined the cover for needle procedures in pancreatic cysts and masses (nCLE, needle-based confocal laser endomicroscopy) by assigning one of the codes covering intervention in the upper tract. In March 2015, the AMA assigned a new CPT code for use in endoscopic retrograde cholangiopancreatography (ERCP), allowing practitioners to diagnose biliary tract pathologies, notably strictures and cancers. This code does not yet give rise to a reimbursement rate, however the Company is working on this.

It is essential to understand the following points to assess the importance of reimbursement in the United States:

- CPT codes are used for out-patient procedures and therefore do not apply to surgical procedures requiring hospitalization for one night or more;
- obtaining a CPT code is one of the three stages in the reimbursement of a procedure: a price also needs to be obtained, as well as payment by government insurers and private insurers;
- it is very difficult to obtain a CPT code, but obtaining its payment by insurers, particularly private insurers, is even harder.

Mauna Kea Technologies has managed to complete most of these three stages: it has secured several repayment codes, obtained a price and arranged complete national medical cover by Medicare/Medicaid and partial cover with private insurers. The Company has changed its mode of attack for private insurers and began to see very good results in the last few months of 2015. It intends to continue this approach in order to obtain not only local cover, but also national cover by one of the large private insurers. The success of these initiatives is a key factor for success for the faster development of applications for gastroenterology. The use of Cellvizio in Barrett's esophagus and in the treatment of patients suffering from gastroesophageal reflux was recommended by several major learned societies in this field, including the American Gastroenterological Association (AGA) and the American Society of General Surgeons (ASGS). The College of American Pathologists (CAP) has also started to recognize technology developed by the Company by creating for example an *in vivo* microscopy (IVM) division.

For applications other than gastroenterology, the need to obtain a code will depend on the nature of the procedure, whether it is an out-patient procedure or not. The Company is now developing a certain number of applications which will not be practiced as out-patient procedures and thus will not require new CPT codes.

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.

For the time being, the Company has ceased active marketing in Germany and is looking for a local partner, which must have knowledge of reimbursement procedures, especially local health insurance funds (KrankenKassen). Reimbursement is also a key factor for commercial success in Germany.

In France, the French National Authority for Health (HAS) approved the use of Cellvizio in mapping Barrett's esophagus in late 2014, but no authorized pricing has been established by UNCAM. Recently, representatives from the *Syndicat des Médecins de l'Appareil Digestif* have had discussions with the *Direction Générale de l'Offre de Soins* about the applicability conditions for a new procedure, and the process is again underway. A priced procedure can be expected for 2017.

In September 2015, the HAS returned an unfavorable opinion for the use of Cellvizio for the characterization of biliary tract strictures. The Group intends to appeal this decision by submitting a new application. The application to use Cellvizio in the colon was to be evaluated sometime in 2017. The Group expects to submit a fast-track application for uses in the pancreas.

SECTION 6 - OVERVIEW OF ACTIVITIES

Summary of reimbursements requested/obtained

Country	Indication	Product	Competent authority	Year of registration	Title	Tariff
USA	Upper digestive tract including needle-based access to the pancreas	GastroFlex/AQ-Flex	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement code CPT 43206. Upper digestive tract. Esophagoscopy with endomicroscopy. Effective date: January 1, 2013.	\$1,334 for hospitals and \$141 for physicians
		GastroFlex/AQ-Flex	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement code CPT 43252. Upper digestive tract. Barrett's esophagus with endomicroscopy. Effective date: January 1, 2013.	\$2,510 for hospitals and \$178 for physicians
		-	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement code CPT 88375. For the interpretation of the images obtained from the endomicroscopy. Effective date: January 1, 2013.	According to the published tariffs
	Bile ducts (ERCP)	CholangioFlex	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2014	Reimbursement code CPT 039X7T. Allocation of a CPT code for a bile duct endomicroscopy technique. Effective date: January 1, 2016.	Still to be obtained
France	Mapping in Barrett's esophagus	GastroFlex	French Health Authority (HAS)/UNCAM	Q4 2010	French Health Authority authorizes the use of optical endomicroscopy in mapping Barrett's esophagus (September 17, 2014)	Awaiting publication in the Official Journal of the decree containing the list of centers authorized to perform the procedure (DGOS), followed by inclusion in the relevant nomenclature and tariff (UNCAM)
	Monitoring colon polypectomy scars	ColoFlex	French Health Authority (HAS)/UNCAM	Q4 2010	Inclusion of the procedure in the HAS work program for the period Q3 2016 to Q1 2017. Medical evaluation by SEAP-CNEDIPTS in progress.	Awaiting publication of the HAS notice to initiate discussions with UNCAM
	Characterization of biliary tract strictures	CholangioFlex	French Health Authority (HAS)/UNCAM	Q4 2010	French Health Authority has not authorized the use of endomicroscopy (July 22, 2015) Additional data are needed to provide evidence of the clinical benefits of endomicroscopy in this indication.	NA
Germany	Confocal endomicroscopy of the digestive tract	All probes	German Institute for documentation and medical information (DIMDI)	2013	Code OPS 3-301 added to the medical nomenclature for an endomicroscopy procedure in the digestive tract, including bile and pancreatic ducts. Effective date: January 1, 2014.	Insufficient volume of procedures for tariff and/or addition to G-DRG (InEK)
UK	Needle-based endomicroscopy for the characterization of lesions of the pancreas	AQ-Flex	National Institute for Health and Care Excellence (NICE)	2015	Rejected by NICE-MTEP (November 30, 2015). Additional data are needed to provide evidence of the clinical benefits of endomicroscopy in this indication. Publication of a technological evaluation report (MIB) on June 26, 2016.	NA
CHINA	Endomicroscopy	GastroFlex/CholangioFlex/ColoFlex/AQ-Flex	Chinese Health Ministry	2016	A tariff has been obtained in several regions allowing hospitals to charge patients according to the Chinese system.	Varies depending on the region

The US is the only country where the Group currently has reimbursement rates.

> **Installed base of more than 550 systems sold**

The Company chose rapid internationalization at the start of the marketing phase. The installed base of more than 550 systems sold is thus well distributed over several continents with more than 150 systems installed in the American zone, more than 200 systems installed in the EMEA zone and more than 100 systems in the Asia Pacific zone (APAC).

> **Size of market**

The number of facilities with endoscopy rooms is estimated at around 70,000 throughout the world, including 12,000 in the United States, 15,000 in Europe and more than 40,000 in Asia (see Section 6.4 below relating to the market).

Thanks to this new market data and the revaluation of the reimbursement by Medicare/Medicaid, the group now targets hospital centers, whether out-patient or not, specializing in the upper digestive tract. These are mainly *community hospitals* with major activity in terms of gastroesophageal reflux and Ambulatory Surgical Centers (ASC), which treat a very large number of these patients. Up-to-date market segmentation makes it possible to estimate the number of Community Hospitals and ASCs meeting these criteria at 1,500 and 1,200 respectively.

The Company estimates that the total number of procedures so far which could be improved by the Cellvizio, in clinically validated indications, is between two and three million for the United States per year.

The potential annual recurring revenue in the United States is consequently very significant, at \$1 billion to \$3 billion dollars.

> **Change in the Group's commercial strategy**

As announced in October 2015, the Company has changed its marketing strategy: from direct marketing in gastroenterology, the Company is now in the process of moving to an expanded marketing system including new indications but through major partners, such as Cook Medical for urology worldwide, or Fujifilm for gastroenterology and pneumology applications in China.

The Company is actively searching for new partners to expand its markets and increase its income. One of the major current priorities is to find a strategic marketing partner in the United States in the field of gastroenterology, the Company's historic activity, and which generates the lion's share of its income. Recent progress made in the US in terms of repayment (see Section 6.3.4.), acknowledgment by learned societies (the American Gastroenterological Association, which has 18,000 members, has acknowledged the interest of endomicroscopy and has considered its use appropriate as a replacement for random biopsy procedures in the esophagus) and of use of installed systems are all pointers for the signature of a partnership under good conditions.

During this transition phase, the Company is continuing its direct marketing for gastroenterology and pneumology in Europe and the United States.

The Company named Bruno Villaret, until then Asia Pacific General Manager, as global Director of Sales. This puts him in charge of all sales personnel.

In the EMEA region at year-end 2016, the team was composed of three people: two sales managers responsible for sales in France, Benelux and southern Europe, and an EMEA Sales Director who oversees our commercial activity in the rest of Europe and APAC countries (excluding China and Japan) and in Latin America.

At the end of December 2016, the U.S. sales team had seven members. The team is composed of four regional "Systems" sales managers and three clinical support managers. These sales teams are led by one sales manager.

Finally, in Asia, development is led by a country manager in Japan and a sales manager in China, along with a head of marketing and clinical activities.

Overall, at the end of 2016, the Group had a sales force of 14 people.

Principaux Partenariats sur les territoires commerciaux prioritaires

Partenariats	Siemens	Siemens	Cook Medical	Fujifilm	AMCO	Edinburgh Molecular Imaging
Indication	CLE en radiologie interventionnelle	CLE en neurochirurgie	CLE en urologie	CLE en gastroentérologie et pneumologie	CLE en gastroentérologie et pneumologie	Imagerie biomoléculaire
Produits	AQ-Flex (IR)	modèle expérimental	CystoFlex /UroFlex	toute la gamme autorisée en Chine	toute la gamme autorisée au Japon	AlveoFlex
Type de contrat	Partenariat de recherche clinique	Partenariat de recherche clinique	Partenariat de commercialisation	Partenariat de commercialisation	Partenariat de commercialisation	Partenariat de recherche clinique
Zone géographique	Strasbourg NHC et Hopital Européen Georges Pompidou de Paris	Essai clinique en Cologne, 150 cas déjà publiés	Worldwide	China	Japon	Essai clinique auprès de Cleveland Clinic (Etats-Unis), UMCG (Netherland) et Royal infirmary Edinburgh

*CLE : Confocal laser endomicroscopy

SECTION 6 - OVERVIEW OF ACTIVITIES

		Geographical regions – Partnerships and distributors								
		Interventions	Products	EMEA Direct sales: France, UK, Germany, Netherlands, Belgium, Switzerland	Indirect sales: EMEA	China	Japan	APAC excluding China	United States	Americas excluding United States
Endoscopy	Biliopancreatic interventions	AQ-Flex/CholangioFlex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Endoluminal interventions	Gastro/Coloflex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Pneumological interventions	AlveoFlex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Urology interventions	UroFlex	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	
Surgery	Anti-reflux surgery	GastroFlex	-	-	-	-	-	Direct	-	
	Oncological surgery	CelioFlex	Direct					Direct		
	Urology surgery	CelioFlex								
	Other surgery	CelioFlex	Direct					Direct		
	Neurosurgery	In progress		Siemens (clinical investigation)						
Other approaches	Interventional radiology	In progress	Siemens (clinical investigation)/Direct							
	Biomolecular imaging	In progress		Clinical trial with Cleveland Clinic (US), UMCG (Netherlands) and Royal Infirmary of Edinburgh						

No marketing or ongoing partnership

> **Conclusion: establish ourselves as the leader in *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 digital optical biopsy as a treatment standard.

The proposed utility of Cellvizio can be applied to all medical sectors which include biopsies, so the Group will continue its clinical validations of Cellvizio in pneumology, urology and surgery, 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 neurosurgery, breast surgery, gynecology or ENT.

> **Highlights of 2016**

Extension of strategic partnership with Fujifilm in China

On February 1, 2016, following the recent approval of Cellvizio 100 by the Chinese FDA, the Company decided to extend its strategic partnership with Fujifilm China. Fujifilm will commercialize Cellvizio for gastroenterological and pulmonary applications in China and will integrate the Cellvizio platform into its commercial offers for advanced endoscopy systems.

Contact II study

On February 25, 2016 the Company announced it had completed the recruitment of 200 patients for the CONTACT II study of the diagnosis of pancreatic cysts with needle-based confocal laser endomicroscopy (nCLE). At the same time, the results of several clinical trials involving confocal laser endomicroscopy were published in two peer-reviewed medical journals: the *World Journal of Gastrointestinal Endoscopy* and the *Romanian Journal of Morphology and Embryology*.

Partnership with Edinburgh Molecular Imaging (EMI)

On April 6, 2016, the Company announced its clinical research partnership with Edinburgh Molecular Imaging, Ltd. (EMI); the aim is to study the potential of a partnership between EMI's biomolecular imaging-optical markers and the Cellvizio platform in diagnosing cancers and other inflammatory pathologies.

Exclusive urology partnership with Cook Medical

On May 9, 2016, Cook Medical unveiled the Cellvizio platform at the Annual Meeting of the American Urological Association (AUA), one of the largest gatherings of urologists in the world, offering them unparalleled access to groundbreaking research, new guidelines and other major advances in urologic medicine.

Commercial repositioning

From early 2016, the Company has been active in ensuring the operational implementation of the global marketing partnership it signed with Cook for urology indications. This indirect sales agreement involves Cook marketing a version of the Cellvizio under its own brand, with the Company being responsible for production. The Company expects to be able to sell its first systems to Cook before the start of the second half of 2016.

In early May 2016, the direct sales force in the USA was organized into two divisions, geographically distributed on the East and West regions of the USA, and placed under the direct responsibility of the Sales Director at the global level.

Clinical results and conferences - the value of optical biopsy

May 11, 2016: at the World Congress for Bronchology and Interventional Pulmonology, the Cellvizio platform was presented at a key symposium on probe-based confocal laser endomicroscopy (pCLE), in addition to many other presentations by leading international teams.

May 19, 2016: Cellvizio® platform features prominently at two major gastroenterology events.

The first meeting highlighting Cellvizio is Digestive Disease Week (DDW) 2016, which is the world's largest gathering of physicians and researchers in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery.

The second meeting was the 91st Congress of the Japan Gastroenterological Endoscopy Society (JGES), which was held in Tokyo.

FDA authorization for the marketing of surgical miniprobes

May 25, 2016: US FDA clearance for its near-infrared surgical miniprobes. FDA 510(k) clearance covers Confocal Miniprobes used with the near-infrared Cellvizio platform for urological and surgical applications.

Image-guided surgery with intra-operative macroscopic fluorescence systems provides surgeons with more accurate anatomical guidance. The addition of microscopic fluorescence in pathological tissue assessments should provide immediate, actionable information that may be used to improve diagnostic potential and further guide surgical treatments. These new probes will be compatible and complementary to the systems currently in place and used by all major players involved in laparoscopic surgery.

September 1, 2016: the American Society of General Surgeons (ASGS) endorses Cellvizio® as integral to the comprehensive assessment of and therapeutic decisions for the treatment of Barrett's esophagus and Gastroesophageal Reflux Disease (GERD).

October 13, 2016: the first study on the contribution of Cellvizio to pediatric heart surgery is launched.

The project, led by the University of Utah School of Medicine and Harvard Medical School, is subsidized by the National Institutes of Health (NIH). This study of cardiac surgery will explore, for the first time, a key new indication in pediatric heart surgery, and will complement the research carried out on the use of Cellvizio in an ever-increasing number of surgical procedures;

October 19, 2016: the CONTACT clinical study confirms the clinical effectiveness of Cellvizio needle-based endomicroscopy in the diagnosis of pancreatic cysts at the 2016 United European Gastroenterology Week (UEGW). 217 patients were recruited from five French hospitals and clinics. The results confirm and reinforce the results that were previously published (CONTACT I pilot study, DETECT, INSPECT) on the contribution of nCLE technology to the diagnosis of pancreatic cystic lesions.

Increase in reimbursement rates at hospitals and ambulatory surgical centers in the United States

November 4, 2016: Centers for Medicare and Medicaid Services (CMS), the body that sets the reimbursement rates for medical care in the United States, publishes the definitive reimbursement terms applicable in 2017 for surgical procedures performed in hospitals and ambulatory surgical centers. These new reimbursement rates have been increased for gastroesophageal reflux and Barrett's esophagus indications, as recently recommended by the ASGS (American Society of General Surgeons), AGA (American Gastroenterological Association) and CAP (College of American Pathologists), and for the imaging of pancreatic cysts, as supported by the high-caliber clinical data presented recently. An increase of 131% in the reimbursement rate for procedures carried out in hospitals, and 86% for procedures carried out in ambulatory surgical centers.

November 30, 2016: publication of the results of the PERSEE study in "Surgical Endoscopy" and the "European Journal of Gastroenterology & Hepatology". The PERSEE study demonstrates the applicability of Cellvizio in digestive cancer surgeries.

Financing

On July 12, 2016, the Company carried out a capital increase of approximately €4.4 million, subscribed by a limited number of investors operating in the health industry. This capital increase will support the execution of Mauna Kea's growth strategy and ongoing transition to a more capital-efficient, partnership-based commercial strategy.

The capital increase covers a total of 2,980,131 new ordinary shares each with a nominal value of €0.04, issued to a limited number of European institutional investors in the health industry falling within the category set out by the twenty-second resolution of the Extraordinary Shareholders' Meeting of May 4, 2016, in accordance with Article L.225-138 of the French Commercial Code.

The issue price of the new shares was set at €1.49 per share, thus a discount of 14.49% based on the volume-weighted average price of the previous three trading sessions.

6.2. Our Technology

6.2.1. Innovation strategy

A High Capacity For Innovation

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

Innovation, in every field, starts with an analysis of applicational needs, and concerning medical devices, clinical need analysis and its constraints.

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, the Group appointed a multidisciplinary team (see below) for upstream integration of all the constraints linked to use, of course, and also to development, industrialization and marketing of its system, well beyond the development of a simple 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 working within the context of an iterative process, was able 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 this microscope and its lenses, the miniprobos;
- optimized image processing to make up for the physical limits of the optical components;
- the high ability to be integrated into standard equipment;
- each component designed so as 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.

- **A High-Level Multidisciplinary Team**

At the end of December 2016, the Research and Development team had 25 employees (doctors, engineers or technicians) covering the fields of expertise necessary for the development of the Group's products and technologies, namely:

- optics and optotronics;
- 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**

Innovation, in every field, starts with an analysis of applicational needs, and concerning medical devices, clinical need analysis and its constraints.

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, the Group appointed a multidisciplinary team (see below) for upstream integration of all the constraints linked to use, of course, and also to development, industrialization and marketing of its system, well beyond the development of a simple 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 working within the context of an iterative process, was able 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 this microscope and its lenses, the miniproboscopes;
- optimized image processing to make up for the physical limits of the optical components;
- the high ability to be integrated into standard equipment;
- each component designed so as 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.

- **A High-Level Multidisciplinary Team**

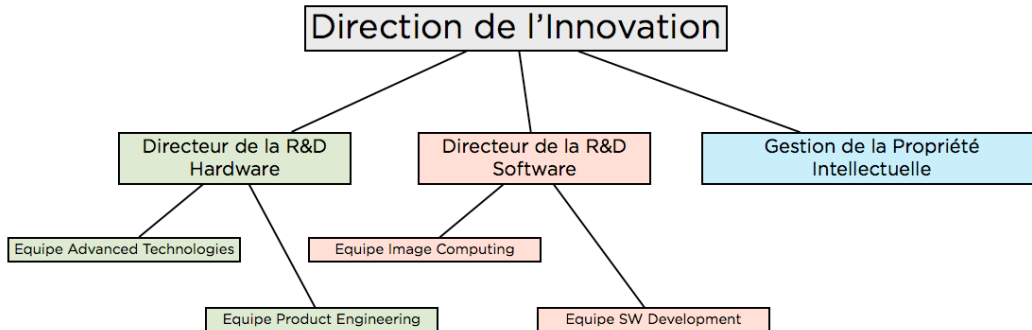
At the end of December 2016, the Research and Development team had 27 employees (doctors, engineers or technicians) covering the fields of expertise necessary for the development of the Group's products and technologies, namely:

- optics and optotronics;
- 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 & Development Division is comprised of two departments under the responsibility of the Innovation Director, as shown in the diagram below.



Each R&D department acts within the Company as a center of expertise and, throughout the life cycle of each product, oversees any work that may fall within its remit, from initial concept to final production.

- **Upstream R&D**

The Company is organized to draw on the necessary resources to directly inspire technological innovations that will enable it to expand in its market, and win new markets, by exploring solutions likely to encourage the development of innovative solutions to improve the care given to patients.

The Innovation department provides ongoing scientific and technological oversight. Its objective is to identify and validate the ability of the technologies or components to remain at the leading edge of technology while limiting any risk of obsolescence relative to key components 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.

On the clinical level, the Company collaborates with various hospitals to assess the potential relevance and usability of the 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. One example is the "Smart Atlas" project, which allows users to search for similarities between images based on their content. 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.

This "Smart Atlas" project will have an innovative commercial use: to offer CAD features (Computer Aided Diagnosis) to Cellvizio users. In other words, assist them in their interpretation of the images produced.

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

The mission of the Research and Development teams is to encourage the development of existing solutions in a continual improvement approach, while listening to internal and external clients, and carrying out the following:

- to ensure and improve 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 held;
- to develop new functions or improve 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 they can be used in accordance with current hygiene regulations in healthcare facilities in the different countries in which it is marketed.

• **Technical product development**

With regard to this mission, the Research and Development teams, and all members of the Operations department in general, work together with the product managers and clinical affairs managers to develop new products as part of the business's project management.

Some of the major projects currently under way are:

The new-generation Cellvizio, or "**GEN3**": the aim of this project is to update the range of Mauna Kea Technologies, via the launch of new products, developed using revamped technological building blocks that include more powerful, smaller and less costly components. By using increased levels of modularity, the Gen3 product line will integrate far more easily within the various existing configurations of any hospital facility, thereby optimizing product use and the service provided, while still producing high-quality images and diagnostics.

The development of Gen3 also provides the opportunity for the R&D cluster to redesign the solutions proposed by the Company to continue reducing manufacturing costs while increasing durability. This is a transverse action which concerns both the systems (stock of equipment) and the miniprobes (consumables).

The "**PERSEE**" project: a genuine technological showcase for the Company, this project obtained €7.6 million in innovation funding from OSEO in April 2010. This funding will stop in August 2018. « "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. Partners on the "PERSEE" project are working on a combination of Cellvizio and robotic technology, enabling the exploration of the abdominal cavity via one incision, so as to provide surgeons with information essential to their decision making. The Company is the leader of this collaborative project, on which it works alongside EndoControl, a developer of robotic solutions to help in surgical and medical procedures; ISIR (Institute for Intelligent Systems and Robotics) at the Université Pierre et Marie Curie; the Digestive Diseases department at the Institut Mutualiste Montsouris (IMM); and the Cellular Imaging, Gastroenterology and Biopathology departments at the cancer-research center Institut Gustave Roussy (IGR). The PERSEE project is structured into four successive phases, the last of which is expected to be completed in August 2018. The third phase was completed in July 2015, and the end of stage 3 report was sent to BPI France in May 2016. Since July 2015, BPI France and the project partners have been working together to prepare for the launch of the fourth phase, which began in 2016 and will run for a period of two years. Only at the end of this fourth phase will the PERSEE project be complete.

6.2.2. Innovation pipeline

These product development projects involve constant work on technological research for the development of new functions, in both hardware and software. This activity covers a vast area, from increasing image resolution, for instance, to assisting in its interpretation. It is strongly based on the Company's monitoring activities, naturally, but also on the very close collaborations set up with users of Cellvizio products, in both clinical and preclinical domains.

The long-term strategy can thus be based on an excellent understanding of users' current and future needs.

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.

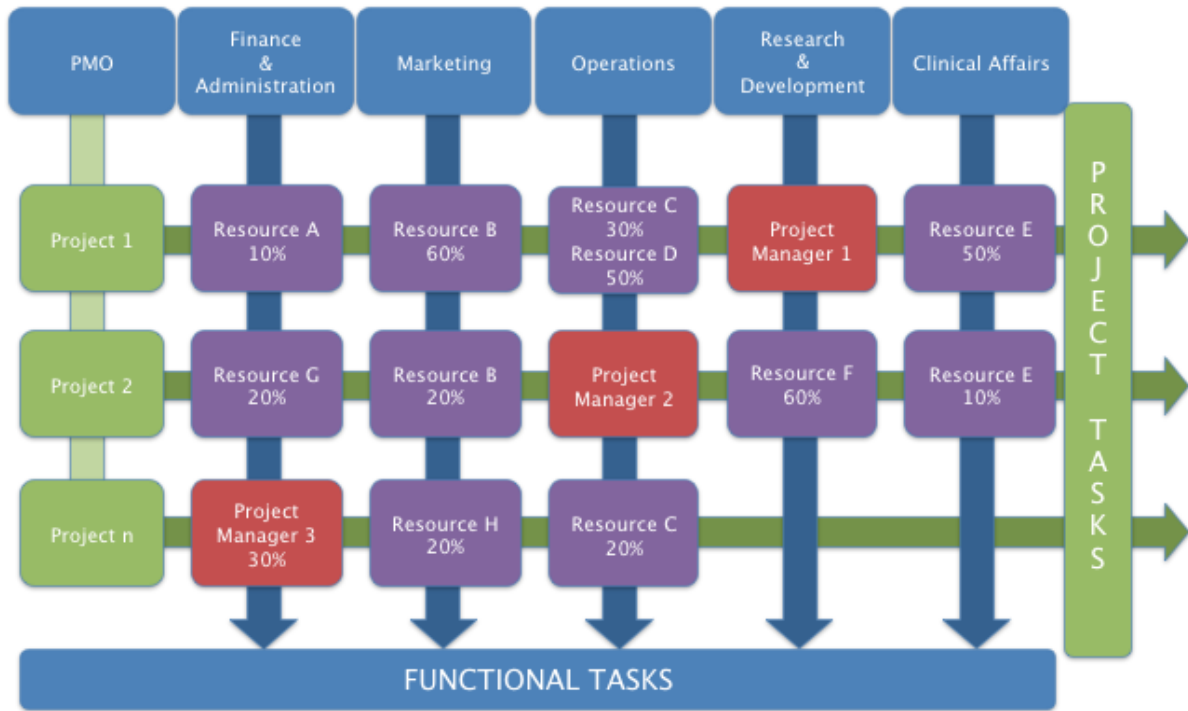
In an extremely practical approach to project management, and depending on the nature of the project, in addition to the Research and Development, marketing and applications associates, representatives from production, the supply chain and the Regulatory Affairs teams come together far upstream in order 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 management 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.

At the beginning of 2016, the Company decided to reinforce its project procedure by creating a PMO, or Project Management Office, under the responsibility of the Operations department and led by a team of two people. This office is incorporated in an organization grid, illustrated below, in which the Company does not have project management-dedicated resources all the time. Its aim is to harmonize project management methodologies within the Company, train and provide support for project leaders, supervise project execution, particularly the allocation of resources with heads of departments, as well as coordinating internal communication and reporting on the projects to Company management.



6.3. Clinical, regulatory and repayment validation

6.3.1. Clinical strategy

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 managing clinical trials of existing or new products, as well as developing medical-economic evidence concerning the use of Cellvizio, a decisive element in requests to have confocal laser endomicroscopy covered by the health authorities (public and private insurers), while clinical data are essential for the adoption by practitioners of recommendations by Learned Societies.

6.3.2. 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 the recommendations for screening, particularly the colonoscopy, 60% of deaths due to colorectal cancer could be avoided (Source: *Center for Disease Control and Prevention, 2014: http://www.cdc.gov/cancer/colorectal/pdf/no_pocket_brochure.pdf*).

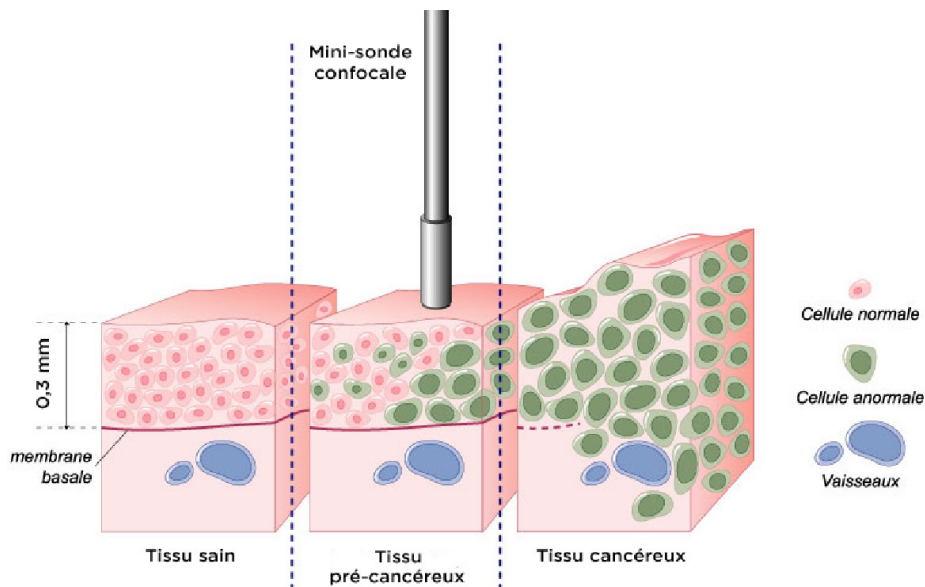


Diagram of cancer cell progression from the mucosa to the surface (progression invisible with endoscopy) and ability of Cellvizio miniprobe to image a precancerous zone.

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.

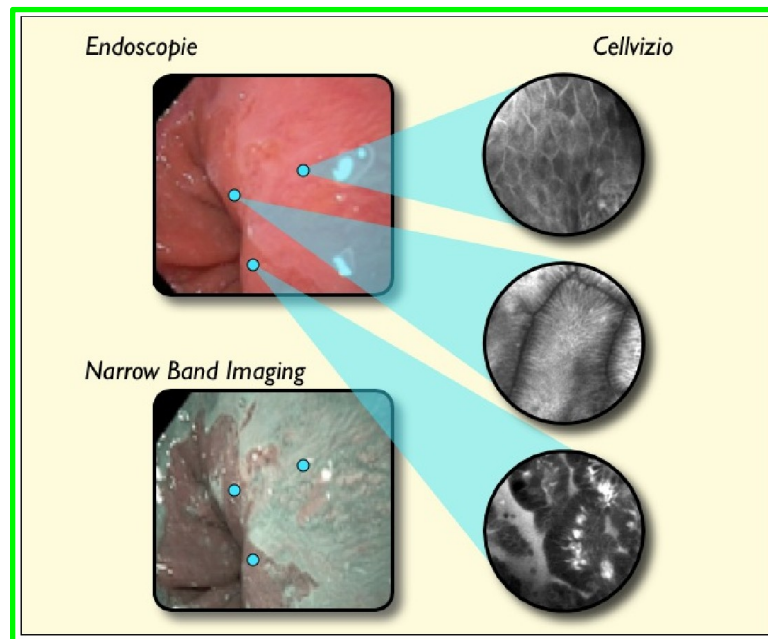
Microscopic analysis of the cellular architecture of the samples is then entrusted to the Histopathology department, which differentiates and characterizes any alterations found. This sampling and testing procedure is always conducted on dead cells over a period of time that may take weeks, so the physician 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.



Overview of a standard flexible endoscope (left) and view of the distal part with the camera, optical fiber illumination and operating channel with biopsy clamp inserted.

In view of this, for the past 20 years, players on the endoscopy market have developed their equipment with the aim of improving the 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 x1,000, 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 in the endoscopic procedure. Indeed, for the first time, the clinician has pertinent real-time cellular information:

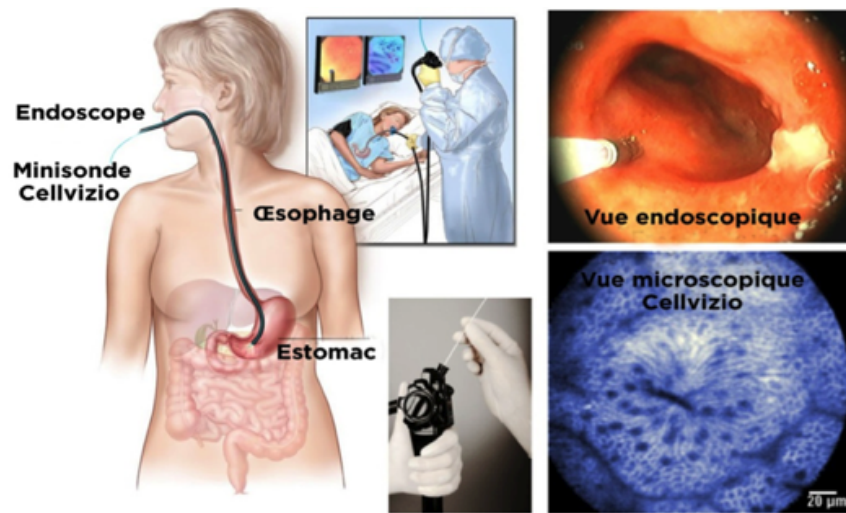
- for optimized diagnosis and better diagnostic yield than traditional biopsies;
- for places which are difficult to access, where performing a biopsy is compromised, the Cellvizio can provide key microscopic information for diagnosis;
- to decide, if necessary, to perform an immediate therapeutic endoscopic 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 simultaneously 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.

Indeed, clinical studies* performed with the Cellvizio have demonstrated the following benefits:

• **for patients:**

- real-time clinical information,
- a less invasive procedure than a biopsy,
- for certain indications, reduction of unjustified endoscopic and surgical procedures;

• **for physicians:**

- *in situ* and *in vivo* cellular-level visualization of the mucosa at suspicious sites defined using macroscopic endoscopic technologies (White light, NBI, etc.), enabling microscopic visual characterization of tissues in real time, which increases diagnostic accuracy,

- additional element for improved patient management by reinforcing the physician’s role during both diagnosis and choice of treatment: the ability to both avoid useless treatments and anticipate those that are necessary,

- being at the cutting edge of technology compared with their peers,

- increased visibility for their department or healthcare facility, thus an increased number of patients treated by their department or facility;

• **for healthcare facilities:**

- presenting themselves as an expert center equipped with cutting edge technology,

- offering advanced endoscopy for the digestive, pulmonary and urinary systems, in laparoscopic surgery and in interventional radiology,

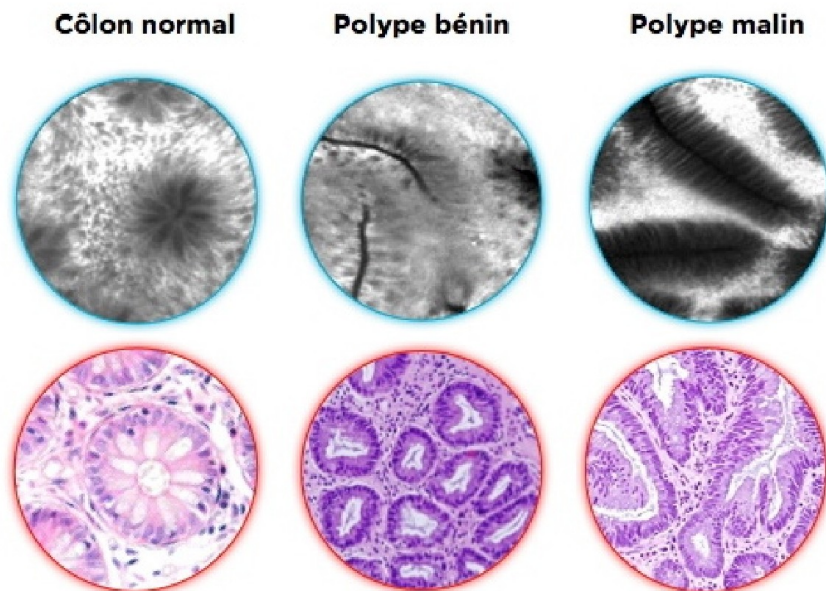
- attracting customers looking for better medical practices,

- optimized performance of the diagnostic treatment,

- improved therapeutic decisions,

- potential reduction in 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, pneumology, surgery and interventional radiology.

As the Company does not have the necessary resources to pursue all of these opportunities head-on, in 2005 it decided to focus on the gastroenterology market, given the Cellvizio's contributions to various pathologies which are particularly hard to diagnose: Barrett's 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 pneumology 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.

The extension of authorizations for laparoscopic surgery in Europe and the USA in 2015, and for interventional radiology in Europe is opening the way to new horizons.

6.3.3. 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.

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:

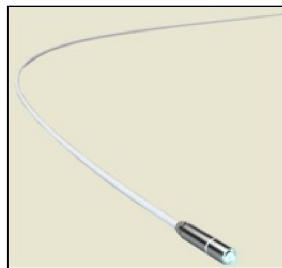
- > for digestive endoscopy applications:
 - GastroFlex UHD probe for eso-gastro-duodenoscopy (EGD),
 - CholangioFlex probe for endoscopic retrograde cholangio-pancreatography (biliary strictures),
 - ColoFlex UHD probe for colonoscopy (colorectal polyps),
 - AQ-Flex probe for cytopuncture using echoendoscopy 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);
- > for digestive endoscopy applications:
- CelioFlex probe for laparoscopy (except for the reproductive organs);
- > for interventional radiology applications:
- AQ-Flex IR probe.

These ten probes are now all on the market except for the CelioFlex probe and the AQ-Flex IR probe, which the Company has not yet launched on the market due to the recent nature of these two probes.



Unité centrale



Mini-sonde confocale à connecter sur l'unité de balayage



Exemple de packaging de mini-sonde

Confocal miniprobe 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 miniprobe 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 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 offer of Cellvizio-associated services, which allows users to add different services to their equipment: preventive and corrective maintenance, loan services or replacement 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 of 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 tracts, pulmonary tracts, etc.), thus enabling the platform to be used by several hospital departments or physicians.

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 both directly and through industrial or academic partners. 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 confocal laser endomicroscopy as compared to existing alternatives and distributing these results to opinion leaders and scientific societies so that they can 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 in accordance with the company's development strategy;
- 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 700 clinical publications about confocal laser endomicroscopy 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, confocal laser endomicroscopy 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.

A general review of CLE performance focusing on the major gastroenterology indications (Fugazza, Biomed Res, 2016) summarizes the state of the art from 662 publications and 102 studies. These show that the unrivalled accuracy of real-time tissue imaging by Cellvizio and similar technologies significantly alters the diagnostic conclusions of practitioners and patient management. 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. The specificity of CLE exceeds 90% in almost all of the applications tested.

EBE (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 EBE-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 EBE, providing a diagnostic tool with reliable and immediate results, enabling an appropriate treatment to be provided for their needs.

In 2015, the American Gastroenterological Association published a white paper emphasizing that it was appropriate for a medical practitioner trained in the technique to replace random biopsies with biopsies targeted by endomicroscopy. The College of American Pathologists also published a similar document. Lastly, the American Society of General Surgeons (ASGS) published a recommendation for the use of Cellvizio for patients with gastroesophageal reflux.

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 (including the Focus trial, sponsored by the group, published in 2015) concerning an accumulated total of 252 patients, revealed that Optical Biopsy detected 88% of biliary strictures of cancerous origin, against 59% using traditional methods of tissue sampling. 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 this type of polyp, Cellvizio also facilitates characterization of the resection site to enable a second treatment 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.* 2012 Mar).

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 results of the second phase of the CONTACT study were presented at the United European Gastroenterology Week (UEGW) in October 2016, with a more complete presentation at DDW 2017. The study, involving 209 patients in five French centers, showed that needle-based endomicroscopy successfully confirmed the benign nature of undetermined pancreatic cysts with 100% specificity by confirming a superficial vascular network found only in this type of cyst and invisible to traditional imaging, identified in the first phase of this study published in 2015 in *Endoscopy* and in *Surgical Endoscopy*. 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. Other characteristic signs of malignant lesions that are equally specific were presented at UEGW in 2016 (mucinous cysts and intraductal papillary mucinous tumors of the pancreas).

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 and removing uncertainty for the practitioner making the final diagnosis.

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.

Pulmonary nodules

Pulmonary nodules (round or oval lesion less than 3 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 the team of J. Liao at Stanford, California (USA) 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 produced a diagnostic accuracy level of 100%, with 100% sensitivity for high-grade lesions. (Source: *interobserver Agreement of Confocal Laser Endomicroscopy for Bladder Cancer, The Journal of Urology, doi: 10.1089/end.2012.0549, May 2012*).

Moreover, in 2015 Prof. Traxer's team (Tenon Hospital, Paris) published the clinical results obtained in the upper urinary tract with the Cellvizio in a series of 11 patients (partially presented at the EAU conference in 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. PERSEE, the first feasibility and clinical validation study in this field for the Cellvizio, was completed at the end of 2015. This has been documented in two publications on the near-instant *in vitro* results obtained in telepathology. Several clinical trials in the fields of digestive surgery, gynecology or neurosurgery are currently in progress. The multicenter phase of the trial is due to start in 2017.

Interventional radiology

Feasibility studies are currently in progress in procedures concerning the liver, kidneys and lungs. The first observations were presented by Prof. Gangi of Strasbourg on the visualization of cryoablation at the Radiological Society of North America's conference (RSNA, 2015).

6.3.4. 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 Clinical and Regulatory Affairs department.

Marketing the Cellvizio® and Confocal miniprobes™, 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® and Confocal miniprobes™ products are subject to the European Directive relating to Medical Devices (Directive 93/42/EEC and amendment 2007/47/EC) (MDD). However, a manufacturer must also take any particularities of national transpositions into account. The European environment is currently in a harmonization phase until 2020, which is the end date of the transition from the MDD to the new Regulation voted in April 2017.

As a medical device (MD) carrying a potential moderate risk (active medical device invasive in the short term), the Cellvizio® 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® and Confocal miniprobes™ as a "fibered confocal microscopic imaging system" obtained CE marking on December 13, 2005. The CE marking certification (No. 7817) is renewed every three years.

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

Moreover, the Company obtained certification under the CB scheme for its Cellvizio 100 Series products in March 2013 (For the electric (60601-1), FR 669265A/A1 and EMC (60601-1-2), FR 669262B). This certification was then used to prove this compliance outside Europe for access to other markets.

American regulation

Marketing the Cellvizio® 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 three categories: class I is the lowest risk and class III the highest for MDs. The various classifications and associated requirements are specified in the Code of Federal Regulations (21 CFR 820).

As the Cellvizio® 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 the Cellvizio® 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® 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, nine new authorizations have been added, either for product and miniprobe upgrades (K111047, K120208, K133466, K141358 and K150831), or to cover more specific indications (K122042, K123676, K132389 and K151593).

Following further applications, the FDA granted 510(k) authorization for laparoscopic surgery in 2016 (K160416).

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

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

The Company has chosen a notified body which has recognition agreements with several competent authorities, and a technical certification organization belonging to the IECEE CB scheme (IEC system for Conformity testing and Certification of Electrotechnical Equipment and Components) which 54 countries belong to. This has enabled it to obtain authorizations in the following countries: Canada (2006), Taiwan (2016), Australia (2013), Mexico (2015).

In some countries, a marketing authorization for a medical device is obtained through a process similar to the CE marking process. The Cellvizio® 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), Uruguay (2016) and Venezuela (2016).

In other countries, the procedures for obtaining marketing authorizations are more complex and, as for the United States, require 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® in China was obtained in December 2012. A new authorization was obtained in December 2015 for the Cellvizio® 100 Series and the new models of Confocal miniprobes (GastroFlex UHD, ColoFlex UHD, CholangioFlex, AQ-Flex 19, AlveoFlex, UroFlex B, CystoFlex F).

Korea

The competent authority is the MFDS (Pharmaceutical and Medical Device Law).

The marketing authorization for Cellvizio® in Korea was obtained in March 2011, then renewed in June 2013 for the Cellvizio® 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® 100 Series was obtained in November 2011.

Japan

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

The Confocal miniprobes are classified as class II, for medical devices under special control, and benefit from a regulatory pathway for marketing (Ninsho), requiring an RCB (Registered Certification Body) approved by the Ministry of Health. 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 the evaluation of the technical dossier submitted and an audit of the manufacturer's quality system based on Japanese legal requirements relative to pharmaceutical products and medical devices, PMDL (Pharmaceutical and Medical Device Law), and prescription No. 169 which defines the relative requirements of the quality management audit system. similar to standard ISO 13485.

In April 2014, the Company obtained dual class I and class II authorization in Japan for all current Cellvizio applications, namely gastroenterology, urology, and pneumology.

In 2015, the Company obtained an extension of the marketing authorizations for the AQ-Flex miniprobe used to observe pancreatic cysts.

Summary of existing marketing authorizations () and those in the process of being obtained (standby)

	Cellvizio systems (1)		Pneumology	Digestive endoscopy				Urology			Interventional radiology	Laparoscopic surgery
	-		Pneumo. int.	Endoluminal interventions		Biliopancreatic interventions		Interventions Urology interventions			Radio. int.	Laparoscopic surgery
	F400	F800	AlveoFlex	GastroFlex	ColoFlex	CholangioFlex	AG-Flex	UroFlex B	CystoFlex F	CystoFlex UHDR	AG-Flex IR	CelioFlex UHD 5
Europe												
Israel									In progress	In progress		
Russia												
Belarus												
Saudi Arabia	In progress		In progress	In progress	In progress	In progress	In progress	In progress	In progress	In progress		
Turkey												
Yemen												
Iran												
Pakistan												
Egypt												
Australia							In progress					
China												
Hong Kong												
India												
Japan												
South Korea										In progress		
Singapore								In progress	In progress	In progress		
Taiwan												
Thailand												
Bangladesh												
Canada							In progress					
USA												
Brazil												
Mexico												
Colombia												
Chile												
Venezuela												
Ecuador												
Peru												
Uruguay												

(1) The Cellvizio F400 and F800 are differentiated by the wavelengths they use; the F800 is only marketed in the EU and USA

Key	
	Marketing authorization applied for and obtained
In progress	Marketing authorization applied for and currently being processed
	Marketing authorization not applied for

This summary presents the marketing authorizations for all of the Company's products for the "clinical" market, intended for hospitals and clinics.

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



Relations with health professionals

The group has applied a code of ethics relative to these relations since 2009 and this will be reviewed and extended during 2017.

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 Company has declared the established agreements and advantages granted to health professionals in accordance with the requirements of the transparency law in France and the United States (Sunshine Act).

Environment

The Group has taken European environmental regulations into account (for example: REACH, ROHS, WEEE, etc.) which aim 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 repayment and market access team is working in close collaboration with Clinical & Regulatory Affairs, Operational Marketing resources teams (and, if necessary, local distributors), as well as external resources dedicated to the United States, in order to draw up and implement the plan for

access to reimbursement for the most strategic countries for the Company from a sales point of view and for indications for which the Company has the most users.

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

In the United States, in March 2012, the Group obtained the creation of three new category 1 CPT® codes for the upper digestive tract (esophagus, stomach, duodenum, pancreas). 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.

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.

In November 2016, the American health authorities (Centers for Medicare & Medicaid Services, CMS) published the Amounts of Medicare Fees for 2017 for Cellvizio procedures in the upper digestive tract, which enables both the hospital and the physician to receive a partner payment from the public insurer in each state. This amount was revalued by 131%, leading to a major change for the company and its business model in the US.

In March 2015, the American Medical Association (AMA) assigned a 4th CPT code linked to the use of endomicroscopy in endoscopic retrograde cholangio-pancreatography procedures (ERCP), an application identified as key, and for which the results of clinical trials have been very positive and which enable practitioners to diagnose biliary duct pathologies, notably strictures and cancers. This code went into effect in January 2016.

In early 2016, a new milestone was reached when the AMA defined the cover for needle-based procedures in pancreatic cysts and masses (needle-based confocal laser endomicroscopy - nCLE) with the CPT codes obtained and described above.

Mauna Kea Technologies has taken action to defend this existing cover and extend it to private insurers, thanks to specialized consultants. The results obtained thanks to these consultants are conclusive and are much better than those obtained by MKT staff, as was the case previously. Several insurers have announced that they would pay for Cellvizio procedures.

- 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.

Recently, representatives from the *Syndicat des Médecins de l'Appareil Digestif* have had discussions with the *Direction Générale de l'Offre de Soins* about the applicability conditions for a new procedure, and the process is again underway. The Group expects a priced procedure by 2017.

In September 2015, the HAS returned an unfavorable opinion for the use of Cellvizio for the characterization of biliary tract strictures. The Group intends to appeal this decision by submitting a new application. The application to use Cellvizio in the colon was to be evaluated sometime in 2017. The Group plans to submit a fast-track application for uses in the pancreas.

- 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 systems 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.

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

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.

SECTION 6 - OVERVIEW OF ACTIVITIES

Summary of reimbursements requested/obtained

Country	Indication	Product	Competent authority	Year of registration	Title	Tariff
USA	Upper digestive tract including needle-based access to the pancreas	GastroFlex/AQ-Flex	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement code CPT 43206. Upper digestive tract. Esophagoscopy with endomicroscopy. Effective date: January 1, 2013.	\$1,334 for hospitals and \$141 for physicians
		GastroFlex/AQ-Flex	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement code CPT 43252. Upper digestive tract. Barrett's esophagus with endomicroscopy. Effective date: January 1, 2013.	\$2,510 for hospitals and \$178 for physicians
		-	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2012	Reimbursement code CPT 88375. For the interpretation of the images obtained from the endomicroscopy. Effective date: January 1, 2013.	According to the published tariffs
	Bile ducts (ERCP)	CholangioFlex	American Medical Association/Centers for Medicare & Medicaid Services, CMS	2014	Reimbursement code CPT 039X7T. Allocation of a CPT code for a bile duct endomicroscopy technique. Effective date: January 1, 2016.	Still to be obtained
France	Mapping in Barrett's esophagus	GastroFlex	French Health Authority (HAS)/UNCAM	Q4 2010	French Health Authority authorizes the use of optical endomicroscopy in mapping Barrett's esophagus (September 17, 2014)	Awaiting publication in the Official Journal of the decree containing the list of centers authorized to perform the procedure (DGOS), followed by inclusion in the relevant nomenclature and tariff (UNCAM)
	Monitoring colon polypectomy scars	ColoFlex	French Health Authority (HAS)/UNCAM	Q4 2010	Inclusion of the procedure in the HAS work program for the period Q3 2016 to Q1 2017. Medical evaluation by SEAP-CNEDIITS in progress.	Awaiting publication of the HAS notice to initiate discussions with UNCAM
	Characterization of biliary tract strictures	CholangioFlex	French Health Authority (HAS)/UNCAM	Q4 2010	French Health Authority has not authorized the use of endomicroscopy (July 22, 2015) Additional data are needed to provide evidence of the clinical benefits of endomicroscopy in this indication.	NA
Germany	Confocal endomicroscopy of the digestive tract	All probes	German Institute for documentation and medical information (DIMDI)	2013	Code OPS 3-301 added to the medical nomenclature for an endomicroscopy procedure in the digestive tract, including bile and pancreatic ducts. Effective date: January 1, 2014.	Insufficient volume of procedures for tariff and/or addition to G-DRG (InEK)
UK	Needle-based endomicroscopy for the characterization of lesions of the pancreas	AQ-Flex	National Institute for Health and Care Excellence (NICE)	2015	Rejected by NICE-MTEP (November 30, 2015). Additional data are needed to provide evidence of the clinical benefits of endomicroscopy in this indication. Publication of a technological evaluation report (MIB) on June 26, 2016.	NA
CHINA	Endomicroscopy	GastroFlex/CholangioFlex/ColoFlex/AQ-Flex	Chinese Health Ministry	2016	A tariff has been obtained in several regions allowing hospitals to charge patients according to the Chinese system.	Varies depending on the region

The United States is the only country where the Group currently has reimbursement rates. These rates correspond to the fees that hospitals and doctors receive for the procedures described above.

6.4. Marketing and market

6.4.1. Marketing strategy and actions

In 2015, the Company decided to refocus part of its marketing strategy on indirect sales via its partners. This has both a commercial and marketing impact. In 2016, the United States was the only market in which the Company still invested significantly and continuously in a direct sales force.

The information below corresponds to the organizational structure of the Company at the end of 2016. It could change significantly as the partnerships already signed become operational, as new commercial and marketing partnerships are signed, and if the direct sales efforts require additional support and further investment in order to be developed properly.

The Marketing department

With half a dozen employees, including one based in the United States and one in Asia, the Marketing department develops the Group's marketing strategy and oversees its implementation.

The Marketing department is organized into three areas:

- event communication and digital marketing;
- production and applications management;
- key account management, which is dedicated to partner support and development.

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, including social networks;
- printed material;
- events;
- public relations and institutional communication;
- local communication actions for hospitals and clinics.

Applicational and product marketing

The Marketing 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 Clinical Affairs department and the direct or indirect sales forces working in the field. In particular, the marketing 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.

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. It is also in charge of the educational and applicational part for each indication.

The Group's business model is based on sales of medical equipment, the Cellvizio, and various types of limited-life miniproboscopes 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 miniproboscopes 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. And by trocars in laparoscopy. 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.

6.4.2. 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.

The Cellvizio market should be defined by geography, applications and products.

The current focus of the Group is on the United States and China, but commercial initiatives remain active in Europe. In application terms, commercial development is focused on gastroenterology, particularly in the field of upper digestive endoscopy. As regards products, the change in business model in the United States encourages a shift in focus to the number of potential procedures, spread over a given number of hospitals and clinics.

United States

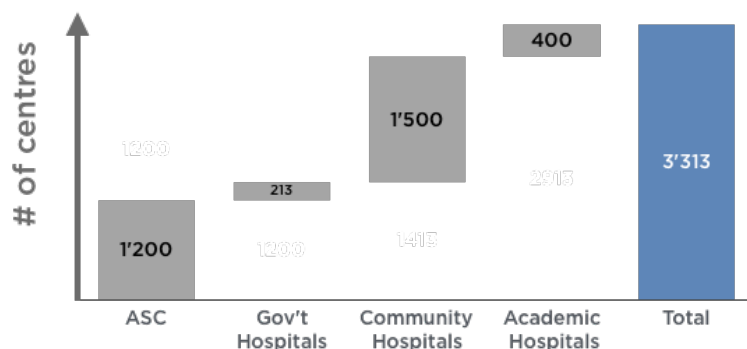
Mauna Kea Technologies' main target in the United States during the next few years includes community hospitals and Ambulatory Surgery Centers.

The American Hospital Association has identified 5,686 hospitals, of which 4,974 are "Community Hospitals". Community Hospitals are non-governmental hospitals that offer short-term patient management. There are also 213 governmental hospitals (Source: *American Hospital Association - Fast Facts on US Hospitals 2015*, <http://www.aha.org/research/rc/stat-studies/fast-facts2015.html>).

The Group is currently targeting the 1,500 community hospitals specializing in interventional endoscopy and the treatment of reflux patients, and some 1,200 ambulatory surgical centers specializing in digestive endoscopy.

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

This brings the total number of target centers for Mauna Kea Technologies in the United States to around 3,000.



Europe

In 2009, the European Union had more than 15,000 hospitals providing cutting-edge treatments (general medicine, surgery, obstetrics) or other activities (psychiatry, medium- or long- term stay hospitals) (Source: "Hospitals" study by Dexia in partnership with Hope, the European Hospital and Healthcare Federation, July 2008). In terms of population, Germany and France are the two European countries with the 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; ⁵	9,000
Other	4,615
Total	23,300

In France, the Group is targeting a market in the region of 300 hospitals and clinics that carry out interventional digestive endoscopy. This ratio applies to the remainder of the countries concerned, bringing to approximately 2,000 the number of centers potentially equipped with Cellvizio, solely for gastroenterology.

Asia

Japan and China are the biggest markets for Cellvizio in Asia. The number of hospitals by country breaks down as follows:

Country	No. of Hospitals
Japan	7,474
China	23,170
Total	30,644

In China, there are over 1,000 hospitals in the first category, which are now the Group's preferred target. In Japan, the Group is seeking to penetrate the academic hospital market, which covers some 200-300 hospitals.

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

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

Source: WHO, European Health for All Database, 2007 <http://www.statista.com/statistics/279322/number-of-hospitals-in-china/>

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

⁵ Source: <http://dcc2.bumc.bu.edu/RussianLegalHealthReform/ProjectDocuments/n970.IIIE1.Analysis.pdf>

South America

Brazil is the largest South American market with around 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*).

The Group is currently focusing on the American and Chinese markets.

6.4.3. 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.

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.

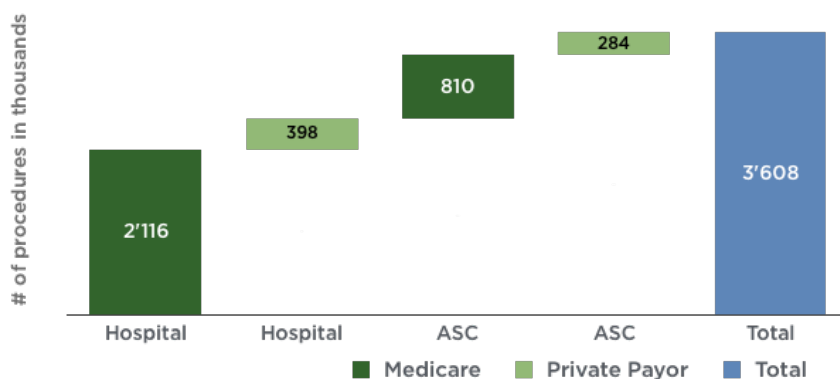
It is therefore possible to estimate the endomicroscopy market in number of procedures, by considering for example the indications for which the greatest number of validation works has been carried out.

Barrett's esophagus and gastro-esophageal reflux disease

In the United States, it is estimated that 1.6% of the adult population has at least one symptom of Barrett's esophagus⁶, i.e. 3.6 million people and 20% of the adult population suffers from gastro-esophageal reflux disease.

The ability to monitor these patients endoscopically is directly linked to the detection of precancerous zones and their potential treatment. In 2016, the American Society of General Surgeons published a major recommendation, based on these compelling arguments, for surgeons to examine their Barrett's or reflux patients using the Cellvizio prior to any surgical treatment.

The total number of upper digestive tract endoscopy procedures is close to 9 million per year in the United States. The Group's assessment shows that more than 3 million annual procedures could benefit from Cellvizio and be reimbursed. This represents potential annual recurring income of over \$2 billion.



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

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

⁶ Source: *Gastroenterology* - Dec 2005 - Ronkainen et Al

The number of colonoscopies carried out per year in the United States is growing constantly and is currently around 14.2 million⁷. 60% of colonoscopies are carried out in hospitals as opposed to ambulatory surgical centers, which represent 40% of colonoscopies⁸. One or more polyps are found in 40% of colonoscopies and 90% of these polyps are benign. Considering only the application to detect recurrent cancers for the Cellvizio (Source: *multicenter study accepted for publication*), the market potential is thus around 340,000 procedures (60% x 40% x 10% x 14.2) which would benefit from using the Cellvizio.

Pancreatic cysts

From 3 to 10% of the American population has a pancreatic cyst, equivalent to several million patients⁹. Today, an estimated 120,000 new cysts are identified each year¹⁰. With a conservative estimate of 40% of patients with these cysts receiving an endoscopic diagnostic procedure justifying the 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 in which the Cellvizio could be used to characterize a pancreatic cyst.

Preclinical 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 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 150 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. The global market was estimated at \$530 million in 2012, and is expected grow to \$1,005 million 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.

6.4.4. Competition

⁷ Source: *Gastroenterology*, Dec 2004, Seef LC et al 127(6): 1670-7

⁸ Source: <http://advancingsurgicalcare.com/index.cfm/news/ambulatory-surgery-center-industry-applauds-new-measure-improving-patient-access-to-colorectal-cancer-screenings/>

⁹ Source: <http://www.ncbi.nlm.nih.gov/pubmed/24091499>

¹⁰ Source: <http://qi.org/guideline/diagnosis-and-management-of-neoplastic-pancreatic-cysts/> and <http://www.cdc.gov/nchs/fastats/hospital.htm>

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 (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 2015 the company raised new funds (\$0.5 million, Source: *proactiveinvestors.com.au*) to launch a small-animal imaging device in September, the CellLive, marketed by MR Solutions. No sales of this device have yet been reported.

In rigid endoscopy, Optiscan is pursuing a partnership with the Zeiss company in the area of neurosurgery. It was recently announced that this partnership had completed several key stages. It is envisaged that Zeiss will launch an endomicroscopy-type product for neurosurgery in the near future.

Olympus

Olympus, a Japanese company which is the world leader in flexible endoscopy with a 71% market share (Source: *Endoscopy Devices Market to 2016, GBI Research, December 2010*), does not have any kind of commercial system for endomicroscopy. A prototype "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. 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) and LASEREO which was launched at the end of 2015. This is a system of electronic filters or a laser source used to enhance some of the colors in the image. Developed to help tissue characterization, the FICE system was shown to be inferior to the Cellvizio in an independent study carried out 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*.)

Moreover, the Company set up a distribution partnership with Fujifilm at the end of 2012 for the Chinese market, which has just been renewed in 2016.

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. This device was distributed by Pentax in some regions, but this was stopped fairly rapidly. SpectraScience is listed on the stock market, however its value is currently less than \$1 million and its share is quoted at \$0.0005.

Oncoscope

The American company Oncoscope has developed a tissue interrogation system called SCOB-E, designed 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*).

The company closed down in 2015 (Source: *bizjournals.com*) and its assets were taken over by SpectraScience.

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 obtained a 510k agreement from the FDA for its Nvision device which allows high-resolution imaging of part of the esophagus. This system is used in around 50 American hospitals. Recently, at the DDW 2017 conference, a meta-analysis of all Nvision studies of the esophagus showed that there was only a very marginal increase in the detection of dysplasia with a very high rate of false positives. The clinical benefit of Nvision has thus not yet been demonstrated, although the procedures can theoretically be reimbursed via CPT 43252, the same code as Cellvizio.

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.

6.4.5. The platform's growth relays, as a Group and via partnerships

Although the Group began selling in the gastroenterology, then pneumology sectors, in 2013, it obtained marketing agreements for a range of miniproboscopes dedicated to urological applications, then for laparoscopy in 2015. 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. Speed of implementation depends particularly on the partnership agreements which are already signed or which are due to be signed in the near future. Technical and commercial partnerships could be entered into in fields currently at the pre-commercial stage, with a view to the partner(s) concerned

benefiting from breakthrough medical technologies at the cutting edge of research. In particular, the development of the partnership with Cook Medical is discussed further on in the paragraph on the endo-urology market.

Interventional pneumology 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. 2004 September; 240(3): 481-489, and CHEST/142/2/385-393 AUGUST 2012*).

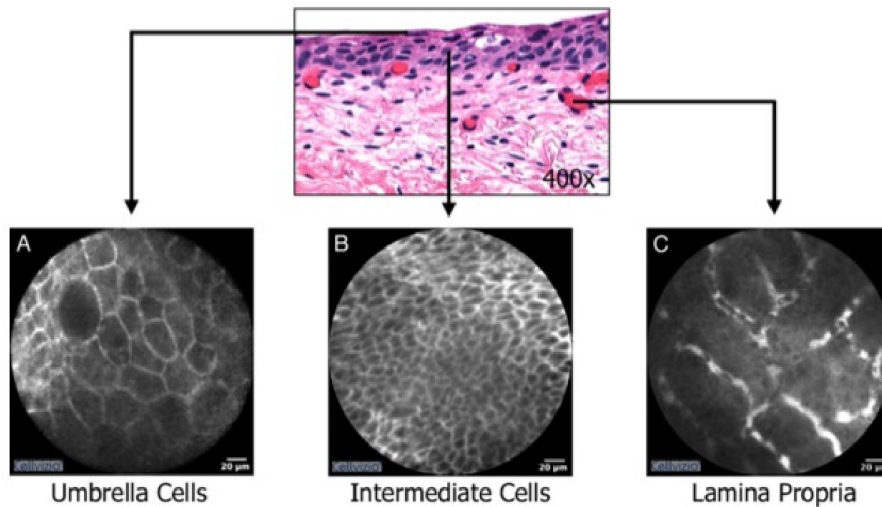
Several techniques can be used to characterize a pulmonary mass. The most effective, when possible, consists in physically sampling a piece of tissue from the nodule, either via a biopsy through a bronchoscope, sometimes equipped with an electromagnetic navigation device in the pulmonary tract, or by 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, which has just completed the patient inclusion phase in several American centers ([https://dmicaltnals.aov/ct23/show/NCT23?tenr\)=lung+reaistrv&rank=23](https://dmicaltnals.aov/ct23/show/NCT23?tenr)=lung+reaistrv&rank=23)) specifically concerns the demonstration of this valuable proposal made by the Cellvizio.



An AlveoFlex confocal miniprobe being inserted into a bronchoscope.

The bronchoscopy market is very similar to that of the digestive endoscopy market with regard 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 pneumology field, and the associated renewal of several tens of thousands of Confocal Miniprobes per year. Source: *Centers for Disease Control and Prevention, www.cdc.gov*

Endo-Urology Market



Example of Cellvizio images obtained in the bladder and correlated to the 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).

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 cystoscopic procedures, as shown in several studies by Prof. Liao of the Palo Alto VA Hospital (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. Using the Cellvizio in endo-urology 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 endo-urological 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.

In December 2015 Mauna Kea Technologies signed a commercial partnership agreement with Cook Medical concerning urological indications. The agreement required Mauna Kea Technologies to develop a customized version of the Cellvizio in 2016, reflecting the corporate identity of Cook Medical. Thanks to its international commercial expertise, its marketing and medical know-how and its comprehensive portfolio of complementary products for urological applications, Cook Medical could quickly optimize sales opportunities for Cellvizio. The Cellvizio Cook prototypes were successfully unveiled at the Annual EAU Congress, the AUA Annual Meeting and the World Congress of Endo-urology (WCE) in 2016.

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 was tested during a feasibility clinical trial on patients, which took place in 2015. In 2016, during the American SAGES conference, two posters were presented and given a very favorable reception. The PERSEE project is structured into four successive phases, the last of which is due to be completed in May 2016. In practice, the third of these phases was finished in July 2015, and the stage 3 end report was submitted to BPI France in May 2016. Since July 2015, BPI France and the project partners have been studying the beginning of the fourth phase; it could begin in 2016, and last for two years. Only at the end of this fourth phase will the PERSEE project be complete.

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.

6.5. Marketing and partnerships

6.5.1. Marketing strategy: refocusing on indirect sales

The Company decided in 2015 to refocus its marketing strategy on sales, mainly indirect sales via partners. This refocusing will have an impact on both its direct commercial organization and that of its distributors.

The information below corresponds to the organizational structure of the Company at the end of 2015, and it may change dramatically as the partnerships already signed become operational, and as new partnerships are signed.

The economic model

The Company's economic model is currently based, outside the United States, on the sale of equipment (or systems), consumables (called miniprobes) which can be used a limited number of times, and services. Specifically in the United States, the Group offers Cellvizio in the form of a supply program with billing on procedure only.

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 2016, earnings through sales of equipment represented 48% of the total sales, with consumables representing 33% and services 19%. 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 €88 thousand in 2016 and €95 thousand in 2015. The average sale price of the probes was €4.1 thousand in 2016 and €3.6 thousand in 2015.

In units, the Group sold 54 systems in 2016 against 51 in 2015, and 716 probes in 2016 against 669 in 2015.

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 69% in 2016, against 70% in 2015 and 67% in 2014.

At the time of writing this Registration Document, the Group had an installed base of more than 500 units, mainly resulting from equipment sales and, to a far lesser extent, the provision of equipment (fewer than 15 units).

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 and France, linked to a distribution network for all other countries in which it has obtained marketing authorization.

The Company signed a partnership agreement with the American company Cook Medical Inc. for marketing the Cellvizio in its "Cook Medical" colors, exclusively for urological applications throughout the world, from March 2016.

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 and in France

In these two 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), while the second team is responsible for consumables

sales and clinical support (Clinical Account Manager – CAM), mainly Cellvizio adoption and procedures, training for hospital personnel, and correct use of the equipment and probes during procedures. This second, so-called "CAM" team will provide support for our partner Cook Inc.

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.

In terms of EMEA sales, at the end of 2016 the team consisted of three people.

At the end of December 2016, the US sales team was comprised of six people.

The Asia-Pacific General Manager was transferred to Boston to head up global sales, with a major focus on the United States.

In total, at the end of 2016, the Group had a sales force of 11 people, led by a Sales Director, compared with 14 as of December 31, 2015.

Recruitment increased in the USA in early 2017, ahead of the sharp increase in sales opportunities forecast from early 2017. This follows the endorsement of American scientific societies and the new reimbursement rates, which are particularly favorable for endomicroscopy.

As of 2017, the Company intends to start offering its U.S. program clients use of Cellvizio systems. This new commercial offer, which is targeting private hospitals as well as ambulatory surgical centers, means that clients can adopt endomicroscopy with no initial investment. The program has been made possible by the new American reimbursement rates, which make the use of endomicroscopy a highly cost-effective clinical practice.

An exclusive distributor network for the other countries

The Group's "export" sales strategy (excluding France and the United States) 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, the Middle East, Asia, and Latin America. The distributors have been selected according to the following criteria:

- comprehensive knowledge and mastery of the sector and specialty within their mission;
- "product" synergy leading to the Cellvizio being inserted into a complementary ecosystem;
- 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. At the end of 2015, this network was placed under the responsibility of the EMEA Marketing Director.

The EMEA Marketing Director and Global Sales Director share the task of operational support for local sales forces deployed by distributors, helping them with training and setting both strategic and operational objectives. He is in permanent communication with the distribution network and ensures 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, Germany, 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.);
- Latin America (Brazil).

As well as providing support for distributors, the EMEA Marketing Director provides 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;
- 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 Korea (agreement obtained in 2011).

The current list of the Group’s commercial partners is available on the website at: www.maunakeatech.com.

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.

Sales refocusing toward partnerships

The organization described above will change very significantly in 2017 (and in subsequent years), to include a reorientation of sales towards indirect marketing via strategic partners.

The first of these agreements was signed at the end of 2015 with Cook Medical, for the global marketing of the Company’s products in the field of urology.

Another partnership agreement was signed in 2016 with Fujifilm, for the exclusive marketing in China of the Company’s products for gastroenterology and pulmonary applications.

The search for strategic partners should not affect the U.S. marketing strategy, which targets the intestinal reflux (GERD) and Barrett’s esophagus (BE) market. As previously mentioned, the Company also plans to accelerate the rollout of the Cellvizio through its pay-per-use program.

6.5.2. The brakes in sales development

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. In 2016, the Group obtained very favorable recommendations from three American learned societies.

3) Reorganization of the sales team in the United States

During the course of 2015, the Group's American subsidiary lost part of its regional sales force. The sales team responsible for "Probes" has for its part remained virtually stable. New recruits have not been hired due to the refocusing of the sales strategy toward indirect sales via partners.

In early 2016, the sales force in the USA was reorganized into two divisions, geographically distributed on the East and West regions of the USA, and placed under the direct responsibility of the Sales Director at the global level.

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

Passed in 2011 but actually coming into force in 2014, 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) Adoption curve: gastroenterology departments are slow to adopt 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. The increase in the reimbursement rate in 2017 will help change this situation.

6) Ecosystem: A technology which needs to be integrated

The complementarity of equipment constituting an operating room is an essential key to sales in the hospital market. The Company must search for industrial partners in order to incorporate its endomicroscopic technology in a complementary and coherent ecosystem.

7) Service offer: An economic reality

The economic pressures on health centers are forcing them to reduce their capital investments and promote the use of leased or pay as you go equipment. The Group has developed this type of offer with the intention of providing access to the Cellvizio through a service offer. In early 2016, the Group piloted a usage payment option with a minimum monthly consumption commitment.

6.5.3. Partnership and business development

The Company has been pursuing business development initiatives to expand its market reach, build brand awareness, and broaden its clinical and technological capabilities through various types of research and commercially oriented partnerships.

Existing partnerships

In 2012, the Company entered into a distribution agreement with FujiFilm Investment Co., Ltd, a subsidiary of Fujifilm Corporation, to commercialize Cellvizio in China. In February of 2016, the Company announced that it had received SFDA clearance for its Cellvizio 100 Series platform, thereby allowing FujiFilm the ability to offer its customers in China the latest Cellvizio platform available, and expand into new clinical areas including bilio-pancreatic applications.

In 2014, the Company entered into a clinical research collaboration with Siemens Healthcare to evaluate the use of Cellvizio in interventional radiology (IR) procedures. Preliminary results of a clinical study using Cellvizio in kidney and liver IR procedures have been presented at the 2015 RSNA Annual Meeting. This study was completed in 2016. The Company is now evaluating the clinical and commercial merit of this application.

In 2014, the Company entered into a clinical research collaboration with Siemens AG to evaluate the use of Cellvizio in surgical applications. Data from an *ex vivo* clinical study have been presented in the peer-reviewed journal, *Neurosurgery*. An *in vivo* feasibility study was also completed in 2016 to determine the clinical and commercial merit of this application.

In 2015, the Company entered into a global commercialization partnership with Cook Medical (Cook) for urology applications. Cook is a privately held company with more than 11,000 employees, and is recognized as a world leader in the urology field. Under the agreement, Cook will have worldwide commercialization rights for Cellvizio in urology applications under its privately labeled brand. The Company completed certain development work in 2016 in anticipation that Cook will begin to commercialize the product in early 2017.

In 2016, the Company entered into a clinical research collaboration with Edinburgh Molecular Imaging, Ltd. (EMI) to explore the combination of EMI's molecular optical imaging agents in combination with Cellvizio to detect cancer and other inflammatory diseases. The two technologies are being evaluated in a number of key academic centers in the US and Europe.

The Company will continue to seek research and commercially oriented partnerships with select companies with technical expertise or strong brand presence in specific markets that are of strategic interest to the Company. Such partnerships could allow the Company to grow at a faster rate and potentially be more profitable than it otherwise could achieve on its own. Examples of areas of interest include: endoluminal (GI and lung applications), surgical, interventional radiology and biopharma applications.

Principaux Partenariats sur les territoires commerciaux prioritaires

Partenariats	Siemens	Siemens	Cook Medical	Fujifilm	AMCO	Edinburgh Molecular Imaging
Indication	CLE en radiologie interventionnelle	CLE en neurochirurgie	CLE en urologie	CLE en gastroentérologie et pneumologie	CLE en gastroentérologie et pneumologie	Imagerie biomoléculaire
Produits	AQ-Flex (IR)	modèle expérimental	CystoFlex/UroFlex	toute la gamme autorisée en Chine	toute la gamme autorisée au Japon	AlveoFlex
Type de contrat	Partenariat de recherche clinique	Partenariat de recherche clinique	Partenariat de commercialisation	Partenariat de commercialisation	Partenariat de commercialisation	Partenariat de recherche clinique
Zone géographique	Strasbourg NHC et Hôpital Européen Georges Pompidou de Paris	Essai clinique en Cologne, 150 cas déjà publiés	Worldwide	China	Japon	Essai clinique auprès de Cleveland Clinic (Etats-Unis), UMCG (Netherlands) et Royal Infirmary Edinburgh

*CLE : Confocal Laser Endomicroscopy

SECTION 6 - OVERVIEW OF ACTIVITIES

		Geographical regions – Partnerships and distributors								
		Interventions	Products	EMEA Direct sales: France, UK, Germany, Netherlands, Belgium, Switzerland	Indirect sales: EMEA	China	Japan	APAC excluding China	United States	Americas excluding United States
Endoscopy	Biliopancreatic interventions	AQ-Flex/CholangioFlex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Endoluminal interventions	Gastro/Coloflex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Pneumological interventions	AlveoFlex	Direct	Distributors	Fujifilm	AMCO	Distributors	Direct	Distributors	
	Urology interventions	UroFlex	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	
Surgery	Anti-reflux surgery	GastroFlex	-	-	-	-	-	Direct	-	
	Oncological surgery	CelioFlex	Direct					Direct		
	Urology surgery	CelioFlex								
	Other surgery	CelioFlex	Direct					Direct		
	Neurosurgery	In progress		Siemens (clinical investigation)						
Other approaches	Interventional radiology	In progress	Siemens (clinical investigation)/Direct							
	Biomolecular imaging	In progress		Clinical trial with Cleveland Clinic (US), UMCG (Netherlands) and Royal Infirmary of Edinburgh						

No marketing or ongoing partnership

6.6. Transactions

6.6.1. 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 miniproboscopes, the Company decided to subcontract the manufacture of certain models of miniproboscopes 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.

6.6.2. 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 miniproboscopes 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 miniproboscopes production to this partner, thus ensuring a growth in productivity without further investment. In 2014, this procedure was extended to other stages of miniproboscopes production. At the end of 2016, the Company had finalized the transfer of the assembly of a new miniproboscopes model to the same sub-contractor.

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 miniproboscopes for the next two years, in accordance with its business plan and without significant investment.

The Company must change its internal processes to implement a growing range of products efficiently, based on identical technological bricks, adapted to different product or market requirements. In 2016, the Company therefore moved its production premises to the ground floor of the building it was occupying at the time, together with its other operational departments (purchasing, logistics, customer service, quality). As well as gaining extra square meters, the newly developed production premises will provide space to grow as the number and models of products manufactured increases, and to facilitate logistics flow to and from the production areas, as well as product inspection and testing.

6.6.3. 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.

It also provides a continuous monitoring process on the standards and regulations which are applicable to its products to guarantee that they remain in compliance. For example, the Company has introduced a unique identification system ("Unique Device Identifier" - UDI) for its medical products to meet new requirements which came into effect in the United States in September 2016. The Company is preparing to conform to the new versions of quality management system standards (ISO 9001:2015 and ISO 13485:2016 for medical systems), and is planning to achieve certification on these new versions at its renewal audit at the end of 2017. The Company also plans to renew its certification at the end of 2017 under the Medical Device Single Audit Program (MDSAP), which harmonizes the quality system audits in different countries (USA, Japan, Canada, Brazil and Australia).

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 to the production line (subcontracting, offshoring, etc.) must be reported to the third-party organization and may be audited to ensure that certification is maintained.

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

6.6.4. 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 non-compliance, 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. In 2016, seven supplier audits were performed, four of them overseas.

6.6.5. 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 leading global player in the manufacture of optical fibers (Source: *Fujikura, annual report 2016*), has entered into a 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.

The Company has continued this externalization strategy with Fujikura by transferring some of the assembly stages of certain Confocal miniprobe models to benefit from this supplier's industrial expertise. In 2016, a new miniprobe model was also transferred to Fujikura

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 the field of industrial optics (Source: *Cambridge Technology Inc. website, under "About": <http://www.camtech.com/about/index.html>*) and inventor of the galvanometer-based optical scanner concept, is the supplier of the solution chosen for Cellvizio. The Company is assessing alternatives to this technology and other suppliers within the context of its Research and Development projects.

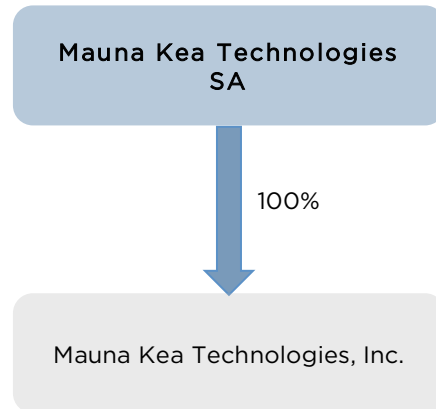
In 2015, the Company also validated a new supplier for the production of electronic boards and electromechanical incorporation of its laser housings for the medical field. This work has led to a joint project between the R&D, purchasing, production, regulatory affairs and quality teams, and provides a simplification of supply chain logistics and reduced manufacturing costs.

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 SA is the Group's parent company.

Mauna Kea Technologies, Inc.: Based in Boston, Massachusetts, 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). At December 31, 2016, it had nine employees and posted revenues of \$3,224 thousand (or €2,913 thousand, at a conversion rate of 1.1066) and a net loss of \$3,246 thousand (or -€2,933 thousand, at a conversion rate of 1.1066).

7.3 Principal intra-group flows

There are primarily three kinds of intra-group flows.

a) **Commercial flows:** Since all equipment sold everywhere in the world is made in France, the Company signed an exclusive distribution agreement with its American subsidiary giving the latter exclusive territory rights to distribute the Group's products (equipment and consumables) in the United States and Canada.

b) **Reinvoiced services:** A services agreement was signed on January 1, 2010 between the Company and its American subsidiary for an initial term of five years, renewable yearly. Therein it is provided that the Company contributes its assistance to Mauna Kea Technologies, Inc. in five areas:

- ✓ management of the subsidiary;
- ✓ 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 2016 financial year, the Company invoiced its subsidiary for the amount of €374 thousand.

c) **Financial flows:** A Group cash management agreement was made 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 2016 financial year, the Company invoiced its subsidiary for interest totaling €728 thousand.

SECTION 8

PROPERTY, PLANT AND EQUIPMENT

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, Paris (75010), the Company's registered office covers five stories of the building with a total floor space of about 1,133 sq. m. (basement included). 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 lease payment in € excl. VAT per year
Ground floor	364 sq. m.	March 1, 2016	9 years	February 28, 2025	98,666
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 €375 thousand for the year ended December 31, 2016.

Sub-leasing: During the first quarter 2017, the company sub-leased its fourth floor and the right side of its second floor under conditions identical to those of the main lease.

In the United States: Formerly based in Suwanee in Georgia, the lease was terminated at the end of 2016. The subsidiary moved its office to 185 Alewife Brook Parkway, Cambridge, Massachusetts, where it will remain until February 2017. The rental charges recorded in the United States for the 2016 financial year total \$48 thousand. In early 2017, the subsidiary relocated its office to 24 Denby Road, Allston, Massachusetts.

8.1.2 Other property, plant and equipment

The principal property, plant and equipment held by the Company are described in Note 4 to the 2016 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, 2016, and to refer to the notes to the 2016 consolidated financial statements contained in Section 20 of this Registration Document. The 2014 and 2015 financial statements can be viewed on the Group's website: www.maunakeatech.com.

9.1 Overview

9.1.1 Consolidated financial statements

Pursuant to EU Regulation 1606/2002 of July 19, 2002, the 2016 consolidated financial statements of Mauna Kea Technologies, approved by the Board of Directors on March 21, 2017 were prepared in accordance with the IFRS as adopted in 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

N/A.

9.2 Results analysis

Simplified consolidated income statement

Consolidated data audited in €K	At December 31		
	2016	2015	2014
Total sales of "equipment"	4,217	5,190	7,175
Total sales of "consumables" (probes)	2,941	2,473	2,958
Total sales of "services"	1,629	884	882
Total sales	8,787	8,547	11,016
Other income	883	1,434	1,267
Total of revenue	9,670	9,981	12,282
Cost of sales	(2,720)	(2,534)	(3,675)
Gross margin	69%	70%	67%
Total operating expenses	(19,660)	(22,939)	(26,088)
Other operating income and expenses	0	232	0
Operating profit (loss)	(9,990)	(12,726)	(13,805)
Profit before tax	(9,744)	(12,643)	(13,973)
Profit/(loss)	(9,744)	(12,643)	(13,973)

9.2.1 Sales and other operating income

2016 sales

(in €K) - IFRS	2016	2015	% change
1 st quarter	1,954	1,855	5%
2 nd quarter	2,511	2,170	16%
3 rd quarter	2,108	1,867	13%
4 th quarter	2,213	2,655	-17%
Total sales	8,787	8,547	3%

2016 sales by category

(in €K) - IFRS	2016	2015	% change
Systems	4,217	5,190	-19%
Consumables	2,941	2,474	19%
Services	1,629	884	84%
Total sales	8,787	8,547	3%

The Company delivered 54 Cellvizio systems in 2016 - including six as part of the recently launched pay-per-use program - compared with 51 in 2015. The Company delivered 43 Clinical systems and 11 Preclinical systems in 2016, compared with 38 and 13 respectively in 2015. The number of probe units sold rose by 7% to 716 units, compared with 669 units in 2015. The number of probe reorders (probes sold to existing customers) increased from 492 in 2015 to 541 in 2016, representing year-on-year growth of 10%. In value terms, probe reorders were up 34% in 2016. The year-on-year growth in probe sales, and particularly the reordering rate, reflects the growing use of Cellvizio systems, especially in the United States, in parallel with the expansion of the installed base.

2016 sales by geographical region with Clinical/Preclinical breakdown

(in €k) - IFRS	2016	2015	% change
Americas	3,811	3,603	6%
Clinical	3,350	2,875	16%
Preclinical	461	728	-37%
Asia-Pacific	2,853	2,491	15%
Clinical	1,890	1,573	20%
Preclinical	962	918	5%
EMEA	2,124	2,453	-13%
Clinical	2,022	1,634	24%
Preclinical	102	820	-88%
Total Clinical sales	7,261	6,082	19%
Total Preclinical sales	1,526	2,465	-38%
Total sales	8,787	8,547	3%

9.2.2 Operating expenses

Consolidated data audited in €K	2016	2015	Change
Cost of sales	(2,720)	(2,534)	7%
Gross margin	69%	70%	
Research & Development	(4,445)	(4,648)	-4%
Sales & Marketing	(8,366)	(11,665)	-28%
Administrative expenses	(3,843)	(3,642)	6%
Share-based payment transaction expenses	(285)	(450)	-37%
Total operating expenses	(19,660)	(22,939)	14%

Research and Development expenses

In 2016, the Research and Development team focused its efforts on plans for the next generation of systems. The product development costs have not been capitalized since the research is still at a very early stage.

In 2016, Research and Development expenses rose to €4,445 thousand, versus €4,648 thousand for 2015.

In 2016, the annual portion of capitalized development expenses was zero. The Company maintains a high level of Research and development spending, mainly on its long-term R&D projects.

Marketing and Sales expenses

Marketing and Sales expenses are currently the largest overhead. These expenses were down by 28%, from €11,665 thousand in 2015 to €8,366 thousand in 2016.

This item remains the largest overhead for the Company, representing 43% of all operating expenses in 2016.

This item includes sales and marketing expenses, as well as expenses related to clinical research and logistics and supply costs directly related to sales.

In marketing, at year-end 2016 the Group had a team of ten persons covering the activities of Operational Marketing (France, Rest of Europe, USA and Asia), the Systems and Probes product development activity, Clinical Affairs and marketing communication.

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

In the EMEA region, the sales team was composed of three people at year-end 2016.

At the end of December 2016, the US sales team was comprised of six people.

The General Manager for Asia-Pacific was transferred to Boston to take the lead in global sales, mainly focusing on the United States.

In total, at the end of 2016, the Group had a sales force of 11 people led by a sales director, compared with 14 as of December 31, 2015.

This change is primarily due to the Company discontinuing direct sales in Germany, but also due to the departure of employees in France and the United States, who were not replaced given the Company's new distribution strategy. Nevertheless, at the end of 2016 new sales staff were being recruited in the United States.

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 expenses were up 5% on 2015, from €3,642 thousand in 2015 to €3,843 thousand in 2016.

9.2.3 Composition of net income

Operating expenses over the whole year were €19,660 thousand, compared with €22,939 thousand in 2015. This 14% decrease was mainly due to lower sales and marketing expenses and to share-based payments.

As a result of this decrease and of the moderate decrease of 3% in sales, the operating loss for 2016 was €(9,990) thousand, compared with €(12,726) thousand in 2015.

After taking into account a financial profit of €246 thousand for the year to December 31, 2016, compared with €84 thousand at December 31, 2015, the Company's net loss comes to €(9,744) thousand, compared with a net loss of €(12,643) thousand for the year ended December 31, 2015.

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 €0.55 and €0.84 per share for the financial years ended December 31, 2016 and 2015.

9.3 Balance sheet analysis

9.3.1 Non-current assets

Consolidated data audited in €K	2016	2015	Change
Intangible assets	2,565	3,135	-18%
Property, plant, and equipment	898	625	43%
Non-current financial assets	162	133	22%
Non-current assets	3,625	3,893	-7%

Non-current assets were €3,625 thousand at December 31, 2016, 7% less than the €3,893 thousand at December 31, 2015.

Non-current assets consist of property, plant and equipment and intangible assets and non-current financial investments.

The fall in this item is primarily due to a fall in intangible assets as a result of reduced capitalization of development expenses over the financial year, and secondly to a reclassification concerning transfers from inventory to property, plant and equipment for €127 thousand.

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

The breakdown of non-current financial assets can be found in Note 5 to the consolidated financial statements, in Section 20.1 "Consolidated financial statements prepared according to IFRS for the financial year ended December 31, 2016" of this Registration Document.

9.3.2 Current assets

Consolidated data audited in €K	2016	2015	Change
Inventories & work in progress	2,331	2,644	-12%
Trade receivables	2,116	3,458	-39%
Other current assets	2,756	1,823	51%
Current financial assets	94	65	45%
Cash and cash equivalents	9,053	10,620	-15%
Current assets	16,349	18,610	-12%

Current assets amounted to €16,349 thousand at December 31, 2016, versus €18,610 thousand at December 31, 2015.

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 €9.1 million at December 31, 2016, versus €10.6 million at December 31, 2015.

Cash and outstanding liabilities in cash represented 55% of current assets at December 31, 2016.

As a beneficiary of the EC SME regime, the short-term portion of the Research tax credit was affected only by the ' change in research and development expenses eligible for the RTC during the years in question. The RTC receivable at December 31, 2016 amounted to €828 thousand compared with €1,201 thousand at December 31, 2015 (see Note 7.2 to the consolidated financial statements, in Section 20.1 "Consolidated financial statements prepared according to IFRS for the year ended December 31, 2016" of this Registration Document).

9.3.3 Equity

Consolidated data audited in €K	2016	2015	Change
Issued capital	800	647	24%
Share premium	72,382	66,050	10%
Reserves	(52,394)	(40,069)	31%
Foreign currency translation on reserve	113	106	7%
Profit/(loss)	(9,744)	(12,643)	-23%
Total of equity	11,157	14,091	-21%

The net changes in Group equity are mainly due to the annual deficits recorded in 2015 and 2016, and to the increase in share premiums following capital increases.

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 bonus preferred shares and stock options to employees, corporate officers and 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	2016	2015	Change
Non-current liabilities			
Long-term loans and borrowings	2,640	2,182	21%
Non-current provisions	261	246	6%
Total of non-current liabilities	2,900	2,428	19%

Long-term liabilities include only refundable grants from BPI (formerly OSEO) as at December 31, 2016.

At December 31, 2016 the Company had received three BPI advances, two of which were completely refunded, and one COFACE advance on which we expect to refund the balance no later than December 31, 2017.

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	2016	2015	Change
Short-term loans and borrowings	404	719	-44%
Trade payables	3,131	2,453	28%
Other current liabilities	2,382	2,812	-15%
Total of current liabilities	5,917	5,984	-1%

SECTION 9 - EXAMINATION OF EARNINGS AND FINANCIAL POSITION

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 liabilities consisting of COFACE advances refundable in one year.

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.

Cash and cash equivalents include available cash and current financial instruments owned by the Company (mostly money market funds). 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 2011, the Company's funding has come primarily from the following sources:

- its IPO in July 2011 raised €56.5 million gross, or €51.6 million net after deducting transaction costs;
- advances received under the PERSEE project for a cumulative amount of €2.3 million;
- a private placement with nine investors in May 2015 for a total gross amount of €4.7 million, i.e. €4.5 million net of transaction costs;
- drawdowns between March and December 2015 on two equity financing lines (PACEO I & PACEO II), totaling €3.2 million net;
- a capital increase in July 2016 for a gross amount of €4.4 million, subscribed by a limited number of investors operating in the healthcare sector;
- drawdowns between November and December 2016 relating to the line of financing established with the intermediary Kepler Cheuvreux, for a total amount of €2.5 million net.

More recently, on February 9, 2017, the Company contracted funding through a bond issue of €7 million with IPF Partners, a fund specialized in alternative financing for European growth companies in the healthcare sector. This funding is made up of two bond portions: the first, which amounts to €4 million, has been issued to date; the second, for the remaining €3 million, will be available over the coming 12 months, subject to the achievement of pre-determined targets.

This funding is made up of 7,000,000 secured bonds for a total value of €7 million. The annual interest rate on these bonds is set at three-month EURIBOR + 8.5%. The term of the first portion is set at 5 years (of which 18 months without repayment of principal) and the second at 4 years (of which 12 months without repayment of principal). The terms and conditions of the bonds impose certain financial commitments.

Summary of drawdowns by Kepler Cheuvreux

	BSA 2016-2
Date of General Meeting	May 4, 2016
Date of Chairman's decisions	Nov. 18, 2016
Number of authorized share warrants (BSA)	-
Total number of BSA issued	1,850,000
Total number of shares that may initially be subscribed for <i>of which the number that may be subscribed by corporate officers</i>	1,850,000 0
Number of beneficiaries who are not corporate officers	1
Start date for exercise of the BSA	Nov 18, 2016
BSA expiration date	Nov 18, 2018
BSA issue price	€3.0000
BSA exercise price	(5)
Exercise procedures	(5)
Number of shares subscribed at December 31, 2016	845,000
Cumulative number of BSA canceled or invalid as of December 31, 2016	0
BSA remaining at December 31, 2016	1,005,000
Number of shares that may be subscribed for as of December 31, 2016	1,005,000

10.1.1 Capital financing

The following table summarizes the principal capital increases, in value, between the Company's creation date and December 31, 2016:

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)
2015	0.3	Exercise of securities giving access to the capital (BSPCE, stock options)
May 2015	4.7	Capital increase
2015	3.2	Exercise of BSA by Société Générale (Paceo)
2016	4.4	Capital increase
2016	2.5	Exercise of BSA by Kepler Cheuvreux (Paceo)
Total	106.2	

10.1.2 Financing through loans

The Company has taken out no loans during the three financial years presented.

On February 9, 2017, the Company contracted funding through a bond issue of €7 million with IPF Partners, a fund specialized in alternative financing for European growth companies in the healthcare sector. This funding is made up of two bond portions: the first, which amounts to €4 million, has been issued to date; the second, for the remaining €3 million, will be available over the coming 12 months, subject to the achievement of pre-determined targets.

This funding is made up of 7,000,000 secured bonds for a total value of €7 million. The annual interest rate on these bonds is set at three-month EURIBOR + 8.5%. The term of the first portion is set at 5 years (of which 18 months without repayment of principal) and the second at 4 years (of which 12 months without repayment of principal). The terms and conditions of the bonds impose certain financial commitments.

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.

Summary of advances received:

At Dec. 31, 2016 (in €k)	Amount granted	Amount received	Amount repaid	Discount effects	Amount still to be repaid
OSEO sub-total	4,436	3,923	1,020	(269)	2,635
Total COFACE advances	1,704	1,704	1,295	(5)	404
Total aid	6,140	5,627	2,315	274	3,038

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 General 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 22 to the financial statements in accordance with IFRS as of December 31, 2016 appearing in Section 20.1 of this Registration Document.

10.2 Cash flows variation

Simplified consolidated cash-flow statements

Consolidated data audited in €K	At December 31	
	2016	2015
Net cash flows from operating activities	(7,836)	(11,729)
Of which self-financing capacity	(8,635)	(11,284)
Of which change in WCR related to business activities	799	(446)
Net cash flows from investing activities	(573)	(326)
Net cash flows from financing activities	6,826	7,618
Change in cash	(1,567)	(4,398)

10.2.1 Cash flows from operating activities

Cash consumption relating to operating activities for the financial years ended December 31, 2016 and 2015 came to €7,836 thousand and €11,729 thousand respectively.

The improvement in cash flows from operating activities is due to a decreased negative self-financing capacity linked to the lower loss for the financial year. The decrease in WCR is primarily due to lower net trade receivables and stock levels.

10.2.2 Cash flows relating to investment activities

The Company's production operations do not require great investment in property, plant and equipment, insofar as the Company sub-contracts some manufacturing. However, the final manufacturing tasks - assembly, control and validation - are performed in-house.

These investments in property, plant and equipment, in particular prototypes, demonstration apparatus and office equipment, came to €107 thousand and €427 thousand respectively for the financial years ended December 31, 2015 and 2016.

On the other hand, the Company activated intangible assets in the course of the 2015 and 2016 financial years, mainly development expenses and its patents. In this respect, the Company invested €255 thousand and €89 thousand respectively for the 2015 and 2016 financial years. This fall is the result of the reduced activation of development costs. In 2016, research and development expenses primarily concerned research without an activation option under IAS 38.

10.2.3 Cash flows from financing activities

The Company recorded a cash flow relating to financing activities of €6,826 thousand and €7,618 thousand for the 2016 and 2015 financial years.

In 2016, cash flows associated with financing activities, totaling €6,826 thousand, mainly consisted of exercised BSA (€2,026 thousand) and a capital increase in the amount of €4,440 thousand.

In 2015, cash flows associated with financing activities, totaling €7,618 thousand, mainly consisted of exercises of founders' warrants (BSPCE) and stock options (€3,485 thousand) and amounts from shareholders in respect of a capital increase in the amount of €4,490 thousand, minus the €300 thousand repayment of the BPI advance.

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

N/A.

10.5 Sources of financing required in the future

Please refer to Section 4.4.2 concerning liquidity risk in this Registration Document.

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 4 to the 2015 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 encourages new ideas and ensures they are captured, notably through team work sessions, such as the Strategic Days, clinical meetings (MED), LAB meetings, Patent Brain Storming, and innovation competitions such as the "Hackfests", supported by continuous transversal (medical, scientific, 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. This is why the Group has established and maintains a continuous patent filing policy.

At end December 2016, the Group had a total of 40 inventions protected by patent registration, grouped in 34 families of separate patents. At December 31, 2016, these 40 inventions had resulted in 206 patents being granted, while 43 are still under consideration.

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.

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 endomicroscopic 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.

Patent portfolio					
Title	MKT number	Priority date	Acronym	Family Ref. No.	Title
P7	B	04/01/1999	P7	WO00/59368	High resolution body observation device
Endoscope	A	09/15/1998	END	WO00/16151	Organism observation device providing perfected observation quality
Afocal correctors	1	12/28/2001	AFO	WO03/056378	Confocal imaging equipment especially designed for endoscopy
Endoscope head	2	12/28/2001	TEM	WO03/056379	Miniaturized focusing optical head especially designed for endoscopes
Fluorescence spectroscopy	3	12/28/2001	TMS	WO03/060493	Subsurface autofluorescence spectroscopy apparatus
CVZ Fluo	4	07/18/2002	CVF	WO2004/008952	Fibered confocal fluorescence imaging apparatus and procedure
CVZ Fluo Divisionnaire (EU only)	4	07/18/2002	CVF	EP 1986031	High-resolution fibered confocal fluorescence imaging apparatus and procedure
Image processing	5	07/18/2002	IMA	WO2004/010377	Processing procedure of images acquired with a scope comprising multiple optical fibers
VCSEL	6	12/20/2002	VCS	WO2004/066015	VCSEL-based parallel confocal laser microscopy system
MEMS	7	12/20/2002	TBL	WO2004/066016	Confocal optical head, in particular miniaturized, with integrated scanner and confocal imaging system to operate the scope head
S probes (FR only)	8	03/11/2003	CV2	FR 2 852 394	High-resolution fibered confocal fluorescence imaging apparatus and procedure
Super Reso	9	12/31/2003	SUR	WO2005/073912	Super-resolution procedure and system for confocal images acquired through an imaging scope, and device used to execute the procedure
Lent. Boule	10	12/31/2003	LEB	WO2005/072597	Miniature optical head with integrated scanner to acquire homogeneous confocal images, and confocal imaging system to operate the scope head

SECTION 11 - INNOVATION, PATENTS, LICENSES, TRADEMARKS AND
DOMAIN NAMES

OCT-OA	11	01/22/2004	DAT	WO2005/080911	High-resolution <i>in vivo</i> lateral and axial tomographic system and procedure for the human retina
Wollaston	12	01/22/2004	MES	WO2005/080912	Device and procedure to measure fringe visibility in a Michelson interferometer, and eye examination system including said device
Active targeting	13	01/22/2004	TOM	WO2005/079655	Aiming procedure and device for eye examination, <i>in vivo</i> eye tomography system equipped with said device
Active targeting (CIP)	13	01/22/2004	TOM	US 7 658 495	Eye examination device by means of tomography with a sighting device
Velocimetry	14	04/02/2004	VIT	WO2005/098474	Blood flow rate measuring system and procedure
Multimarking	15	06/14/2004	MTM	WO2006/000704	Multimarking fibered fluorescence microscopic imaging system and procedure
2Photons	16	10/22/2004	2PH	WO2006/045936	Sample fibered multiphoton microscopic imaging procedure and system
Methylene blue	17	03/31/2006	BDM	WO2007/118954	Methylene-blue based fibered fluorescence microscopy
UHD probe	18	05/05/2006	UHD	WO2007/128909	High-sensitivity, high spatial resolution miniaturized optical head, especially designed for fibered confocal fluorescence imaging
Multiple probes	19	05/12/2006	SMU	WO2007/132085	Endoscopy procedure and device for the simultaneous observation of multiple areas of interest
Alveolar imaging	20	08/17/2006	ALV	WO2008/020130	In situ use of an <i>in vivo</i> fibered confocal fluorescence imaging system, <i>in situ in vivo</i> fibered confocal fluorescence imaging procedure and system
Mosaicing	21	08/02/2007	MOS	FR 2 904 927	Robust mosaicing method. Notably with correction of motion distortions and tissue deformations for <i>in vivo</i> fibered microscopy
CVZ 2	22	10/11/2007	VZ2	WO2009/053632	Modular imaging device, module for the device and procedure performed by device
ERCP	23	03/12/2008	RCP	US2009-0240143	Method and anoptical probe for <i>in vivo</i> imaging of a mucosa in a biliary or pancreatic system and a method for selectively operating a tissue sampling of a mucosa in a biliary or pancreatic system
Automatic Calibration	24	12/29/2008	CAL	WO2010/076662	Image processing method and apparatus
OBF	25	12/31/2008	OBF	US 8 267 869	Multi-purpose biopsy forceps
Freeze algorithms	26	01/30/2009	FRZ	WO2010/086751	Processing method and system for images acquired in real-time by a medical device
Connector and polished probes	27	03/12/2009	CON	WO2010/103406	Connector for fibered probe with compatible fibered probe
Jerry (provisional)	28	07/29/2009	JRY	NA	Fiber-bundle brain microscopic imaging procedure and apparatus
Microscopy in solid organs (provisional)	29	09/17/2009	MSO	NA	Investigational procedure, optical probe and confocal microscopy system for solid organs
Jerry 2 (prov. JRY + new matter PCT)	30	07/29/2010	JR2	WO2011/013011	Fiber-bundle brain microscopic imaging procedure and apparatus
Microscopy in Solid Organs 2 (prov. MSO + new matter PCT)	31	09/17/2010	MS2	WO2011/033390	Investigational procedure, optical probe and confocal microscopy system for solid organs

Cellvizio with Photoactivation (CIP of CVZ2)	32	01/10/2011	CVP	US 8 644 663	Modular imaging system, modules for the system and procedure performed with the system
Continuous calibration (RICE)	33	05/16/2011	RIC	WO2012156826	Continuous, real-time calibration of fiber-optic microscopy images
Stabilized micro-positioner	34	06/29/2011	MPS	WO2013/000873	Endoscopic instrument with supporting base
Mosaicing (Cont of MOS)	35	07/08/2011	MOS_C	US 8 218 901	Continuation of Mosaicing
Spiraler	36	04/13/2012	SPI	WO2013/153448	Miniaturized scanning system
Fluorescent markers	37	05/18/2012	RED	WO2013/171583	Red and far-red fluorescent dyes to characterize biological tissues at cellular level
Smart Review (provisional)	38	10/11/2013	EVA	NA	Characterization method of images acquired with a medical video device
Smart Review 2 (prov. Smart Review + new matter PCT)	39	05/23/2014	EV2	WO2015052351	Characterization method of images acquired with a medical video device
Jerry 3 (Div US)	40	06/05/2015	JR3	US2015-0265153	Fiber-bundle brain microscopic imaging procedure and apparatus

In general, the coverage of the Company's patents or patent applications accurately reflects the main aspects of the architecture of the technical solutions developed by the Company, namely:

- the system proper (photoexcitation, detection, scanning means, etc.);
- the endomicroscopic probes (optical probes + distal optics);
- image analysis and 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.

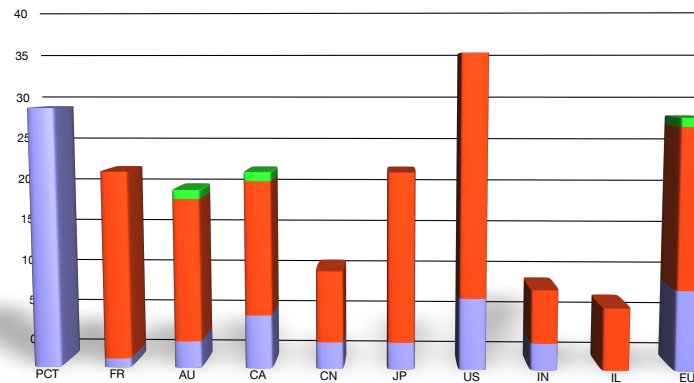
11.2.3. Territories protected

With a very limited number of exceptions, all of the Company's patent applications are systematically extended abroad through the PCT procedure. The minimum territories selected are still:

- the 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 (blue: under consideration; red: granted; green: approved/pending).



11.2.4. Litigation

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.

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.

The PERSEE project is structured into four successive phases, the last of which is expected to be completed in August 2018. In practice, the third of these phases was finished in July 2015, and the stage three end report was submitted to BPI France in May 2016. Following the end of this third phase in July 2015, BPI France and the partners embarked on the fourth phase, involving a multicenter clinical trial. After a technical validation provided by the third phase, this fourth phase should demonstrate the clinical benefit of a robotic endomicroscopy solution for cancer surgery. The fourth phase began in 2016 and will last for two years. Only at the end of this fourth phase will the PERSEE project be complete.

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.

The agreement will remain in force until the later of: the expiration date of the most recent patent, or at the end of ten years from when the product is first marketed if said product is not protected under a patent in the country where it is marketed.

The Company does not believe the loss of these exclusive licenses would have a material negative impact on its business.

11.4. Other elements of intellectual property

The Company holds the “Cellvizio®” trademark in numerous countries and regions, 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 2017 sales

In the first quarter, the Company delivered six Cellvizio systems (one of which resulted from the conversion of a consignment agreement delivered in 2016) and signed consignment agreements for six new systems in the United States, as compared to nine systems sold and one consignment agreement signed in the first quarter of 2016. Sales of consumable probes totaled 125 units, as compared to 197 units in the first quarter of 2016.

Reorders of probes (orders from existing clients) amounted to 115 units, as compared to 167 a year earlier, with volumes stable in the United States and down in other markets.

Provision of funding through a bond issue of €7 million

On February 8, 2017, funding was arranged through a €7 million bond issue with IPF Partners, a fund specialized in alternative financing for European growth companies in the healthcare sector.

This funding is made up of two bond portions: the first, which amounts to €4 million, has been issued to date; the second, for the remaining €3 million, will be available over the coming 12 months, subject to the achievement of pre-determined targets.

This funding is made up of 7,000,000 secured bonds for a total value of €7 million. The annual interest rate on these bonds is set at three-month EURIBOR + 8.5%. The term of the first portion is set at 5 years (of which 18 months without repayment of principal) and the second at 4 years (of which 12 months without repayment of principal). The terms and conditions of the bonds impose certain financial commitments.

Advantage of endomicroscopy in the *in vivo* diagnosis of stomach cancer

On March 2, 2017, the Company announced the publication of a general overview by the Singapore Gastric Cancer Consortium¹ team in a peer-reviewed journal, highlighting the superior performance of endomicroscopy in terms of improving the diagnosis of gastric cancer. The use of endomicroscopy may also reduce the number of biopsies required to confirm this diagnosis by two thirds.

The incomparable effectiveness of Cellvizio and the inter-observer consistency in the diagnosis of pancreatic cysts

On March 27, 2017, the Company announced the publication of a new study demonstrating the strong performance of needle-based confocal laser endomicroscopy (nCLE) in the diagnosis of pancreatic cysts. This blinded study proves Cellvizio's diagnostic accuracy of 95% for malignant pancreatic cysts and 98% for benign cysts, with almost perfect inter-observer consistency and reliability.

12.2 Known trend, uncertainty, request for commitment, or event reasonably likely to influence Company outlook

N/A.

SECTION 13

PROFIT PROJECTIONS AND ESTIMATES

The Company does not intend to make any profit projections or estimates.

SECTION 14

ADMINISTRATIVE, EXECUTIVE AND SUPERVISORY BODIES AND GENERAL MANAGEMENT

14.1 Executives and directors

14.1.1 Members of the Board of Directors

The Board is composed of at least three members, two of whom, wherever possible, must be independent members within the meaning of the corporate governance code as published in September 2016 by MiddleNext and approved as a model code by the *Autorité des Marchés Financiers* (AMF) (the "MiddleNext Code").

Board members are considered independent if they have no financial, contractual, family or other significant close relationship with the Group or its management that is likely to influence their judgment.

The independence of the Board members must be verified by the Board in accordance with the following criteria set out by the Governance Code:

- is not, and has not over the past five years been, an employee or executive officer of the Company or of any company in its group;
- is not, and has not over the past two years been, in a significant relationship with the Company or its group (as a client, supplier, competitor, service provider, creditor, banker, etc.);
- is not a reference shareholder of the Company and does not hold a significant portion of its voting rights;
- does not have a close relationship or family ties with a corporate officer or reference shareholder; and
- has not, over the past six years, been a statutory auditor of the Company.

If possible, at least one of the independent members must also have special expertise in financial or accounting matters so as 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 May 3, 2017.

SECTION 14 - ADMINISTRATIVE, EXECUTIVE AND SUPERVISORY
BODIES AND GENERAL MANAGEMENT

At December 31, 2016, the Company's Board of Directors was composed of five directors. No non-voting Board member was appointed by the last Annual General Meeting on May 3, 2017.

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 Re-elected at the CGM of May 3, 2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019
Alexandre Loiseau	Director and Chief Executive Officer	OGM of 05/25/2011, re-elected at the OGM of 06/11/2014 and the GM of May 3, 2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019
Jean-Luc Boulnois	Independent director	OGM of 06/11/2014 Re-elected at the CGM of May 3, 2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019
Marie Meynadier	Independent director	OGM of 06/11/2014 Re-elected at the CGM of May 3, 2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016
Joseph DeVivo	Independent director	OGM of 05/04/2016 Re-elected at the CGM May 3, 2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019

The Combined General Meeting of May 3, 2017 appointed Jennifer F. Tseng as a Director for a term of three years expiring at the end of the Ordinary General Meeting of Shareholders called to approve the financial statements for the fiscal year ending December 31, 2019.

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;
- Jean-Luc Boulnois is domiciled at Quadrature, 85 East India Row, Boston, MA 02110, United States;
- Marie Meynadier is domiciled at EOS Imaging, 10 rue Mercoeur, 75011, Paris, France;
- Joseph DeVivo is domiciled at InTouch Health, 7402 Hollister Ave., Goleta, CA 93117, United States.

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.

14.1.2 Other corporate positions as of December 31, 2016

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	Canyon Healthcare Partners, Managing Partner	<ul style="list-style-type: none"> - Foundation Radiology Group, independent director - ValueCentric, LLC, independent director - The Natural History Museum of the Adirondacks, Director and Manager - InnovaTel Telepsychiatry, Chairman of the Board of Directors
Alexandre Loiseau - Chief Executive Officer	N/A	- Mauna Kea Technologies Inc., Chief Executive Officer
Jean-Luc Boulnois - independent director	Quadrature LLC, Chairman and Chief Executive Officer	<ul style="list-style-type: none"> - FineHeart, Chairman of the Board of Directors - Fiberoptic Components, director
Marie Meynadier - independent director	CEO of EOS Imaging	- STENTYS, director
Joseph DeVivo - independent director	Chief Executive Officer of InTouch Health	- ALSAC/St. Jude, 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. From 1999 to 2008, Mr. McFadden was a Senior Financial Analyst at Goldman, Sachs & Co. in New York, before directing investments in healthcare for Goldman Sachs' Americas Special Situations Group. Mr. McFadden is also a director of the Montefiore Medical Center in New York and the Natural History Museum of the Adirondacks.



Jean-Luc Boulnois
Member of the Board

Jean-Luc Boulnois is the Chairman and Chief Executive Officer of Quadrature LLC and Chairman of the Board at Fineheart. He was involved in Microline Surgical for 18 years, an innovative minimally-invasive surgical instrument company, firstly as an investor and then, from 2005 to 2013 as CEO, heading a period of uninterrupted growth. He was then appointed Executive Chairman of the Board of Directors, a position he held until 2016. He was also CEO of Sometec from 1995 to 1999 and CEO of Technomed International, two medical technology companies which knew a very strong development. 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.



Alexandre Loiseau, PhD
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. She began her career at the prestigious Bell Labs, then went on to steer 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.



Joseph DeVivo
Member of the Board

Joseph DeVivo is Chief Executive Officer of InTouch Health. He was CEO of AngioDynamics from September 2011 until March 2016. Previously, Mr. DeVivo was Chairman and CEO of RITA Medical Systems. More recently, Mr. DeVivo served as President, Chief Operating Office and Director of Computer Motion Incorporation (CMI). Before that, he had been Vice-Chairman & CEO of the Health Services division of TYCO International, with revenues of \$350 million, and of U.S. Surgical/Davis and Geck Sutures. During his nine years at U.S. Surgical, Mr. DeVivo held several senior executive positions in sales and marketing, overseeing numerous product introductions and carrying out new sales and marketing strategies. Mr. DeVivo received his B.S. In Business Administration from the E. Claiborne Robins School of Business at the University of Richmond.

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 the financial year 2016, 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 on February 2, 2016. These objectives took into account, inter alia, the Company's sales growth.

At its meeting on March 21, 2017, the Board of Directors, acting on the proposal from the Compensation Committee meeting of March 14, 2017, examined the level of achievement of these targets and resolved to pay the Chief Executive Officer the variable compensation corresponding to those targets, which are contingent on the Company's performance.

Executive officers do not receive directors' fees in respect of their corporate office within the Company. In addition, they are not entitled to any deferred compensation, retirement benefits or pension plans, in accordance with recommendation Nos. 16 and 17 of the MiddleNext Code.

Within the framework of its executive and employee compensation and incentives policy, the Company granted bonus preference shares to Company employees and stock options to employees of its subsidiary respectively on February 2, July 26 and November 15, 2016.

Contrary to recommendation No. 18 of the MiddleNext Code, the Company has introduced a policy of granting free shares to its Chief Executive Officer. It should be noted that with regard to the granting of free shares, when the plans have benefited the executive officer, they have also benefited all Group employees, who will have received either free shares or stock options.

15.1.1 Executive compensation

The following information was prepared by referring to the Code on Corporate Governance for small- and mid-caps, as amended in September 2016 by MiddleNext.

All members of the Board may receive directors' fees of an amount voted for by the Ordinary General Meeting and distributed as decided by the Board, in accordance with the attendance record and time dedicated by members to their roles including, where applicable, on any committees established by the Board.

The compensation of the Chairman is set by the Board, after consultation with the Compensation Committee.

Board members may also receive compensation for specific duties assigned to them by the Board of Directors over and above their regular duties with the Board.

Every director is entitled to the reimbursement of reasonable transport costs incurred in the exercise of their duties.

Summary table of compensation and options and shares granted to each executive officer		
(Chairman of the Board of Directors) Chris McFadden	Year ended 12/31/2016 (in euros)	Year ended 12/31/2015 (in euros)
Compensation due for the period (detailed in Table 2)	76,000	59,000
Valuation of options granted during the period	12,160 (1)	N/A
Valuation of performance shares granted during the period	N/A	N/A
(Chief Executive Officer) Alexandre Loiseau	Year ended 12/31/2016 (in euros)	Year ended 12/31/2015 (in euros)
Compensation due for the period (detailed in Table 2)	265,357	244,457
Valuation of options granted during the period	N/A	N/A
Valuation of performance shares granted during the period	70,240	N/A

Summary of compensation for each executive officer				
(Chairman of the Board of Directors) Christopher McFadden	Amounts due for the year ended 12/31/2016 (in euros)		Amounts due for the year ended 12/31/2015 (in euros)	
	Amounts due	Amounts paid	Amounts due	Amounts paid
- fixed compensation	0	0	0	0
- variable compensation	0	0	0	0
- exceptional compensation	0	0	0	0
- directors' fees	76,000	76,000	59,000	59,000
- benefits in kind	0	0	0	0
TOTAL	76,000	76,000	59,000	59,000
(Chief Executive Officer) Alexandre Loiseau	Amounts due for the year ended 12/31/2016 (in euros)		Amounts due for the year ended 12/31/2015 (in euros)	
	Amounts due	Amounts paid	Amounts due	Amounts paid
- fixed compensation	205,000	205,000	205,000	205,000
- variable compensation	45,850	24,250	25,113	0
- exceptional compensation	0	0	0	0
- directors' fees	0	0	0	0
- benefits in kind (2)	14,507	14,507	14,344	14,344
TOTAL	265,357	244,007	244,457	219,344

(1) Premium due for the previous financial year

(2) Benefits in kind consist of a lease and unemployment insurance for company managers and executives

Pierre Forest, having held the position of Deputy CEO from June 1, 2016 until January 18, 2017, received fixed compensation in the amount of €131,250, benefits in kind amounting to €2,512 and variable compensation of €15,750 with respect to the period between June 1, 2016 and December 31, 2016.

Stock options granted during the financial year to each executive officer by the issuer and by any 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	07/26/2016	BSA	12,160 (1)	40,000	1.68	07/26/2017-07/26/2026
TOTAL						

(1) €0.16 per stock warrant

Stock options exercised during the financial year by each executive officer				
Christopher McFadden (Chairman of the Board of Directors)	Plan No. and date	Number of options exercised during the period	Exercise price	Year of grant
N/A				
Alexandre Loiseau (Chief Executive Officer)	Plan No. and date	Number of options exercised during the period	Exercise price	Year of grant
N/A				

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
Alexandre Loiseau	07/26/2016	160,000	70,240	07/26/2017	07/26/2019	(1)

(1) Performance conditions are listed in the minutes of the Combined General Meeting of May 4, 2016, in resolutions 19 and 20, which can be accessed via the following link: http://www.maunakeatech.com/sites/default/files/investors/documentation/eui_1200483797_1_mkt_-_pv_agm_4_mai_2016.pdf

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-competete 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 of office expired:	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2016							
	Yes	No	Yes	No	Yes	No	Yes	No
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 of directors' fees and other compensation received by non-executive officers				
Members of the Board of Directors	Directors' fees paid for the year ended 12/31/2016 (in euros)	Directors' fees paid for the year ended 12/31/2015 (in euros)	Plans awarded in 2016	Plans awarded in 2015
André-Michel Ballester				
- directors' fees	0	17,000		
- other compensation	-	-		
- value of BSA granted			-	-
TOTAL	0	17,000		
Jean-Luc Boulnois				
- directors' fees	34,000	25,000		
- other compensation	-	-		
- value of BSA granted (1)			4,000	-
TOTAL	34,000	25,000		
Marie Meynadier				
- directors' fees	31,000	25,000		
- other compensation	-	-		
- value of BSA granted (1)			4,000	-
TOTAL	31,000	25,000		
Joseph DeVivo				
- directors' fees	40,000	-		
- other compensation	-	-		
- value of BSA granted (1)			4,000	-
TOTAL	40,000	-		

(1) €0.16 per stock warrant

At its meeting on May 25, 2016, the Board of Directors set its members' compensation as follows, in accordance with the budget set by the Annual General Meeting on May 4, 2016:

- the Board of Directors allocates directors' fees on a yearly basis and pays them on a quarterly basis;
- the Chairman of the Board of Directors is allocated €55,000 per year, prorata temporis,
- the independent directors, with the exception of the Chairman of the Board of Directors, are each allocated €25,000 pro rated to their attendance rate at Board meetings,
- the Chairmen of the Audit and Compensation Committees are allocated €9,000 per year for this office,
- the members of the Audit and Compensation Committees other than the Chairmen are allocated €6,000 for this office.

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 General Meeting	06/11/2014	05/04/2016	Plan No. 3	etc.
Date of the Board of Directors' meeting	09/01/2014	07/26/2016		
Total number of shares that may be subscribed for or bought, including the number that may be subscribed for or bought by corporate officers:	120,000	115,000	N/A	N/A
Start date for exercise of the options	09/01/2015	07/26/2017		
Expiration date	09/01/2024	07/26/2026		
Issue price	€0.61	€0.16		
Exercise price	€6.12	€1.68		
Exercise procedures (where the plan consists of several tranches)	In thirds every 3 years	In thirds every 3 years		
Number of shares subscribed at 12/31/2016	N/A	N/A		
Cumulative number of stock options canceled or invalid	60,000	-		
Stock options remaining at year-end	60,000	115,000		

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 preference share grants		
Information on bonus preference shares granted		
Date of General Meeting	05/04/2016	05/04/2016
Date of the Board of Directors' meeting	07/26/2016	11/15/2016
Total number of bonus shares granted	7,765	570
Share vesting date	07/26/2017	11/15/2017
Expiration of the holding period	07/26/2019	11/15/2019
Number of shares subscribed for	-	-
Cumulative number of shares canceled or invalid	-	-
Bonus preference shares remaining at year-end	7,765	570

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 during the 2016 financial year:

Beneficiaries		BSA	Founders' warrants (BSPCE)	Stock options
Christopher McFadden	Chairman of the Board of Directors	40,000	-	-
Joseph DeVivo	Director	25,000	-	-
Jean-Luc Boulnois	Director	25,000	-	-
Alexandre Loiseau	Director and Chief Executive Officer	-	-	-
Marie Meynadier	Director	25,000	-	-

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.

During FY 2016, the Board of Directors of the Company, as a public limited company (*société anonyme*) met 6 times, on February 2, March 23, May 25, July 26, September 20 and November 15, 2016. All meetings were chaired by the Chairman of the Board. The directors' attendance rate was 100%.

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.

On February 2, 2017, the Company announced the appointment of John Soto as Chief Operating Officer (COO). With over 25 years' experience in the medical devices industry, John Soto will oversee all transactions and the implementation of the Company's global business strategy.

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 decided to create two specialized committees: the Audit Committee and the 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. The term of service of Audit Committee members is the same as that of their directorships. 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, 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 are as follows:

- Jean-Luc Boulnois, Chairman of the Audit Committee, independent director, appointed by the Board of Directors on June 11, 2014,

- Chris McFadden, Chairman of the Board of Directors, independent director, appointed by the Board of Directors on June 11, 2014,
- Joseph Devivo, member of the Audit Committee, appointed by the Board of Directors on March 23, 2016.

The appointment of three 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, Director 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 statutory auditors proposed for appointment by the Annual General Meeting and reviewing the terms of their compensation;
- monitoring the independence of the statutory auditors;
- examining the conditions for the use, if any, of derivatives;
- periodically reviewing the status of major litigation; and
- in general, providing any advice and making any appropriate recommendation in the above areas.

Operations

The Company's Board of Directors at its meeting of May 25, 2011 voted to create an Audit Committee.

This duty of the Audit Committee is to assist the Board of Directors independently of the Company management, in order to ensure the accuracy of the financial statements, the quality of the internal control system, the utility of the information provided and the proper execution by the statutory auditors of their assignment.

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 statutory auditors proposed for appointment by the Annual General Meeting and reviewing the terms of their compensation;
- monitoring the independence of the statutory auditors;
- examining the conditions for the use, if any, of derivatives;
- periodically reviewing the status of major litigation; and
- in general, providing any advice and making any appropriate recommendation in the above areas.

The Audit Committee is, if possible, comprised of at least three members appointed by the Board of Directors. The term of service of Audit Committee members is the same as that of their directorships. 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, 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 are as follows:

- Jean-Luc Boulnois, Chairman of the Audit Committee, independent director, appointed by the Board of Directors on June 11, 2014,
- Chris McFadden, Chairman of the Board of Directors, independent director, appointed by the Board of Directors on June 11, 2014,
- Joseph Devivo, member of the Audit Committee, appointed by the Board of Directors on March 23, 2016.

The appointment of three 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, Director of Administration and Finance). It has the right of direct, independent and confidential consultation with the statutory auditors.

The Audit Committee met twice in FY 2016: on March 22 and September 19, 2016.

16.3.2 Compensation Committee

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 and 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 arrangements and in particular, the personal allocations to the members of the Board of Directors;
- examining the total amount of director's 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 the members of the Board of Directors;
- preparing and presenting the reports, where applicable, set forth in the Board of Directors' internal rules of procedure; and
- preparing any other recommendation that might be asked of it by the Board of Directors with respect to compensation.

In general, the Committee provides any advice and makes any appropriate recommendation in the above areas.

The Compensation Committee consists if possible of at least two members appointed by the Board of Directors, with the provision that no member of the Board of Directors who serves as an executive in the Company can serve on the Committee. The term of service of Compensation Committee members is the same as that of their directorships.

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:

- Chris McFadden, Chairman of the Compensation Committee, Chairman of the Board of Directors and independent director,
- Marie Meynadier, independent director.

As part of its duties, the 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 Committee met four times in FY 2016: on February 2, March 23, July 25 and September 19, 2016.

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
<i>I. Executive power</i>				
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			
<i>II. Supervisory power</i>				
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

2.1. General principles of risk management

A) Definition

Mauna Kea Technologies continues to formalize its risk management process.

This process aims to identify all the risks and risk factors that can impact the Company's business activities and operations and to define the means of managing such risks and of containing them or bringing them down a level the Company can accept. The aim is to encompass every type of risk and apply the process to every activity of the Company and the Group.

B) Objectives of risk management

Mauna Kea Technologies has adopted the definition of risk management proposed by the *Autorité des Marchés Financiers*¹¹ (the French Financial Markets Authority), whereby risk management is one of the Company's management tools that helps to:

- create and preserve the Company's value, assets and reputation;
- add security to the Company's decision making and processes so as to make the attainment of its objectives more likely;
- ensure the Company's actions are consistent with its values;
- enlist the employees in a common vision of the Company's principal risks.

C) Components of the risk management system

The risk factors identified to date by the Company are presented in Section IV of the Registration Document filed with the AMF on June 13, 2016, and which will be updated in 2017.

To date, the Company has identified the following major families of risk:

- competitive environment;
- commercialization, related in particular to the adoption rate by healthcare professionals, the reimbursement terms for endomicroscopic procedures, and the recruitment of a loyal sales force;
- intellectual property;
- manufacturing processes;
- risks relating to potential product liability;
- financial risks;
- legal risks, relating in particular to regulations governing medical devices, and to authorizations already obtained or in progress and the regulatory environment;
- organizational structure of the Company.

2.2. Congruence between risk management and internal control

¹¹ Guide to the implementation of the reference framework for internal control adapted to small- and mid-caps (updated on July 22, 2010)

The point of risk management is to identify the major risks and risk factors that might impact the activities, processes or objectives of the business and to define the means of containing these risks at an acceptable level, including by adopting preventive measures and controls that fall within the scope of the internal control system.

At the same time, the internal control system relies primarily on the risk management system to identify the major risks that need to be controlled. The Company devised and developed an internal control system from its initial founding, while the formalization of a risk management process has been more recent. The Company is now engaged in a process of coordinating the two systems, with the primary goal of identifying the control procedures that must apply to the business's key activities which might be affected by risks that analysis shows to be "major".

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*¹² (the French Financial Markets Authority), 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 of the validation system

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 functions concerned by this software are Purchasing/Suppliers, Sales/Customers, Accounts and Management Control.

Every year, the Company is the subject of a systems-information audit. In 2016, this audit did not find any significant anomalies. The weaknesses of the system, if applicable, are covered by compensatory means of control.

Everyone in the Company is affected by the internal control system.

Procedures relating to operational processes

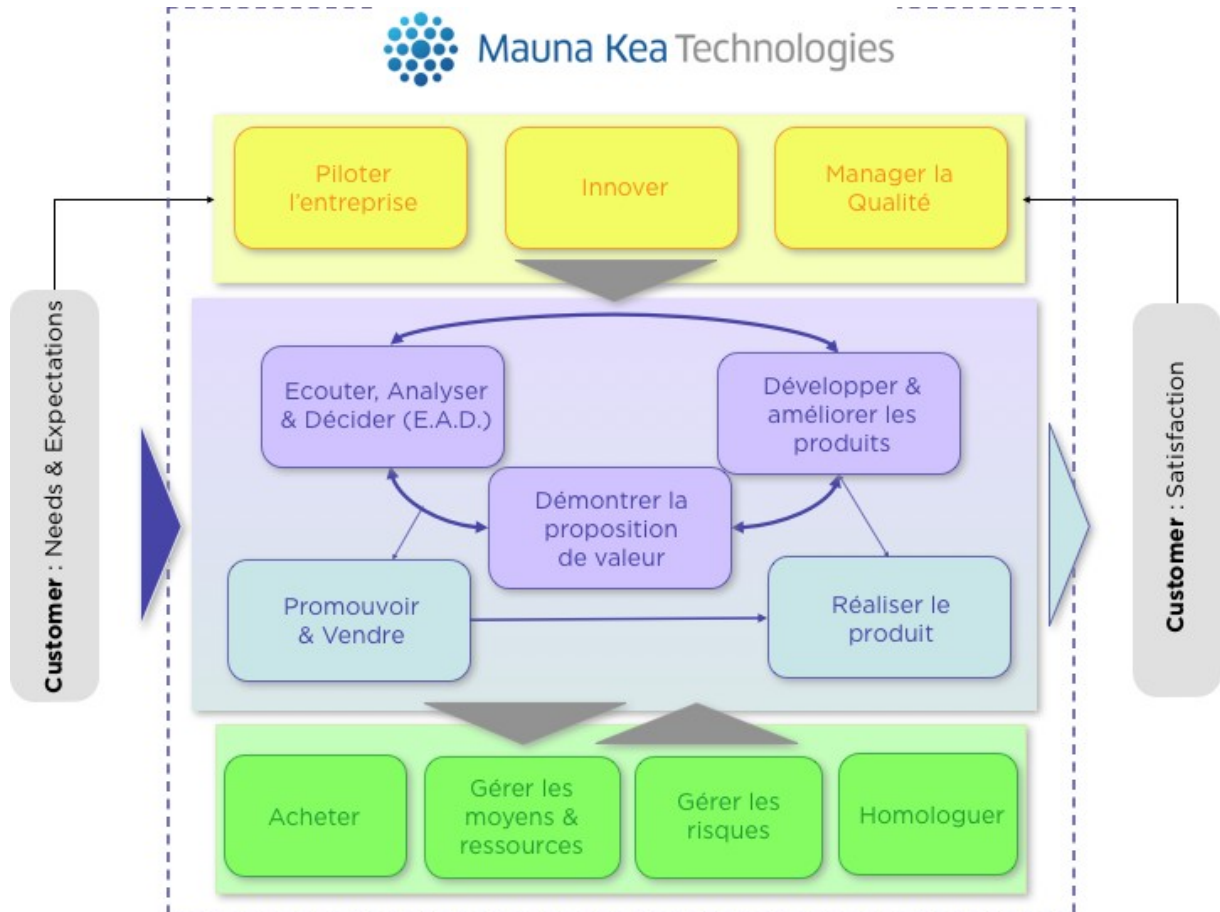
All documentation relating to the quality management system (QMS) is stored on a dedicated intranet which optimizes access to the documents and their ongoing adaptation to business developments (document life cycle management). The aim is to foster a continuous improvement in

¹² Guide to the implementation of the reference framework for internal control adapted to small- and mid-caps (updated on July 22, 2010)

the quality and functional processes of the Company and the Group, be they operational, management or support processes.

Each one of these processes is placed under the responsibility of a steering person, who manages, along with responsibility for quality, all of the quality-control procedures and forms describing the activities covered by the process, as well as the performance indicators connected to the process. The various processes are reviewed on a regular basis by the corporate management, at the time of the management's review.

The quality assurance system covers the following areas:



The system of quality management is audited once yearly by the certifying entity LNE GMED within the framework of the CE certification. In November 2015, following Recommendation No. 2013/473/UE of the European Commission, which makes it obligatory at least once during a three-year certification cycle, the Company was the subject of an unscheduled one-day audit. The results were positive, and if any nonconformities were found, the corrective actions were rapidly defined, and this audit did not cause the Company's CE certification to be called into question.

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 by the registered office accounting team,
- Payroll management in France and the review of U.S. payroll 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

The Company seeks to adapt its risk management system to its 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.

Chairman of the Board of Directors

16.6 Statutory auditors' report on the report prepared by the Chairman of the Board of Directors

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

COFIDEC
155, boulevard Haussmann
75008 Paris
S.A.R.L. with € 32,800 of paid capital

Statutory auditors
Member of the Compagnie
Régionale de Paris

ERNST & YOUNG et Autres
1/2, place des Saisons
92400 Courbevoie - Paris-La Défense 1
S.A.S. with variable capital

Statutory auditors
Member of the Compagnie
Régionale de Versailles

Mauna Kea Technologies

Year ended december 31, 2016

Statutory auditor's 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, 2016.

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;
- 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 et Paris-La Défense, March 31, 2017

The Statutory Auditor
French original signed by

COFIDEC

ERNST & YOUNG et Autres

Olivier Robinault

Cédric Garcia

SECTION 17 EMPLOYEES

17.1 Human resources

17.1.1 Number and distribution of employees

Distribution of employees by category:

	12/31/2016	12/31/2015	Change
Permanent contract	80.1	105.6	-24.15%
Fixed-term contract	0.1	0.4	-79.17%
Professional training contract	1.6	1.4	-14.29%
Total workforce	81.8	107.4	-23.81%
Executives	70.6	93.8	-24.75%
Non-executives	11.2	13.6	-17.28%

Distribution of employees by gender:

	12/31/2016	12/31/2015	Change
Men	54.5	68	-19.85%
Women	27.3	39.4	-30.63%
Total workforce	81.8	107.4	-23.81%

Distribution of workforce by geographical area:

	12/31/2016	12/31/2015	Change
France	66.5	83.9	-20.74%
Europe excluding France	0	0.9	-100%
America	11.5	19.5	-41.03%
Asia-Pacific	3.8	3.1	+23.66%
Total employees	81.8	107.4	-25.36%

Entries and departures:

Number of new hires	2016	2015
Permanent contracts	16	10
Fixed-term contracts	0	1
Apprentice/intern	2	1
Total	18	12

Departures by reason	2016	2015
Redundancies/dismissals	3	9
Voluntary departure	23	23
End of fixed-term contract	0	3
Others	5	8
Total	31	43

In 2016, Mauna Kea Technologies continued its targeted recruitment strategy, which partly explains the general drop in headcount.

However, this is more marked in the Americas region, where the relocation of our subsidiary led to the departure of several employees. Our recruitment drive - particularly for sales profiles - is especially focused in this region, given its strategic role in the Company's expansion.

In France, the Company is also faced with the difficulty of hiring certain specific profiles.

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
	Number	% of the capital	
Christopher McFadden	-	-	30,000 BSA 2014 40,000 BSA 2016
Alexandre Loiseau	549,240	2.67%	499,996 BSPCE A 08 to be exercised at the rate of 4 BSPCE A 08 for one new share, which equals 124,999 shares. 100,000 BSPCE 2014 to be exercised at the rate of 1 BSPCE 2014 for one new share (see Section 21.1.4 of this document for the exercise conditions) 1,600 Preference Shares at the rate of 1 Preference Share for 100 new shares
Jean-Luc Boulnois	-	-	30,000 BSA 2014 25,000 BSA 2016
Marie Meynadier	-	-	25,000 BSA 2016
Joseph DeVivo	-	-	25,000 BSA 2016

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, 2017, Group employees held 84,775 shares and 139,550 voting rights, or 0.41% of the capital and 0.68% of Company voting rights.

17.4 Profit-sharing and participation agreements

N/A.

SECTION 18 PRINCIPAL SHAREHOLDERS

18.1 Breakdown of the capital and voting rights

Memorandum and bylaws

Shareholders	31/12/16						31/12/15					
	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
CREADEV (**)												
Alexandre Loiseau	549 240	2,75%	1 075 080	4,99%	1 075 080	4,99%	549 240	3,40%	1 040 980	5,81%	1 040 980	5,82%
Subtotal Board of Directors												
Finavance												
Seventure (4 funds)	396 012	1,98%	792 024	3,67%	792 024	3,68%	660 021	4,08%	1 320 042	7,36%	1 320 042	7,38%
Seventure (porteur)	110 892	0,55%	110 892	0,51%	110 892	0,51%						
Health Evolution partner (***)												
Callpers (***)							607 021	3,75%	607 021	3,39%	607 021	3,39%
Inocap	1 760 175	8,80%	1 760 175	8,16%	1 760 175	8,17%	1 099 560	6,80%	1 099 560	6,13%	1 099 560	6,14%
The Capital Group Companies, Inc (***)							958 400	5,92%	958 400	5,35%	958 400	5,36%
Subtotal major shareholders												
Other registered	702 691	3,51%	1 339 857	6,21%	1 339 857	6,22%	706 571	4,37%	1 308 717	7,30%	1 308 717	7,31%
Other free float	18 107 090	90,53%	18 107 090	83,98%	18 107 090	84,07%	11 559 531	71,46%	11 559 531	64,47%	11 559 531	64,60%
Own shares	23 681	0,12%	23 681	0,11%	0	0,00%	36 363	0,22%	36 363	0,20%	0	0,00%
Total shares comprising the share capital	20 001 838	100,00%	21 561 156	100,00%	21 537 475	100,00%	16 176 707	100,00%	17 930 614	100,00%	17 894 251	100,00%

Shareholders	31/12/14						31/12/13					
	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
CREADEV (**)	-	-					2 332 375	16,90%	4 449 317	24,27%	4 449 317	24,29%
Alexandre Loiseau	604 240	4,32%	1 150 980	6,99%	1 150 980	6,99%	546 740	3,96%	1 093 480	5,97%	1 093 480	5,97%
Subtotal Board of Directors	604 240	4,32%	1 150 980	6,99%	1 150 980	6,99%	2 879 115	20,86%	5 542 797	30,24%	5 542 797	30,26%
Finavance	717 059	5,12%	1 434 118	8,70%	1 434 118	8,71%	717 059	5,19%	1 367 886	7,46%	1 367 886	7,47%
Seventure (4 funds)	660 021	4,72%	1 320 042	8,01%	1 320 042	8,02%	660 021	4,78%	1 259 079	6,87%	1 259 079	6,87%
Seventure (porteur)												
Health Evolution partner (***)							607 021	4,40%	607 021	3,31%	607 021	3,31%
Callpers (***)	607 021	4,34%	607 021	3,68%	607 021	3,69%						
Inocap												
The Capital Group Companies, Inc (***)	881 400	6,30%	881 400	5,35%	881 400	5,36%	881 400	6,39%	881 400	4,81%	881 400	4,81%
Subtotal major shareholders	2 865 501	20,48%	4 242 581	25,75%	4 242 581	25,78%	2 865 501	20,76%	4 115 386	22,45%	4 115 386	22,47%
Other registered	739 998	5,29%	1 300 245	7,89%	1 300 245	7,90%	775 047	5,61%	1 387 878	7,57%	1 387 878	7,58%
Other free float	9 765 243	69,79%	9 765 243	59,27%	9 765 243	59,33%	7 270 313	52,67%	7 270 313	39,66%	7 270 313	39,69%
Own shares	17 537	0,13%	17 537	0,11%	0	0,00%	13 481	0,10%	13 481	0,07%	0	0,00%
Total shares comprising the share capital	13 992 519	100,00%	16 476 586	100,00%	16 459 049	100,00%	13 803 457	100,00%	18 329 855	100,00%	18 316 374	100,00%

(**) 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

N/A.

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 at March 31, 2017, the following shareholders are eligible for double voting rights:

Shareholders	Shares with double voting rights
FUJIKURA	424,882
JACQUES BOGART SA	44,914
ALEXANDRE LOISEAU	1,075,380
SBN	38,262
SCHNEIDER	48,852
SEVENTURE (through two funds)	792,024
CREDIT AGRICOLE LUXEMBOURG	229,238
IPERIUM INTRENATIONAL	154,994
Various individuals and legal entities	401,847
TOTAL	3,210,393

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

As at the date hereof, as part of the debt contracted with IPF Partners on February 9, the Company is subject to pledges on all of its bank accounts and part of its fixed assets.

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, 2016

COFIDEC
155, boulevard Haussmann
75008 Paris
S.A.R.L. with € 32,800 of paid in capital

Statutory auditors
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1/2, place des Saisons
92400 Courbevoie - Paris-La Défense 1
S.A.S. with variable capital

Statutory auditors
Member of the compagnie
régionale de Versailles

Mauna Kea Technologies
General meeting of shareholders to approve the financial statements for the year ended December 31, 2016

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, as well as the reasons why they benefit the Company. 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 et Paris-La Défense, March 31, 2017

The Statutory Auditor
French original signed by

COFIDEC

ERNST & YOUNG et Autres

Olivier Robinault

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, 2016

STATEMENT OF FINANCIAL POSITION (Amounts in thousands of euros)

	Note	12/31/2016	12/31/2015
ASSETS			
Non-current Assets			
Intangible assets	3	2 565	3 135
Property, plant, and equipment	4	898	625
Non-current financial assets	5	162	133
Total of non-current assets		3 625	3 893
Current assets			
Inventories & Work in progress	6	2 331	2 644
Trade receivables	7	2 116	3 458
Other current assets	7	2 756	1 823
Current financial assets	8	94	65
Cash and cash equivalents	9	9 053	10 620
Total of current assets		16 349	18 610
TOTAL OF ASSETS		19 974	22 503
EQUITY AND LIABILITIES			
Equity			
Issued capital	10	800	647
Share premium	10	72 382	66 050
Reserves		(52 394)	(40 069)
Foreign currency translation on reserve		113	106
Profit / (loss)		(9 744)	(12 643)
Total of equity		11 157	14 091
Non-current Liabilities			
Long-term loans and borrowings	11	2 640	2 182
Non-current provisions	12	261	246
Total of non-current liabilities		2 900	2 428
Current liabilities			
Short-term loans and borrowings	11	404	719
Trade payables	13	3 131	2 453
Other current liabilities	13	2 382	2 812
Total of current liabilities		5 917	5 984
TOTAL OF EQUITY AND LIABILITIES		19 974	22 503

SECTION 20 - FINANCIAL INFORMATION CONCERNING THE ISSUER'S
ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND
LOSSES

COMPREHENSIVE INCOME STATEMENT

(Amounts in thousands of euros)

	Note	12/31/2016	12/31/2015
Operating Revenue			
Sales	15	8 787	8 547
Other income	15	883	1 434
Total of revenue		9 670	9 981
Operating Expenses			
Cost of sales		(2 720)	(2 534)
<i>Gross margin</i>		<i>69%</i>	<i>70%</i>
Research & Development	18	(4 445)	(4 648)
Sales & Marketing	18	(8 366)	(11 665)
Administrative expenses	18	(3 843)	(3 642)
Share-based payments	17	(285)	(450)
Total of expenses		(19 660)	(22 939)
Current operating profit		(9 990)	(12 958)
Other operating profit/expense			232
Operating profit		(9 990)	(12 726)
Financial revenue	19	412	383
Financial expenses	19	(166)	(299)
Profit before tax		(9 744)	(12 643)
Income tax expense	20		
Profit / (loss)		(9 744)	(12 643)
Other comprehensive income			
<i>Items that will not be reclassified to profit or loss</i>			
Actuarial differences on defined benefit plans	12	18	117
Total of items that will not be reclassified to profit or loss		18	117
<i>Items that will be reclassified subsequently to profit or loss</i>			
Exchange differences on translation of foreign operations		8	84
Total of items that will be reclassified subsequently to profit or loss		8	84
Other comprehensive income for the year, net of tax		26	200
Comprehensive income		(9 718)	(12 443)
Weighted average number of shares outstanding (in thousands)		17 587	15 031
Basic earnings per share (EUR/share)	23	(0,55)	(0,84)
Weighted average number of potential shares (in thousands)		20 607	16 814

SECTION 20 - FINANCIAL INFORMATION CONCERNING THE ISSUER'S
ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND
LOSSES

CONSOLIDATED FINANCIAL STATEMENTS

STATEMENT OF CHANGES IN EQUITY

(Amounts in thousands of euros)

		Issued capital	Share premium	Treasury shares	Reserves	Foreign currency translation on reserve	Profit / (loss)	Total of equity
Equity as of	12/31/2014	560	58 162	(105)	(26 499)	23	(13 973)	18 168
Allocation of the profit / (loss)					(13 973)		13 973	
Allocation of carry forward								
Capital transactions		87	7 888					7 975
Share-based payment transactions					450			450
Treasury shares transactions				(11)	(48)			(59)
Comprehensive income as of *	12/31/2015				117	84	(12 643)	(12 442)
Equity as of *	12/31/2015	647	66 050	(117)	(39 953)	106	(12 643)	14 091
Allocation of the profit / (loss)					(12 643)		12 643	
Allocation of carry forward								
Capital transactions		153	6 332		(20)			6 466
Share-based payment transactions (1)					285			285
Treasury shares transactions				45	(11)			34
Comprehensive income as of	12/31/2016				18	8	(9 744)	(9 718)
Equity as of	12/31/2016	800	72 382	(72)	(52 322)	113	(9 744)	11 157

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	12/31/2016	12/31/2015
Cash flows from operating activities			
Profit / (loss)		(9 744)	(12 643)
Elimination of amortisations, depreciations and provisions		929	773
Share-based payment transaction expense and revenue	17	285	450
Other items excluded from the auto-financing capacity		(105)	135
<i>Revenue and expenses related to the discounting of repayable advances</i>	11/19	(174)	(43)
<i>Net financial interest paid</i>	19	(11)	(2)
<i>Other non-cash items</i>		80	180
Capital gain or loss from asset sales		(1)	0
Auto-financing capacity		(8 635)	(11 284)
Change in WCR related to business activities (1)		799	(446)
<i>Inventories & Work in progress</i>		232	(585)
<i>Trade receivables</i>		1 378	483
<i>Other current assets</i>		(990)	179
<i>Trade payables</i>		673	208
<i>Other current liabilities</i>		(493)	(731)
Net cash flows from operating activities (A)		(7 836)	(11 729)
Cash flows from investing activities			
Purchase of property, plant and equipment and intangible assets	3/4	(516)	(363)
Proceeds from sale of property, plant and equipment and intangible assets		1	0
Proceeds from sale of current financial assets			
Change in loans and advances granted		(58)	36
Other cash flows from investing operations			
Net cash flows from investing activities (B)		(573)	(326)
Cash flows from financing activities			
Proceeds from exercise of share options	10	2 026	3 485
Proceeds from issue of shares	10	4 440	4 490
Repurchases and resales of treasury shares		34	(59)
Net financial interests paid	19	11	2
Other cash flows from financing operations	11	315	(300)
Net cash flows from financing activities (C)		6 826	7 618
Net foreign exchange difference (D)		15	41
Change in cash (A) + (B) + (C) + (D)		(1 567)	(4 398)
Cash at the beginning of the period	9	10 620	15 018
Cash at the end of the period	9	9 053	10 620
Change in cash		(1 567)	(4 398)

(1) Change in WCR are presented in the notes of the current assets and liabilities

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Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer thanks to real-time *in vivo* microscopic visualization. The Company's flagship product, Cellvizio, has received clearance to sell a wide range of applications in more than 40 countries including the United States, Europe, Japan, China, Canada, Brazil and Mexico.

NOTE 1: ACCOUNTING POLICIES AND 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 at its meeting of March 21, 2017. These financial statements will be definitive only after their approval by the Annual General Meeting.

The financial statements are prepared on the basis of historical cost with the exception of financial assets, which are measured at their fair value. The preparation of the financial statements according to IFRS principles requires that estimates be made and assumptions formulated which impact the amounts and information provided therein with respect to measuring the cost of share-based payments, measuring the value of the research tax credit, and measuring value in use with regard to impairment testing. These assumptions and estimates were made on the basis of information or positions at the date the financial statements were prepared and may differ from actual results. As applicable, a sensitivity analysis may be implemented if this variation is significant.

The Board of Directors worked on the assumption of a going concern, taking into account the cash position at the end of December 2016, sales prospects (including from partnership agreements), receipt of the 2015 research tax credit, the bond issue in February 2017, and provisional cash flows. Following a specific review of its liquidity risk, the Company considers that it is able to meet its scheduled repayments until December 31, 2017.

This financial information was prepared on the basis of the principles underlying all the mandatory standards and interpretations adopted by the European Union and applied by the Company at December 31, 2016. The standards and interpretations in question are available on the website of the European Commission at http://ec.europa.eu/internal_market/accounting/ias/index_fr.htm.

New standards, amendments, revisions and interpretations adopted by the European Union with mandatory application for accounting periods beginning on or after January 1, 2016 and applied for the first time by the Company this financial year are:

- amendments to IAS 19 "Defined Benefit Plans: Employee Contributions";
- annual improvements to IFRS: 2010-2012 cycle;
- annual improvements to IFRS: 2012-2014 cycle;
- amendments to IFRS 11 "Accounting for Acquisitions of Interests in Joint Operations";
- amendments to IAS 16 and IAS 38 "Clarification of Acceptable Methods of Depreciation and Amortization";
- amendments to IAS 1 "Disclosure Initiative";
- amendments to IFRS 10, IFRS 12 and IAS 28 "Investment Entities: Applying the Consolidation Exemption".

These standards have no impacts on the consolidated financial statements.

Furthermore, the Company did not apply ahead of time other standards, amendments, revisions or interpretations that will become compulsory for financial years beginning after January 1, 2016. The standards, amendments, revisions and interpretations in question are:

- amendments to IFRS 9 "Financial instruments";
- IFRS 15 "Revenue from Contracts with Customers".

The company began its analysis of the impacts of implementing IFRS 15. The main expected impacts in terms of revenue recognition methodology will relate to system sales.

The Company did not apply ahead of time any standards, amendments, revisions or interpretations not yet adopted by the European Union:

- IFRS 16 “Leases”;
- amendments to IAS 12 “Income Taxes”;
- amendments to IAS 7 “Statement of Cash Flows”;
- amendments to IFRS 2 “Share-based Payment”;
- annual improvements to IFRS: 2014-2016 cycle;
- IFRIC 22 “Foreign Currency Transactions and Advance Consideration”;
- amendments to IAS 40 “Transfers of Investment Property”.

The impacts of the application of these standards on the consolidated financial statements are currently being analyzed.

1.2. Consolidation methods

Subsidiaries are all the entities over which the Company exercises control with regard to financial and operating policy and of which it generally holds 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 from the date on which control 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 accordance with IAS 21.15, foreign exchange gains and losses on long-term receivables in US dollars owed by a subsidiary to the Company are 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 accordance with IAS 38, 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, development costs are recognized as intangible assets only if all the following criteria are met:

- (a) The Company has established the technical feasibility of the asset for sale or use;
- (b) The Company intends to complete the asset and use it;
- (c) The Company is able to complete the asset and use it;
- (d) The Company is able to demonstrate how the asset will generate future economic benefits;
- (e) The Company has the technical, financial and other resources necessary to complete the asset;
- and
- (f) The Company is able to measure the costs of developing the asset.

In application of this standard, the Company recognized all its R&D costs as expenses, until the first prototypes of Cellvizio were refined.

Development expenses related to finalizing new products were recognized as assets. Expenses related to research and the improvements of existing products remain as expenses for the financial year.

SECTION 20 - NOTE 1: ACCOUNTING POLICIES AND PRINCIPLES

Development costs carried as assets are amortized on a straight-line basis over seven years or five years for Cellvizio's second generation development costs, i.e. their useful life. Useful life is incorporated into the current period until the asset becomes obsolete.

No development costs were capitalized for the 2016 financial year.

Patents

Patent filing costs incurred by Mauna Kea Technologies until the patents are obtained are recognized as intangible assets in line with the criteria for capitalizing development costs stipulated by IAS 38.

They are amortized on the basis of the straight line method over the term of protection granted.

Software packages

Costs relating to the acquisition of licenses for software packages are recognized as assets on the basis of the costs incurred to acquire and implement them.

They are amortized using the straight-line method over a period of one to three years.

1.5 Property, plant, and equipment

Property, plant, and equipment is recognized at 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.

Cellvizios entrusted to hospitals under partnership agreements (reference centers) and Cellvizios lent out under consignment contract are recorded under capital assets.

Depreciation and amortization periods are as follows:

Fixtures and fittings	7 years;
Research and development	2 to 5 years;
Production tools	3 to 7 years;
Cellvizios entrusted to reference centers and lent out	5 years;
Research equipment and technical facilities	7 years;
Office equipment and furniture	5 years;
Computer equipment	3 years.

1.6 Recoverable amount of 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 intangible assets in progress and tangible assets with useful life over 5 years, even in the absence of indicators of impairment, an impairment test is conducted annually.

An impairment loss is recognized to the extent that the carrying amount exceeds 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 Company's intangible assets, there are no market data that allow the net fair value of the costs of sale to be determined other than by an estimation of future cash flows. Consequently, the recoverable amount is essentially equal to the value in use.

Value in use is determined each year in accordance with IAS 36 and corresponds to the discounted value of estimated future cash flows expected from the continuous use of the assets and their

derecognition at the end of the use expected by the Company. It does not take into account the impact of the financial structure, 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 accounting treatment of financial assets and liabilities are defined by IAS 39 "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 at their fair value and then at amortized cost using the effective interest rate (EIR) method. Short-term receivables without a nominal interest rate are measured at the amount of the original invoice unless the application of an implicit interest rate has a material impact. For variable-rate loans and receivables, a periodic reestimation of cash flow variations, in order to translate changes in market interest rates, modifies the effective interest rate and consequently the valuation of the loan or receivable.

The Company analyzes each of its trade receivables past due to determine whether an impairment loss should be recognized.

Loans and receivables are monitored to pick up 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

Assets considered to be held for sale include assets that the Company intends to resell in the near future in order to realize a capital gain and that are part of a portfolio of financial instruments managed together for which there exists a practice of selling in the short term.

1.8 Inventories & 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.

Inventories of raw materials are valued according to the weighted average cost method.

Inventories of semi-finished and finished products are valued at the standard cost taking into account the cost of materials used, labor costs and a share of overheads.

The demonstration equipment intended for sale in the short term is recognized in inventories.

1.9 Cash and cash equivalents

Cash equivalents are held to meet short-term cash commitments rather than for investment or other purposes. They are readily convertible, into a known amount of cash, and are subject to 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

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 proceeds of 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 financial 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 BSPCEs (special stock warrants with tax benefits) granted to employees and/or executives, stock warrants granted to non-employee members of the Board of Directors or the Supervisory Board, stock options granted to employees of the subsidiary Mauna Kea Technologies Inc., and bonus preference shares awarded to employees and/or executives.

In accordance with IFRS 2, the cost of transactions settled in equity instruments is recorded as an expense with a counterpart increase in equity over the vesting period.

The Company has applied IFRS 2 to all equity instruments granted since 2002 to employees, members of the Board of Directors or the Supervisory Board, natural persons, or entities.

The fair value of stock options granted to employees is determined using the Black-Scholes option valuation model. The same applies to options granted to other natural persons who provide similar services, the market value of the latter not being ascertainable.

The determination of the fair value of options includes the vesting conditions 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

Borrowings and other financial liabilities are valued initially at their fair value and then at amortized cost using the EIR method.

Transaction costs that are directly attributable to the acquisition or issue of a financial liability are deducted from 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 at which expected future cash outflows are equal to the net present carrying amount of the financial liability from which their amortized cost is deducted.

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 Conditional government loans

The Company receives government assistance in the form of subsidies or conditional loans. The details concerning this assistance are provided in Note 11: Borrowings and financial debts.

A conditional non-repayable loan is treated as a public subsidy if there is reasonable assurance that the Company will fulfill the conditions under which the loan need not be repaid. If the contrary is the case, it is classified under debts.

The unpaid interest benefit resulting from an interest-free repayable loan is considered a subsidy. It is calculated by applying a discount rate equal to the contractual rate, if known, or to 10-year OAT yields (French Treasury bonds).

1.15 Provisions

Provisions for risks and expenses

Provisions for risks and liabilities correspond to obligations 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 which is likely or certain to cause an outflow of resources to that third party, without the expectation of at least equal compensation from it, and for which the future outflows of liquid assets can be estimated reliably.

An amount recognized as a provision is the best estimate of the expenditure necessary to settle the obligation, which is discounted 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:

- Retirement benefits paid by the Company to employees upon their retirement (defined benefit plans);
- Payment of pension benefits paid by Social Security agencies and financed by contributions made by employers and employees (defined contribution 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 accordance with amendments to IAS 19 "Defined Benefit Plans: Employee Contributions", service costs and net interest are recorded under operating profit (loss) and other rereasurements are recorded under 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.

1.16 Revenue from ordinary activities

Sales primarily comprise the sale of innovative medical imaging devices for medical diagnostics, research and related services.

Revenue from ordinary activities is measured as the fair value of the consideration received or receivable for the sale of goods in the ordinary course of the Company's business. Revenue from ordinary activities is presented net of value-added tax, product returns, rebates and discounts, and intragroup sales.

Revenue is recorded when the amount can be valued reliably and it is likely that the future economic benefits will go to the Company. Revenue from the sale of products is recognized when they are either made available or delivered to the customer 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 Cellvizio is made available to a customer, it remains an asset of the Company and the revenue is recognized under sales of consumables or services performed by health care professionals.

1.17 Other income

Subsidies

Since it was created, and because of its innovative nature, the Company has received financial assistance or subsidies from the French government or local public authorities intended to fund its operations or recruit specific personnel.

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 to be received as compensation for either costs or losses already incurred, or as immediate financial support without associated future costs, is recorded under "Other income" for the year in which the loan is granted. Otherwise, it is recorded under "Other income" for the year in which the corresponding charges or expenses are recorded.

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 with proven expenditures that meet the 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 and that has concluded a tax treaty with France containing an administrative assistance clause) receive a tax credit that can be offset against the corporate tax due for the financial year in which the expenditures were incurred and the next three financial years, or, as applicable, reimbursed for the excess portion.

The part of the tax credit used to finance research costs is recognized under "Other income" for the year in which the costs are incurred. The part used to finance eligible development costs is deducted from costs recorded under assets.

1.18 Other operating income and expenses

This concerns unusual income or expenses of a significant amount and limited in number and frequency that the Company presents as a separate item on its income statement in order to facilitate understanding of its recurring operational performance and provide useful information for a forward-looking analysis of results.

1.19 Cost of sales

Cost of sales is made up of raw material consumption, labor costs, depreciation and amortization, inventory allowances, and overheads relating to production.

1.20 Leases

The Group does not have any finance leases pursuant to the IAS 17 standard.

Leases under which the lessor retains a significant portion of the risks and benefits are classified as operating leases. Payments made under operating leases, net of any incentives, are recognized as expenses on the income statement on a straight-line basis over the duration of the lease.

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 stipulated by law at the closing date are used to determine deferred taxes.

Deferred tax assets are only recognized to the extent that probable future profits will be sufficient to absorb the losses carried forward. In view of its stage of development, the Company does not recognize net deferred tax assets.

1.22 Segment information

The Company has not at this date identified separate operating segments. It conducts its business in 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 exchange differences relating to the subsidiary Mauna Kea Technologies, Inc.;
- Changes in pension plan provisions arising from changes in actuarial assumptions.

1.24 Decisive accounting estimates and judgments

Estimates and judgments made by management when applying the accounting policies described above are based on historical information and other factors, notably the anticipation of future events judged to be reasonable in light of circumstances. These estimates and judgments are primarily the following:

Valuation of stock warrants and stock options

The fair value of stock warrants and stock options granted to employees or service providers is measured on the basis of actuarial models. These models rest on certain calculation assumptions such as the expected volatility of the security.

Valuation of the Research Tax Credit

Income relating to the research tax credit is measured on the basis of methods detailed in Note 1.17 "Other income - Research Tax Credits".

Valuation of the long-term intangible assets

The value in use of intangible assets is measured on the basis of assumed sales growth and a discount rate that reflect the best estimates of management.

1.25 Subsequent events

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. Adjustments are made until the date on which the financial statements are approved by the Board of Directors.

Events subsequent to the closing date that did not result in adjustments are presented in Note 25 "Subsequent events".

NOTE 2: COMPANY AND SCOPE

Founded in May 2000, Mauna Kea Technologies SA ("the Company") develops and markets medical devices, particularly optical instruments for medical imaging.

As part of its development in the United States, the Company created Mauna Kea Technologies Inc. on January 3, 2005.

Sociétés	12/31/2016		12/31/2015		Consolidation method
	% of interests	% of control	% of interests	% 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

No change in scope took place during the period.

NOTE 3: INTANGIBLE ASSETS

The changes in intangible assets break down as follows:

INTANGIBLE ASSETS					
(Montants en milliers d'euros)					
	12/31/2014	Increase	Decrease	Reclassification	12/31/2015
Development costs	3 623				3 623
Patents, licenses and trademarks	1 340	64		130	1 534
Software packages	413	131			545
Development costs in progress					0
Patents, licenses and trademarks in progress	596	60		(130)	526
Total gross of intangible assets	5 972	255			6 228
Amort. / dép. of development costs	(1 741)	(481)			(2 222)
Amort. / dép. of patents, licenses and trademarks	(454)	(105)			(559)
Amort. / dép. of software packages	(236)	(76)			(313)
Total amort. / dép. of intangible assets	(2 431)	(662)			(3 093)
Total net of intangible assets	3 542	(407)			3 135

INTANGIBLE ASSETS					
(Amounts in thousands of euros)					
	12/31/2015	Increase	Decrease	Reclassification	12/31/2016
Development costs	3 623				3 623
Patents, licenses and trademarks	1 534	6		18	1 559
Software packages	545	15		6	566
Patents, licenses and trademarks in progress	526	67		(18)	575
Total gross of intangible assets	6 228	89		6	6 324
Amort. / dép. of development costs	(2 222)	(466)			(2 688)
Amort. / dép. of patents, licenses and trademarks	(559)	(112)			(671)
Amort. / dép. of software packages	(313)	(87)			(400)
Total amort. / dép. of intangible assets	(3 093)	(665)			(3 759)
Total net of intangible assets	3 135	(576)		6	2 565

ANNUAL CHANGE IN DEVELOPMENT COSTS (CAPITALISED PORTION)

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
External costs	0	0
Wages and salaries, social security costs	0	0
Research Tax Credit	0	0
Share-based payment transaction expense	0	0
Gross change in development costs	0	0
Amortization of development costs	(466)	(481)
Net change in development costs	(466)	(481)

Patents pending are subject to an annual impairment test to determine their value in use calculated using the discounted cash flow method as follows:

- Cash flow projections are determined for the years 2017 to 2021 on the basis of future sales forecasts, which correspond to the best estimates, made by management. For the tests conducted on patents pending, a final value calculated by taking into account a normalized flow discounted by an infinite growth rate of 2% is integrated to the extent that the residual period of protection is greater than five years;
- The discount rate used is the weighted average cost of the share capital of the Group of 15%. 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.

The effect of a change in the discount rate, the growth rate of sale and the infinite growth rate of +/- 10% have also no impact on the impairment of the assets tested.

SECTION 20 - NOTE 4: PROPERTY, PLANT, AND EQUIPMENT

NOTE 4: PROPERTY, PLANT, AND EQUIPMENT

The changes in property, plant and equipment break down as follows:

PROPERTY, PLANT AND EQUIPMENT						
(Amounts in thousands of euros)						
	12/31/2014	Increase	Decrease / Scrapping	Exchange differences	Reclassments	12/31/2015
Industrial equipment	1 293	33	0	25	(27)	1 324
Fixture in buildings	51					51
Other tangible assets	914	75	(3)	11		998
Total gross of property, plant and equipment	2 259	107	(3)	36	(27)	2 373
Amort. / dép. of industrial equipment	(864)	(152)	6	(8)	1	(1 017)
Amort. / dép. of fixture in buildings	(31)	(7)				(37)
Dep other tang assets	(570)	(117)	2	(9)		(693)
Total amort. / dép. of property, plant and equipment	(1 465)	(275)	8	(17)	1	(1 748)
Total net of property, plant and equipment	794	(167)	5	19	(26)	625

PROPERTY, PLANT AND EQUIPMENT						
(Amounts in thousands of euros)						
	12/31/2015	Increase	Decrease / Scrapping	Exchange differences	Reclass.	12/31/2016
Industrial equipment	1 324	47	(70)	7	127	1 436
Fixture in buildings	51					51
Other tangible assets	998	380	(4)	4	(29)	1 348
Total gross of property, plant and equipment	2 373	427	(74)	11	98	2 835
Amort. / dép. of industrial equipment	(1 017)	(132)	47	(6)		(1 107)
Amort. / dép. of fixture in buildings	(37)	(7)				(44)
Dep other tang assets	(693)	(92)	4	(4)		(785)
Total amort. / dép. of property, plant and equipment	(1 748)	(230)	51	(9)		(1 937)
Total net of property, plant and equipment	625	197	(23)	2	98	898

Reclassifications in the year concerned transfers of systems in stock to inventory for €127 thousand.

In the absence of impairment indicators, no impairment tests were conducted on property, plant, and equipment.

NOTE 5: NON-CURRENT FINANCIAL ASSETS

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

NOTE 6: INVENTORIES AND WORK IN PROGRESS

Inventories and work in progress break down as follows:

INVENTORIES & WORK IN PROGRESS

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Inventories of raw materials	769	819
Inventories & work in progress of finished goods	1 668	1 925
Total gross of inventories & work in progress	2 437	2 744
Dep. of inventories of raw materials	(58)	(51)
Dep. of inventories & work in progress of finished goods	(48)	(49)
Total dep. of inventories & work in progress	(107)	(99)
Total net of inventories & work in progress	2 331	2 644

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 assets are kept by the Company for use by the after-sales customer service. They are impaired by 80%.

NOTE 7: TRADE RECEIVABLES AND OTHER CURRENT ASSETS

7.1. Trade and other receivables

TRADE RECEIVABLES

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Trade receivables	3 127	3 885
Dep. of trade receivables	(1 011)	(427)
Total net of trade receivables	2 116	3 458

Trade receivables past due and not impaired at December 31, 2016 amounted to €961 thousand compared with €1,921 thousand at December 31, 2015. The €960 thousand decrease was largely due to an additional provision of €584 thousand and the payment in early 2016 of trade receivables due in 2015.

The provision for doubtful accounts represented 32% of total receivables. The increase in this provision was mainly due to the impairment of certain receivables due for more than one year.

7.2 Other current assets

The other current assets break down as follows:

OTHER CURRENT ASSETS

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Personnel and related accounts	10	39
Research Tax Credit	2 030	1 201
Other tax receivables	268	184
Other receivables	240	289
Prepaid expenses	209	109
Total gross of other current assets	2 756	1 823
Dep. of other current assets		
Total net of other current assets	2 756	1 823

Other tax receivables related to deductible VAT and reimbursement of VAT requested for a total of €251 thousand compared to €136 thousand at December 31, 2015.

Other receivables mainly included advances to suppliers amounting to €140 thousand compared to €128 thousand at December 31, 2015.

Prepaid expenses in 2016 mostly corresponded to insurance, survey costs and communication expenses.

Changes in the Research Tax Credit were as follows:

CHANGES IN THE RESEARCH TAX CREDIT RECEIVABLE

(Amounts in thousands of euros)

	31/12/2014	Operating revenue	Payment received	Capitalised portion	12/31/2015
Research Tax Credit	1 251	1 201	(1 251)		1 201

CHANGES IN THE RESEARCH TAX CREDIT RECEIVABLE

(Amounts in thousands of euros)

	12/31/2015	Operating revenue	Payment received	Capitalised portion	12/31/2016
Research Tax Credit	1 201	828			2 029

The Company had requested the reimbursement of the research tax credit for 2015 under the regime for EU SMEs in accordance with the legislation in force. This reimbursement was made in January 2017 in full.

The company also claimed the research tax credit for financial year 2016.

NOTE 8: CURRENT FINANCIAL ASSETS

Current financial assets correspond to the cash balance of the securities account opened under the Company's liquidity contract domiciled with Gilbert Dupont, i.e. €94 thousand at December 31, 2016 versus €65 thousand at December 31, 2015.

NOTE 9: CASH AND CASH EQUIVALENTS

Cash and cash equivalents are broken down as follows:

CASH AND CASH EQUIVALENTS

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Short-term bank deposits	9 053	9 983
Money market funds	0	637
Total of cash and cash equivalents	9 053	10 620

NOTE 10: SHARE CAPITAL

10.1 Issued capital

The share capital is set at eight hundred thousand and seventy-three euros, fifty-two cents (€800,073.52). It is divided into 20,001,838 ordinary shares, fully subscribed and paid up, each with a par value of €0.04.

This figure does not include stock warrants, BSPCEs or 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, 2016:

Date	Type of transaction	Issued capital (en K€)	Share premium (en K€)	Nombre d'actions créées	Number of shares comprising the issued capital (in thousand)
12/31/15	Total	647	66 050		16 177
02/02/16	New SO plan	0			0
07/15/16	Capital increase	119	3 907		2 980
07/26/16	Withdrawal for BP reserves	0			0
07/26/16	New BSA	0	18		0
07/26/16	New SO	0			0
11/18/16	PACEO	0	-50		0
11/21/16	BSA	10	766		250
11/29/16	BSA	2	147		50
12/01/16	BSA	3	215		75
12/02/16	BSA	5	353		120
12/06/16	BSA	4	282		100
12/08/16	BSA	4	282		100
12/16/16	BSA	2	137		50
12/21/16	BSA	2	133		50
12/22/16	BSA	2	141		50
12/31/16	Total	800	72 382		20 002

In 2016, the Company completed a capital increase of €4.4 million at an issue price of 1.49 euros per share for 2,980,131 new shares.

The Company opened also, in November 2016, an equity financing facility with Kepler Cheuvreux for a maximum number of 1,850,000 shares open for subscription over a maximum period of 24 months. At December 31, 2016, 845,000 shares were subscribed via the financing line with Kepler.

10.2 Share purchase warrants, stock options and preferred stock

The Company issued various types of stock warrants, including BSPCEs, for its employees, as well as stock options. The Company has issued a new free share plan, the terms of which have been approved by the shareholders at the General Meeting of May 4, 2016.

The changes since December 31, 2016 are represented below:

Type	Date of granting	Exercise price	Outstanding as of 31.12.2015	Granted	Exercised	Cancelled	Outstanding as of 31.12.2016	Potential number of shares
Options granted before January 1, 2016			3 513 156			1 291 750	2 221 406	925 289
SO	02/02/16			96 000		15 000	81 000	81 000
SO	07/26/16			80 000		0	80 000	80 000
BSA	07/26/16			115 000		0	115 000	115 000
PS	07/26/16			7 765		205	7 560	756 000
PS	11/15/16			570		0	570	57 000
BSA	11/18/16			1 850 000	845 000	0	1 005 000	1 005 000
			3 513 156	2 149 335	845 000	1 306 955	3 510 536	3 019 289

Following the consolidation of shares (4 old shares for 1 new one) on May 25, 2011, four stock warrants, BSPCEs or stock options granted before that date are needed to subscribe for one new share. For warrants and options granted after that date, the ratio is one to one.

Starting from July 2014, the Company could no longer issue any new BSPCE plans, because it had exceeded the threshold of €150 million in market capitalization more than three years ago.

The BSAs granted on 18 November 2016 relate to the equity financing line set up with Kepler. At December 31, 2016, 845,000 warrants were exercised.

10.3 Share buybacks

The Combined General Meeting of May 27, 2015 authorized the Board of Directors, for a period of thirty-eight months from the date of the meeting, to implement a share buyback program, on one or more occasions, in accordance with Article L.225-209 *et seq.* of the French Commercial Code and the General Regulation of the 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 concluded with an investment services provider in accordance with a Code of Conduct approved by the AMF;
- To meet obligations related to stock option plans, bonus share awards, employee savings plans, or other share awards to employees and executives of the Company or its related entities;
- 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 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 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 shares purchased and sold over the year:

	2016				
	1st quarter	2nd quarter	3rd quarter	4th quarter	Total
Securities purchased	142 752	188 258	261 821	379 671	972 502
Price	3,22	2,10	2,52	3,23	
Total amount	459	395	659	1 227	2 739
Securities sold	143 227	193 864	264 678	383 415	985 184
Price	3,12	2,10	2,47	3,24	
Total amount	447	407	655	1 243	2 752

At December 31, 2016, the Company held 23,681 Mauna Kea Technologies shares purchased at an average price of €2.99 and valued at €3.02. No impairment was recorded in the financial statements.

NOTE 11: BORROWINGS AND DEBT

11.1 Loans from BPI (formerly OSEO)

Conditional loans from public authorities were made subject to a contract with OSEO Innovation.

At December 31, 2016, the Company had entered into three loan contracts of this type from which two have been totally reimbursed as of December, 31 2016. Third (Persee project) is still pending at year-end. 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 portion of loans repayable in more than one year is posted as "Long-term loans and borrowings" while the portion repayable in less than one year is posted as "short-term loans and borrowings".

First advance

On August 5, 2004, OSEO gave Mauna Kea Technologies an interest-free loan of €400 thousand to develop an industrial prototype of a multi-wavelength fiber confocal microscopy system for *in vivo* molecular imaging. This first advance was totally repaid as from December 31, 2013.

Second advance

On October 10, 2006, Mauna Kea Technologies obtained an interest-free innovation loan in the amount of €620 thousand from OSEO to develop a multimodal endoscopic device for medical diagnostics. Payments by OSEO were made 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 the innovation loan began once the project achieved technical and commercial success, as follows:

- September 30, 2012 €150 thousand;
- September 20, 2013 €170 thousand;
- No later than September 30, 2015 €300 thousand;

As of December 31, 2015, this advance had been fully repaid.

Third advance

On May 31, 2010, Mauna Kea Technologies obtained an innovation loan in the amount of €3,416 thousand from OSEO as part of the PERSEE project. The PERSEE project aims to develop, validate and then market a device capable of improving diagnostic and preoperative assessment techniques for cancer patients. The first payments of the loan were 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;
- Fourth payment of €626 thousand on December 22, 2016.

The loan maturity was renegotiated in late 2016: the end of Key Stage 4 was put back to 2018. The agreement with OSEO stipulates one final payment of €512 thousand which should be made in 2018 once Key Stage 4 is reached.

This offsetting reimbursement resulted in a discounting effect (profit) on advances received in key stages 1 to 3 (see table of change below)

Based on the initial contract, the Company must repay 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.

Article 2.13 of the Framework agreement governing the PERSEE project (OSEO / BPI), provides for two types of advance repayments:

1 / Immediate reimbursement in case of judicial liquidation / cessation of activity / dissolution / liquidation amicable.

2 / A reimbursement by right and at the sole initiative of Oseo in case of:

- Failure by the Company to comply with any of its obligations (*) [..],
- Non-regular situation regarding its tax and social obligations,
- Any inaccurate or untrue declarations.

11.2 COFACE loans

The Company received interest-free repayable loans from COFACE for its development activities in the USA and Canada, as follows:

- 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.

Repayments are determined and made on the basis of sales projections in the USA and Canada from the use of products and services generated by the project up to the following limits:

- 14% of sales related to services provided;
- 7% of sales related to goods sold.

In the event that sales are inadequate for the expected repayments, no additional repayments are made to COFACE.

From 2011 to 2016, the Company made repayments to COFACE amounting in all to €986 thousand. In January 2016, on the basis of the most recent sales forecasts, the Company repaid €311 thousand of the €719 thousand outstanding from the loan granted for canvassing in the United States. The balance should be repaid no later than year-end 2017.

**CHANGES IN REPAYABLE
ADVANCES**

(Amounts in thousands of euros)

	<u>12/31/2014</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Others</u>	<u>12/31/2015</u>
OSEO Funding (1st advance)					
OSEO Funding (2nd advance)	300		(300)		
OSEO Funding (3rd advance)	2 224			(47)	2 177
COFACE	715			4	719
Total des avances remboursables	3 239		(300)	(43)	2 896

	<u>12/31/2015</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Others</u>	<u>12/31/2016</u>
OSEO Funding (1st advance)					
OSEO Funding (2nd advance)					
OSEO Funding (3rd advance)	2 177	626		(169)	2 635
COFACE	719		(311)	(5)	403
Total des avances remboursables	2 896	626	(311)	(174)	3 038

11.3 Long-term loans and borrowings

Long-term loans and borrowings break down as follows:

**LONG-TERM LOANS
AND BORROWINGS**

(Amounts in thousands of
euros)

	<u>12/31/2014</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Reclassification</u>	<u>Others</u>	<u>12/31/2015</u>
Shareholders' accounts	5					5
Repayable advances OSEO Funding	2 224				(47)	2 177
Repayable advances COFACE	377			(377)		
Total of long-term loans and borrowings	2 606			(377)	(47)	2 182

	<u>12/31/2015</u>	<u>Receipt</u>	<u>Repayment</u>	<u>Reclassification</u>	<u>Others</u>	<u>12/31/2016</u>
Shareholders' accounts	5					5
Repayable advances OSEO Funding	2 177	626			(169)	2 635
Repayable advances COFACE						
Total of long-term loans and borrowings	2 182	626			(169)	2 640

Changes listed under "Others" involve the discounting of long-term conditional loans.

11.4 Cash flow hedges

In order to cover the exchange rate risk exposure of part of its foreign currency operating flows, the Group had set up a yen hedging policy in 2013. The group has no longer held any derivative financial instrument as from December 31, 2014.

11.5 Repayment terms of financial liabilities

The repayment terms of financial liabilities as of December 31, 2016 break down as follows:

REPAYMENT TERMS OF FINANCIAL LIABILITIES

(Amounts in thousands of euros)

	Gross amount	Less than one year	One to three years	Three to five years
Long-term loans and borrowings	2 640			2 640
Short-term loans and borrowings	404	404		
Trade payables	3 131	3 131		
Other current liabilities	2 382	2 382		
Total of financial liabilities	8 557	5 917		2 640

The repayment terms of long-term and short-term loans and borrowings relating to repayable loans are determined on the basis of planned repayment estimates at December 31, 2016.

NOTE 12: NON-CURRENT PROVISIONS

Non-current provisions break down as follows:

NON-CURRENT PROVISIONS

(Amounts in thousands of euros)

	12/31/2014	Allowance	Unused reversals	Used reversals	Others	12/31/2015
Pension plan provision	287	3	(34)		(117)	140
Provisions for personnel disputes	91					91
Provision for software update	15					15
Others provisions for expenses	125		(48)	(85)	8	
Total of non-current provisions	518	3	(82)	(85)	(109)	246

NON-CURRENT PROVISIONS

(Amounts in thousands of euros)

	12/31/2015	Allowance	Unused reversals	Used reversals	Others	12/31/2016
Pension plan provision	140	61	(27)		(18)	155
Provisions for personnel disputes	91					91
Provision for software update	15					15
Others provisions for expenses						
Total of non-current provisions	246	61	(27)		(18)	261

Changes listed under "Others" related to actuarial differences in the valuation of pension obligations of €(18) thousand in 2016 versus €(117) thousand in 2015.

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

	<u>12/31/2016</u>	<u>12/31/2015</u>
% social security expenses	48%	48%
Salary increases	2%	2%
Discount rate	1,71%	2,43%

- Retirement age: 65;
- Terms of retirement: voluntary retirement;
- Mortality table: INSEE 2015 in 2016 and INSEE 2015 in 2015;
- Collective agreement: metal industries;
- Digressive employee turnover based on age;
- Turnover: high.

The Company does not finance its pension plan provision. No retirements took place over the last two financial 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 Provision for labor disputes

As of December 31, 2016, no new labor dispute was reported. The provision in the balance sheet for €91 thousand concerns disputes which arose in 2014. There was no change in the assessment of these provisions during the course of the 2016 financial year.

12.3 Other provisions for risks and liabilities

Provisions for updating software packages were recognized to cover the costs of updating Cellvizio products from version 1.0 to version 1.5.

The provision for electronic equipment waste is no longer relevant and was reversed in full. The Company subcontracts directly with a service provider for the recycling of electronic equipment waste.

NOTE 13: TRADE PAYABLES 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 financial year in question.

13.1 Trade payables

Trade payables break down as follows:

TRADE PAYABLES
(Amounts in thousands of euros)

	<u>12/31/2016</u>	<u>12/31/2015</u>
Trade payables	<u>3 131</u>	<u>2 453</u>

13.2 Other current liabilities

Other current liabilities break down as follows:

OTHER CURRENT LIABILITIES
(Amounts in thousands of euros)

	<u>12/31/2016</u>	<u>12/31/2015</u>
Taxes payable	93	80
Staff and social security payable	1 559	2 122
Other payable	47	45
Deferred revenue	683	564
Total of other current liabilities	<u>2 382</u>	<u>2 812</u>

The tax liabilities mainly concern payroll taxes, sales tax and value added tax.

Payroll-related liabilities represent provisions for paid leave, provisions for bonuses and commissions and social security contributions.

A decrease of €563 thousand, due to employee departures in France and the United States, which were not replaced due to the Company's new distribution strategy.

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 - NOTE 14: FINANCIAL INSTRUMENTS ON BALANCE SHEET

NOTE 14: FINANCIAL INSTRUMENTS ON BALANCE SHEET

FINANCIAL INSTRUMENTS ON BALANCE SHEET AND THEIR IMPACT ON THE PROFIT (OR LOSS)

(Amounts in thousands of euros)

As of 31 December 2015	Value on the balance sheet	Fair value through profit or loss	Fair value through equity	Loans and receivables	Debt at amortised cost
Assets					
Non-current financial assets	133			133	
Trade receivables	3 458			3 458	
Other current assets (2)	1 585			1 585	
Current financial assets (1)	65			65	
Cash equivalents	637	637			
Cash	9 983	9 983			
Total of assets	15 861	10 620		5 241	
Liabilities					
Long-term loans and borrowings	2 182				2 182
Short-term loans and borrowings	719				719
Trade payables	2 453				2 453
Other current liabilities (2)	2 253				2 253
Total of liabilities	7 608				7 608

FINANCIAL INSTRUMENTS ON BALANCE SHEET AND THEIR IMPACT ON THE PROFIT (OR LOSS)

(Amounts in thousands of euros)

As of 31 December 2016	Value on the balance sheet	Fair value through profit or loss	Fair value through equity	Loans and receivables	Debt at amortised cost
Assets					
Non-current financial assets	162			162	
Trade receivables	2 116			2 116	
Other current assets (2)	2 407			2 407	
Current financial assets (1)	94			94	
Cash equivalents	0	0			
Cash	9 053	9 053			
Total of assets	13 832	9 053		4 779	
Liabilities					
Long-term loans and borrowings	2 640				2 640
Short-term loans and borrowings	404				404
Trade payables	3 131				3 131
Other current liabilities (2)	1 699				1 699
Total of liabilities	7 874				7 874

(1) The assessment of the fair value of these financial assets 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, and deferred income and prepaid expenses that are not defined as financial liabilities, are not included.

NOTE 15: SALES AND OPERATING REVENUE

Sales and operating revenue consist of the following:

SALES AND OPERATING REVENUE

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Sales	8 787	8 547
Subsidies		145
Research Tax Credit and other tax credits	864	1 265
Autres produits	19	24
Total of revenue	9 670	9 981

The Group's sales comprise sales of Cellvizio® products and accessories (e.g. probes, software) together with services.

The competitiveness and employment tax credit is accounted under Research tax credit and other tax credits.

SALES BY TYPE

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Total sales of "equipements"	4 217	5 190
Total sales of "consumables" (probes)	2 941	2 473
Total sales of "services"	1 629	884
Total sales by type	8 787	8 547

Sales by region as of December 31, 2016 can be broken down as follows:

SALES BY GEOGRAPHICAL AREA

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
EMEA (Europe, Middle-east, Africa)	2 124	2 453
<i>including France</i>	<i>464</i>	<i>974</i>
America	3 811	3 603
<i>including USA</i>	<i>3 621</i>	<i>3 230</i>
Asia	2 852	2 491
<i>including China</i>	<i>962</i>	<i>189</i>
<i>including Japan</i>	<i>1 014</i>	<i>1 182</i>
Total sales by geographical area	8 787	8 547

For the purposes of geographical analysis, the management of the Group allocates the sales revenue according to the place of delivery, or, in the case of services, according to the location of the customer's registered office.

At December 31, 2016 one distributor (APAC area) accounted for more than 10.38% of sales.

NOTE 16: STAFF COSTS

.The Group employed 76 persons as of December 31, 2016 compared with 91 persons as of December 31, 2015.

Employee benefits expense breaks down as follows:

EMPLOYEE BENEFITS EXPENSE

(Amounts in thousands of euros)

	<u>12/31/2016</u>	<u>12/31/2015</u>
Wages and salaries, social security costs	8 744	11 515
Net pension costs	34	(30)
Share-based payment transaction expenses	285	450
Total of employee benefits expense	<u>9 063</u>	<u>11 935</u>

NOTE 17: SHARE-BASED PAYMENTS

Share-based payments concern all stock warrants, stock options and preference shares awarded to employees or service providers.

They are recorded under expenses from the year in which they are awarded, the exercise conditions of BSPCEs and stock options being as follows:

- 25% of the BSPCEs/stock options may be exercised starting on the first anniversary of their allocation;
- 25% of the BSPCEs/stock options may be exercised starting on the second anniversary of their allocation;
- 25% of the BSPCEs/stock options may be exercised starting on the third anniversary of their allocation;
- the remaining balance, i.e., 25% of the BSPCEs/stock options, may be exercised starting on the fourth anniversary of their award;
- within ten years of their issue, or seven years for stock options granted before 2011, it being specified that BSPCEs/stock options not yet exercised by the end of this 10-year period automatically become null and void.

The terms and conditions governing the exercise of stock warrants awarded in 2011 and 2014 are as follows:

- 33.3% of the warrants may be exercised starting on the first anniversary of their award;
- 33.3% of the warrants may be exercised starting on the second anniversary of their award;
- the remaining balance, i.e., 33.3% of the warrants, may be exercised starting on the third anniversary of their award;
- warrants not yet exercised, within 10 years of their issue, automatically become null and void.

The terms for exercising preference shares are set out in the minutes of the Combined General Meeting of May 4, 2016 in Resolutions 19 and 20 which can be accessed via the following link: http://www.maunakeatech.com/sites/default/files/investors/documentation/eui_1200483797_1_mkt_-_pv_agm_4_mai_2016.pdf.

The main characteristics and terms are as follows:

The Preferred shares permanently vested in their beneficiaries on the Acquisition Date will be convertible into ordinary new or existing shares at the choice of the Company (the "Ordinary Shares") at any time as from the third anniversary of the Acquisition Date (the "Retention Period") according to the following terms:

- a. In the event of Departure between the Acquisition Date (inclusive) and the first anniversary of the Acquisition Date (exclusive), each Preferred share will be convertible into twenty Ordinary Shares

- b. In the event of Departure between the first anniversary of the Acquisition Date (inclusive) and the second anniversary of the Acquisition Date (exclusive), each Preferred share will be convertible into thirty-three Ordinary Shares
- c. In the event of Departure between the second anniversary (inclusive) and the third anniversary (exclusive) of the Acquisition Date, the conversion ratio will be calculated as follows:
- (i) if the Reference Price 1 is strictly lower than the Floor Price, each Preferred share will be convertible into thirty-three Ordinary Shares;
 - (ii) if the Reference Price 1 is strictly higher than the Intermediate Price, each Preferred share will be convertible into sixty-six Ordinary Shares;
 - (iii) if the Reference Price 1 is between the Floor Price (inclusive) the Intermediate Price (inclusive), the number of Ordinary shares to which each Preferred share gives the right will be equal to;

$$33 + 33 \times [(Reference\ Price\ 1 / Floor\ Price) - 1]$$

Where:

- the term "Acquisition Price" means the average closing price recorded on Euronext or any other place of primary listing of Mauna Kea Technologies shares during the last 60 trading days preceding the Acquisition Date;
 - the term "Floor Price" means the Acquisition Price increased by 2 euros;
 - the term "Intermediate Price" means double the Floor Price; and
 - the term "Reference Price 1" means the average closing price recorded on Euronext or any other place of primary listing of Mauna Kea Technologies shares during the last 120 trading days preceding the second anniversary of the Acquisition Date;
- d. In the event of Departure following the expiry of the Retention Period, the number of Ordinary Shares to which each Preferred share gives right will be equal to the sum:
- (x) of the number of Ordinary Shares calculated in accordance with the provisions of paragraph 3.c) above as if the Departure of the beneficiary had occurred between the second and the third anniversary of the Acquisition Date, and;
 - (y) of the following number of Ordinary Shares:
 - (i) if the Reference Price 2 is strictly lower than the Floor Price: none;
 - (ii) if the Reference Price 2 is strictly higher than the Ceiling Price: the difference between one hundred Ordinary Shares and the number of Ordinary Shares calculated in (x) (so that the sum of (x) and (y) is equal to 100);
 - (iii) if the Reference Price 2 is between the Floor Price (inclusive) and the Ceiling Price (inclusive): the difference, if this is positive, between:
 - $33 + 67 \times [(Reference\ Price\ 2 / Floor\ Price) - 1] / 2$;
 - the number of Ordinary Shares calculated in (x).

Where:

- the term "Floor Price" has the meaning given to it in 3.c). above;

SECTION 20 - NOTE 17: SHARE-BASED PAYMENTS

- the term “Ceiling Price” means three times the Floor Price; and
- the term “Reference Price 2” means the average closing price recorded on Euronext or any other place of primary listing of Mauna Kea Technologies shares during the last 120 trading days preceding the third anniversary of the Acquisition Date.

Is stipulated that this ratio will be adjusted to take account of shares to be issued to conserve the rights of holders of securities giving access to the Company’s capital and beneficiaries of Preferred shares, in accordance with applicable legal and regulatory provisions.

The Preferred shares may only be converted during a period of five years and six months from the date of the end of the Retention Period the “Conversion Period”).

They break down as follows:

SHARE-BASED PAYMENTS

Type	Date of granting	Exercise price	Maturity	Number of shares	Cancelled	Exercised	Oustanding bond at 12/31/2016	Vestable bond at 12/31/2016	Exercisable bond at 31/12/2016
BSPCE 5	03/10/06	0,916	03/10/16	310 950	132 500	178 450	0	0	0
BSPCE 5	08/10/06	0,916	08/10/16	100 000	55 000	45 000	0	0	0
BSPCE 5	09/13/06	0,916	09/13/16	20 000	20 000	0	0	0	0
BSPCE 5	10/09/06	0,916	10/09/16	25 000	25 000	0	0	0	0
SO 2008	06/02/08	1	06/02/18	670 000	270 000	188 592	211 408	52 852	52 852
BCE-A	08/04/08	1	08/04/18	500 000	0	4	499 996	124 999	124 999
BSPCE 6	08/04/08	1	08/04/18	1 225 000	590 008	382 492	252 500	63 125	63 125
BSPCE 6	12/08/08	1	12/08/18	35 000	10 000	0	25 000	6 250	6 250
BSPCE 6	11/24/09	1	11/24/19	637 500	323 756	192 492	121 252	30 313	30 313
SO 2008	03/01/10	1	03/01/17	250 000	100 000	10 000	140 000	35 000	35 000
SO 2010	01/31/11	1	01/31/21	245 000	173 750	56 250	15 000	15 000	15 000
BSPCE 2010	02/15/11	1	02/15/21	915 000	268 748	278 252	368 000	92 000	92 000
SO 2010	02/15/11	1	02/15/21	50 000	50 000	0	0	0	0
BSPCE 2010	03/01/11	1	03/01/21	200 000	0	150 000	50 000	12 500	12 500
BSA	07/05/11	13	07/05/21	80 000	80 000	0	0	0	0
BSPCE 2011	12/05/11	13	12/05/21	129 500	117 000	0	12 500	12 500	12 500
SO 2011	12/05/11	11,44	12/05/21	288 153	288 153	0	0	0	0
BSPCE 2012	12/04/12	10,79	12/04/22	239 500	154 625	625	84 250	84 250	84 250
SO 2012	12/04/12	10,79	12/04/22	161 000	143 000	0	18 000	18 000	18 000
BSPCE 2013	05/07/13	10,28	05/07/23	63 000	27 000	0	36 000	36 000	27 000
SO 2013	12/09/13	10,05	12/09/23	101 000	101 000	0	0	0	0
SO 2014	02/12/14	10,56	02/12/24	10 000	8 000	0	2 000	2 000	1 000
BSPCE 2014	02/12/14	10,56	02/12/24	181 000	88 000	0	93 000	93 000	46 500
BSPCE 2014	02/12/14	10,56	02/12/24	100 000	0	0	100 000	100 000	50 000
BSA 2014	09/01/14	6,12	09/01/24	100 000	0	0	100 000	100 000	66 667
SO 2015	09/08/15	2,94	09/08/25	57 500	10 000	0	47 500	47 500	11 875
SO 02.2016	02/02/16	2,54	02/02/26	96 000	15 000	0	81 000	81 000	0
SO 07.2016	07/26/16	1,6	07/26/26	80 000	0	0	80 000	80 000	0
BSA 07.2016	07/26/16	1,68	07/26/26	115 000	0	0	115 000	115 000	0
PS 07.2016	07/26/16	*	NA	7 765	205	0	7 560	756 000	0
PS 11.2016	11/15/16	*	NA	570	0	0	570	57 000	0
				6 993 438	3 050 745	1 482 157	2 460 536	2 014 289	749 831

The other main assumptions used to determine share-based payment expenses using the Black-Scholes options valuation model were as follows:

- Risk-free interest rate: rate of government borrowing (GFRN index);
- Dividend: none;
- Turnover: 15%;
- Volatility: 60% for BSAs, BSPCEs and stock options granted before December 31, 2011, 35% for BSPCEs and stock options granted in 2012, 34% for BSPCEs and stock options granted in 2013, 32% and 33% for plans granted in 2014, 33% for plans granted in 2015 and 29.99% for plans granted in 2016.

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 has a market capitalization and traded share volume comparable with those of the Company. Listed companies whose shares were traded for less than €1 were excluded from the panel.

The exercise price, estimated lifespan and fair value of underlying shares at the award date of the warrants were used to value each category of share-based compensation.

Share-based payment expenses during the period break down as follows:

**DETAILS OF THE RESTATEMENT OF
SHARE-BASED PAYMENTS**

(Amounts in thousands of euros)

	Au 31 décembre	
	2016	2015
Share-based payments (share activated)	0	0
Share-based payments (expense)	285	450
	285	450

Note 18: External expenses

18.1 Research & Development department

RESEARCH & DEVELOPMENT

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Purchases consumed	169	26
Employee benefits expenses	2 415	2 692
External expenses	1 142	1 294
Impôts et taxes	44	
Net change in amortisation and depreciation	675	636
Total of Research & Development	4 445	4 648

18.2 Sales & Marketing department

SALES & MARKETING

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Purchases consumed	84	91
Employee benefits expenses	4 642	6 496
External expenses	2 948	4 702
Net change in amortization and depreciation	692	375
Total of Sales & Marketing	8 366	11 665

This decrease reflects the Company's partnership strategy as well as workforce adjustments associated with a targeted reduction in direct sales and marketing costs.

18.3 Administrative Expenses

ADMINISTRATIVE EXPENSES

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Purchases consumed	45	58
Employee benefits expenses	1 208	1 826
External expenses	2 353	1 522
Taxes	84	75
Net change in amortisation and depreciation	154	161
Total of Administrative expenses	3 843	3 642

NOTE 19: FINANCIAL INCOME AND EXPENSES

Financial income and expenses break down as follows:

FINANCIAL REVENUE AND EXPENSES

(Amounts in thousands of euros)

	12/31/2016	12/31/2015
Foreign exchange gains	227	327
Gains on cash equivalents	11	13
Other financial incomes	174	43
Total of financial revenue	412	383
Foreign exchange losses	(166)	(288)
Losses on cash equivalents	0	(11)
Discounting expenses	0	(0)
Total of financial expenses	(166)	(299)
Total of financial revenue and expenses	246	83

NOTE 20: INCOME TAX

Under current tax laws, the Group has total tax losses of €67,930 thousand that may be carried forward indefinitely in France and total tax losses of €36,482 thousand that may be carried forward for 20 years in the United States, that is, a total of €104,412 thousand at December 31, 2016. Out of caution the deferred tax asset base net of temporary passive differences was not capitalized in accordance with the principles set out 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)

	12/31/2016	12/31/2015
Profit / (loss)	(9 744)	(12 643)
Income tax expense		
Profit before tax	(9 744)	(12 643)
Theoretical tax expense - 34,43%	(3 355)	(4 353)
Other non-deductible expenses and tax-exempt income	34	62
Effect of tax rate differences	(13)	(26)
Deferred tax assets not recognised	3 334	4 317
Actual income tax expense		

NOTE 21: COMMITMENTS

Obligations pursuant to ordinary rental agreements

The Group uses the following premises:

Registered office in Paris: located at 9, rue d'Enghien (75010) on 6 floors of the building, the surface area of which is approximately 1,133 sq. meters (including the basement). The Company has six separate leases contracted with SCI Enghien 9, which is the owner thereof.

Premises in the United States: commercial lease between Capkey Gates at Sugarloaf Partners LLC and Mauna Kea Technologies Inc. signed on January 15, 2013 and renewed until February 28, 2017 for the rental of the offices located at 1325 Satellite Boulevard, Unit 108, Suwanee, GA, 30024, United States, terminated at end-2016.

A new lease was signed on 12/16/2016 with Geros LLC for the rental of offices at 29 DENBY RD, ALLSTON, MA 02134. This lease takes effect on January 1, 2017 for a term of three years.

In addition, the Company has entered into leases on vehicles and office equipment.

Firm and unconditional commitments under operating leases break down as follows at December 31, 2016:

**OBLIGATIONS PURSUANT TO
ORDINARY RENTAL AGREEMENTS**
(Amounts in thousands of euros)

	<u>12/31/2016</u>	<u>12/31/2015</u>
Portion with terms of less than 1 year	352	257
Portion with terms of between 1 and 5 years	976	862
Portion with terms of more than 5 years	341	208
Total of commitments pursuant to ordinary rental agreements	<u>1 669</u>	<u>1 328</u>

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)

	<u>12/31/2016</u>	<u>12/31/2015</u>
Portion with terms of less than 1 year	1 760	1 832
Portion with terms of between 1 and 5 years	1 248	1 977
Total of supplier commitments	<u>3 008</u>	<u>3 809</u>

The Company undertook to make donations to the Fondation San T Dige for a total amount of €20 thousand in yearly payments of €5 thousand from 2014 to 2017. At December 31, 2016, a provision of €5 thousand was recorded. This foundation has as its mission the development of research in the area of hepato-gastroenterology.

There were no material changes to the Company's other commitments over the year.

NOTE 22: TRANSACTIONS WITH RELATED PARTIES

The compensation presented below, which was granted to members of the Company's general management and other related parties, was recognized under expenses during the periods presented:

RELATED PARTY TRANSACTIONS
(Amounts in thousands of euros)

	<u>12/31/2016</u>	<u>12/31/2015</u>
Wages and salaries - General direction	244	219
Share-based payments - General direction	70	

NOTE 23: EARNINGS PER SHARE

Basic earnings per share

Basic earnings per share are calculated by dividing the net earnings to which Company shareholders are entitled by the weighted average number of ordinary and preference shares outstanding during the financial year.

EARNINGS PER SHARE

	12/31/2016	12/31/2015
Profit / (loss) (in K€)	(9 744)	(12 643)
Weighted average number of shares outstanding (in thousands)	17 587	15 031
Earnings per share (in €)	(0,55)	(0,84)
Weighted average number of potential shares (in thousands)	20 607	16 814

Instruments that grant rights to the share capital on a deferred basis (BSAs, BSPCEs or stock options) are considered antidilutive because they cause an increase in earnings per share. Thus, diluted earnings per share are identical to basic earnings per share

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. In 2013, the Company acquired for the first time a derivative financial instrument for hedging future cash flow, which expired in 2014.

Since December 31, 2014, the Company has no longer derivatives.

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 Massachusetts 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 EUR/USD parity fluctuation. In fact, the Group markets the product and services in the United States 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 +10% change in the EUR/USD exchange rate would result in a rise in earnings of €267 thousand at December 31, 2016;
- A -10% change in the EUR/USD exchange rate would result in a drop in earnings of €(326) thousand at December 31, 2016.

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.

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.

At December 31, 2016, the Company's debt was not subject to interest rate risk because it primarily involved interest-free repayable loans for a total nondiscounted amount of €3,038 thousand as described in Note 11 "Borrowings and debt".

To date, the Company has secured a non-dilutive, €7.0 million senior debt financing with IPF Partners, a leading provider of alternative financing solutions for emerging, commercial-stage European healthcare companies.

This debt financing is comprised of two bond tranches of bonds: the first tranche of €4.0 million issued to date; the second for the remaining €3.0 million available in the next 12 months, subject to preset closing conditions.

This financing consists of 7,000,000 secured bonds with a total value of €7 million. The interest on the bonds will bear interest at an annual rate equal to the 3-month EURIBOR +8.5%. The term of the first portion is set at five years (of which eighteen months without repayment of capital) and the second at four years (of which twelve months without repayment of capital).

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 cash on hand only.

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 that its customers have an appropriate credit risk history.

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 financial assets held by the Company are the purchase prices in effect on the market at 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 February 9, 2017, the Company has secured a non-dilutive, €7.0 million senior debt financing with IPF Partners, a leading provider of alternative financing solutions for emerging, commercial-stage European healthcare companies.

This debt financing is comprised of two tranches of bonds: the first tranche of €4.0 million issued to date, the second for the remaining €3.0 million available in the next 12 months, subject to preset closing conditions. The terms of the obligations contain certain financial commitments.

This financing consists of 7,000,000 secured bonds with a total value of €7.0 million. The interest on the bonds will bear interest at an annual rate equal to the 3-month EURIBOR +8.5%. The first tranche of bonds has a 5-year maturity, with interest-only payments for the first 18 months, and the second tranche of bonds has a 4-year maturity, with interest-only payments for 12 months. The terms of the bonds contain certain financial covenants.

20.2 Pro forma financial information

Not applicable.

20.3 Historical financial statements of Mauna Kea Technologies SA

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

Report of the statutory auditors on the consolidated financial statements prepared in accordance with the IFRS as adopted by the European Union for the year ended December 31, 2016

COFIDEC
155, boulevard Haussmann
75008 Paris
S.A.R.L. with €32,800 of paid-in capital

Statutory auditors
Member of the Compagnie
régionale de Paris

ERNST & YOUNG et Autres
1/2, place des Saisons
92400 Courbevoie - Paris-La Défense 1
S.A.S. à with variable capital

Statutory auditors
Member of the Compagnie
régionale de Versailles

Mauna Kea Technologies
Year ended December 31, 2016

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, 2016, 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, 2016 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.

- 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 works, 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 works, we assessed 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.

- The methods used by your Company to recognize the Research Tax Credit are specified in note "1.17: Other - Research Tax Credit" and the income amount for the year under this tax credit is mentioned in note "7.2 Other Current Assets - Research Tax Credit" of the consolidated financial statements. As part of our works, we have reviewed the methodology used by your Group to assess the amount and performed tests on research expenses included in the calculation. On this basis, we concluded on the reasonableness of the revenue recognized.

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 et Paris-La Défense, March 31, 2017

The Statutory Auditor
French original signed by

COFIDEC

ERNST & YOUNG et Autres

Olivier Robinault

Cédric Garcia

20.5 Date of most recent financial information

December 31, 2016.

20.6 Consolidated interim financial information

Not applicable.

20.7 Dividend distribution policy

20.7.1 Dividends paid during the last three financial years

N/A.

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.

No unfunded litigation currently exists.

As of December 31, 2016, no new labor dispute was reported.

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, 2016.

SECTION 21

ADDITIONAL INFORMATION

21.1 Shared capital

21.1.1 Amount of share capital

At December 31, 2016, the Company's share capital totaled €800,073.52, divided into 20,001,838 shares with a par value of €0.04 each, fully paid up.

21.1.2 Securities not representing capital

N/A.

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.

This 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, 2016, under this contract, the Company held 23,681 of its shares and €94,289.08 in the cash account.

These shares, valued based on the FIFO method, were acquired based on a carrying amount of €70,761.49.

Summary of transactions performed by the Company on its own securities between January 1, 2016 and December 31, 2016

	2016				
	1st quarter	2nd quarter	3rd quarter	4th quarter	Total
Securities purchased	142 752	188 258	261 821	379 671	972 502
Price	3,22	2,10	2,52	3,23	
Total amount	459	395	659	1 227	2 739
Securities sold	143 227	193 864	264 678	383 415	985 184
Price	3,12	2,10	2,47	3,24	
Total amount	447	407	655	1 243	2 752

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 concluded with an investment services provider, in accordance with a Code of Conduct approved by the AMF;
- 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 May 27, 2015 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

Four different types of securities give access to the capital:

- founders' warrants (BSPCE);
- stock options (SO);
- share warrants (BSA);
- preference shares (AP).

Summary of dilutive instruments

Please refer to Section 4.4.7 of this Registration Document.

Founders' warrants (BSPCE)

See following pages

SECTION 21 - ADDITIONAL INFORMATION

Plan no.	BSPCE 08			BSPCE 08 A	BSPCE 10		BSPCE 11	BSPCE 12		BSPCE 13
	05/27/08 and 06/16/09	05/27/08 and 06/16/09	05/27/08 and 06/16/09	05/27/08 and 06/16/09	06/30/10		05/25/11	06/15/12		06/19/13
Date of Chairman's decisions	08/04/08	12/08/08	11/24/09	08/04/08	02/15/11	03/01/11	12/05/11	12/04/12	05/07/13	02/12/14
Number of BSPCE authorized (1)	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 BSPCE granted (1)	1,225,000	35,000	637,500	500,000	915,000	200,000	129,500	239,500	63,000	281,000
Total number of shares that may initially be subscribed for (2) <i>of which the number that may be subscribed by corporate officers:</i> <i>Alexandre Loiseau</i>	1,225,000 <i>0</i>	35,000 <i>0</i>	637,500 <i>0</i>	500,000 <i>500,000</i>	915,000 <i>0</i>	200,000 <i>0</i>	129,500 <i>0</i>	239,500 <i>0</i>	63,000 <i>0</i>	281,000 <i>100,000</i>
Number of beneficiaries who are not corporate officers	45	3	21	0	27	1	13	46	7	42
Start date for exercise of the BSPCE	08/04/09	12/08/09	11/24/10	08/04/09	02/15/13	03/01/12	12/05/12	12/04/13	05/07/14	02/12/15
BSPCE expiration date	08/04/18	12/08/18	11/24/19	08/04/18	02/15/21	03/01/21	12/05/21	12/04/22	05/07/23	02/12/24
BSPCE exercise price (3)	€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)	(5)	(5)	(5)	(6)
Number of shares subscribed at December 31, 2016 (3)	83,123	0	38,748		79,562	37,500	0	625	0	0
Cumulative number of BCE canceled or invalid as at December 31, 2016 (1)	640,008	10,000	361,256	1	228,752	0	117,000	154,625	27,000	88,000
BSPCE remaining at December 31, 2016 (1)	252,500	25,000	121,252	499,999	368,000	50,000	12,500	84,250	36,000	193,000
Total number of shares that may be subscribed for at December 31, 2016 (3)	63,125	6,250	30,313	124,999	92,000	12,500	12,500	84,250	27,000	96,500

(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 account of the 4-for-1 reverse stock split approved by the General Meeting held 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 BSPCE can be exercised.

(5) The procedures 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 S.O., 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 December 31, 2016, the exercise of all BSPCE could lead to the creation of 549,437 new ordinary shares following the 4-for-1 reverse stock split, that could potentially be exercised or not as of the date of this report, in view of the vesting under the conditions set out in point (5).

SECTION 21 - ADDITIONAL INFORMATION

Stock Option Plans

Information on the Stock Option Plans								
Date of General Meeting	05/27/08	05/27/08	06/30/10	06/15/12	06/19/13	05/27/15	05/27/15	05/27/15
Date of Chairman's decisions	06/02/08	03/01/10	01/31/11	12/04/12	02/12/14	09/08/15	02/02/16	07/26/16
Total number of options authorized	960,000	960,000	750,000	800,000	800,000	400,000	400,000	400,000
Total number of options granted (1)	670,000	250,000	245,000	161,000	10,000	57,500	96,000	80,000
Total number of shares that may initially be subscribed for (2) <i>of which the number that may be subscribed by corporate officers</i>	670,000 <i>0</i>	250,000 <i>0</i>	245,000 <i>0</i>	161,000 <i>0</i>	10,000 <i>0</i>	57,500 <i>0</i>	96,000 <i>0</i>	80,000 <i>0</i>
<i>Number of beneficiaries who are not corporate officers</i>	<i>5</i>	<i>3</i>	<i>5</i>	<i>11</i>	<i>4</i>	<i>4</i>	<i>10</i>	<i>2</i>
Start date for exercise of the options	06/02/09	03/01/11	01/31/12	12/04/13	02/12/15	09/08/16	02/02/17	07/26/17
Option expiration date	06/02/19	03/01/21	01/31/21	12/04/22	02/12/24	09/08/25	02/02/26	07/16/26
Subscription price (3)	€4.00	€4.00	€4.00	€10.79	€10.56	€2.94	€2.54	€1.60
Exercise procedures	(4)	(4)	(4)	(5)	(5)	(5)		
Number of shares subscribed at December 31, 2016 (3)	47,148	2,500	14,062	0	0	0		
Cumulative number of stock options canceled or invalid (1)	270,000	100,000	128,752	143,000	8,000	10,000	15,000	0
Stock options remaining at December 31, 2016 (1)	211,408	140,000	60,000	18,000	2,000	47,500	81,000	80,000
Number of shares that may be subscribed for as of December 31, 2016 (3)	52,852	35,000	15,000	18,000	1,000	11,875	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 stock options allocated, canceled, 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 account of 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 procedures for exercising stock options (S.O.) 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 from the fourth anniversary of their allocation.

As of December 31, 2016, the exercise of all stock options granted could lead to the creation of 133,727 new ordinary shares, that could potentially be exercised or not as of the date of this report under the conditions set forth in point (5).

Share Warrant (BSA) Plan

	BSA 2014	BSA 2016	BSA 2016-2
Date of General Meeting	06/11/14	05/04/16	05/04/16
Date of Chairman's decisions	09/01/14	07/26/16	11/18/16
Number of authorized share warrants (BSA)	400,000	400,000	-
Total number of BSA issued (1)	100,000	115,000	1,850,000
Total number of shares that may initially be subscribed for (2)	100,000	115,000	1,850,000
<i>of which the number that may be subscribed by corporate officers</i>	60,000	115,000	0
<i>André Michel Ballester</i>			
<i>Christopher McFadden</i>	30,000	40,000	
<i>Jean-Luc Boulnois</i>	30,000	25,000	
<i>Joseph Devivo</i>		25,000	
<i>Marie Meynadier</i>		25,000	
Number of beneficiaries who are not corporate officers	1	0	1
Start date for exercise of the BSA	09/01/15	07/26/17	11/18/16
BSA expiration date	09/01/24	07/26/26	11/18/18
BSA issue price	€0.61	€0.1600	€3.0000
BSA exercise price (3)	€6.120	€1.6800	(5)
Exercise procedures	(4)	(4)	(5)
Number of shares subscribed at December 31, 2016 (3)	0	0	845,000
Cumulative number of BSA canceled or invalid as of December 31, 2016 (1)	0	0	0
BSA remaining at December 31, 2016 (1)	100,000	115,000	1,005,000
Number of shares that may be subscribed for as of December 31, 2016 (3)	66,667	0	1,005,000

(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 BSA authorized, issued, void, canceled or remaining. Only their exercise conditions are adjusted (price and parity).

(2) The exercise conditions of the BSA have been amended to take account of the 4-for-1 reverse stock split approved by the General Meeting held 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) BSA 2015: please refer to Section 10.1 of this Registration Document.

As of December 31, 2016, the full exercising of all share warrants allocated could lead to the creation of 1,071,667 ordinary new shares potentially exercisable or not on the date of this report as regards the conditions stipulated in paragraph (4).

Preference shares (AP)

Information relating to the preference shares		
Date of General Meeting	05/04/16	05/04/16
Date of Chairman's decisions	07/26/16	11/15/16
Total number of options authorized	8,500	8,500
Total number of options granted (1)	7,765	570
Total number of shares that may initially be subscribed for (2)	7,765	570
<i>of which the number that may be subscribed by corporate officers</i>	2,875	0
<i>Number of beneficiaries who are not corporate officers</i>	62	4
Expiration of the vesting period	07/26/17	11/15/17
Expiration of the holding period	07/26/19	11/15/19
Subscription price	*	*
Exercise procedures	*	*
Number of shares subscribed at December 31, 2016	0	0
Number of shares subscribed at December 31, 2016	0	0
Cumulative number of canceled preference shares returned to the pool	205	0
Preference shares remaining at December 31, 2016	7,765	570
Number of shares that may be subscribed for as of December 31, 2016	0	0

*The main characteristics are as follows:

The Company may decide to convert the Preference Shares definitively acquired by the Beneficiaries on the Acquisition Date into new or existing ordinary shares ("Ordinary Shares") at any time from the third anniversary of the Acquisition Date (the period between the Allocation Date and said third anniversary (inclusive), known as the "Holding Period"), in accordance with the following:

a. in the event of the Beneficiary's Departure between the Acquisition Date (inclusive) and the first anniversary of the Acquisition Date (exclusive), each Preference Share shall be convertible into twenty Ordinary Shares;

b. in the event of the Beneficiary's Departure between the first anniversary of the Acquisition Date (incl.) and the second anniversary of the Acquisition Date (excl.), each Preference Share shall be convertible into thirty-three Ordinary Shares;

c. in the event of the Beneficiary's Departure between the second anniversary (incl.) and the third anniversary (excl.) of the Acquisition Date, the conversion rate will be determined as follows:

(i) if the Benchmark Price 1 is strictly less than the Minimum Price, each Preference Share shall be convertible into thirty-three Ordinary Shares,

(ii) if the Benchmark Price 1 is strictly higher than the Intermediate Price, each Preference Share shall be convertible into sixty-six Ordinary Shares,

(iii) if the Benchmark Price 1 is between the Minimum Price and the Intermediate Price (inclusive), each Preference Share shall carry entitlement to the following number of Ordinary Shares:

$$33 + 33 \times [(Benchmark\ Price\ 1 / Minimum\ Price) - 1]$$

where:

- the term "Acquisition Price" means the average closing price on Euronext, or any other major stock exchange, of Mauna Kea Technologies shares over the 60 trading sessions preceding the Acquisition Date,

- the term "Minimum Price" means the Acquisition Price plus two (2) euros,

- the term "Intermediate Price" means the Minimum Price multiplied by two, and

- the term "Benchmark Price 1" means the average closing price on Euronext, or any other major stock exchange, of Mauna Kea Technologies shares over the 120 trading sessions preceding the second anniversary of the Acquisition Date;

d. in the event of the Beneficiary's Departure after the Holding Period, each Preference Share shall carry entitlement to the following number of Ordinary Shares:

(x) the number of Ordinary Shares determined in accordance with the provisions of paragraph 3.c) above as though the Beneficiary had departed between the second and third anniversaries of the Acquisition Date; and

(y) the following number of Ordinary Shares:

- (i) if the Benchmark Price 2 is strictly less than the Minimum Price: zero,
(ii) if the Benchmark Price 2 is strictly higher than the Ceiling Price: the difference between one hundred (100) Ordinary Shares and the number of Ordinary Shares determined under (x) (such that the sum of (x) and (y) is equal to 100),
(iii) if the Benchmark Price 2 is between the Minimum Price and the Ceiling Price (inclusive): the difference, if positive, between:

where:

- $33 + 67 \times [(Benchmark\ Price\ 2 / Minimum\ Price) - 1] / 2$,
- the number of Ordinary Shares determined under (x);

- the term "Minimum Price" has the meaning assigned to it in paragraph 3.c). above;

- the term "Ceiling Price" means the Minimum Price multiplied by three; and

- the term "Benchmark Price 2" means the average closing price on Euronext, or any other major stock exchange, of Mauna Kea Technologies shares over the 120 trading sessions preceding the third anniversary of the Acquisition Date. It should be noted that this conversion rate may be adjusted to take account of shares to be issued to protect the rights of holders of securities giving access to the Company's share capital, and the beneficiaries of Preference Shares, in accordance with applicable legal and regulatory provisions. The Preference Shares may be converted only during the period of five years and six months following the expiration of the Holding Period (the "Holding Period").

21.1.5 Authorized Share Capital

The resolutions approved by the Extraordinary General Meetings of May 4, 2016, and May 27, 2015 are summarized below:

Summary table of current delegations of authority and powers granted by the Annual General Meeting to the Board of Directors regarding capital increases in accordance with Articles L. 225-129-1 and L. 225-129-2 of the French Commercial Code and the use made of these delegations during the 2016 financial year

<u>Date of the Annual General Meeting</u>	<u>Purpose of the authorization</u>	<u>Expiration date</u>	<u>Use made by the Board of Directors</u>
Combined General Meeting of May 27, 2015			
May 27, 2015 (12 th resolution)	<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 - Maximum number of share warrants: 400,000.</i>	November 27, 2016 (18 months) <i>This delegation was replaced by the delegation with the same purpose granted by the Meeting of May 4, 2016.</i>	The Board made no use of this delegation during 2016.

<p>May 27, 2015 (14th resolution)</p>	<p><i>Delegation of authority granted to the Board of Directors 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>November 27, 2016 (18 months)</p>	<p>The Board made no use of this delegation during 2016.</p>
<p>Combined General Meeting of May 4, 2016</p>			
<p>May 4, 2016 (9th resolution)</p>	<p><i>Delegation of authority granted to the Board to increase the capital through the issue of ordinary shares and/or all marketable securities which are equity securities giving access to other equity securities or securities carrying entitlement to the allocation of debt securities, and/or marketable securities giving access to equity securities to be issued, with preferred subscription right for shareholders - Nominal ceiling: €194,000*.</i></p> <p><i>(Articles L. 225-129 to L. 225-129-6, L. 228-91, L. 228-92 and L. 228-93 of the French Commercial Code)</i></p>	<p>July 4, 2018 (26 months)</p>	<p>The Board made no use of this delegation during 2016.</p>
<p>May 4, 2016 (10th resolution)</p>	<p><i>Delegation of authority granted to the Board to increase the share capital by issuing ordinary shares and/or any securities giving access to other equity securities or to the allocation of debt securities, and/or securities giving access to future equity securities, without preferential subscription rights for shareholders and a public offering - Maximum nominal amount: €194,000, included in the overall maximum amount of €194,000 set by the Annual General Meeting.</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, L. 228-92 and L. 228-93 of the French Commercial Code)</i></p>	<p>July 4, 2018 (26 months)</p>	<p>The Board of Directors made no use of this delegation during 2016.</p>

<p>May 4, 2016 (11th resolution)</p>	<p><i>Delegation of authority granted to the Board to increase the share capital by issuing ordinary shares and/or any securities giving access to other equity securities or to the allocation of debt securities, and/or securities giving access to future equity securities, without preferential subscription rights for shareholders as part of an offering for qualified investors or a limited group of investors as referred to in Section II of Article L. 411-2 of the French Monetary and Financial Code - Maximum nominal amount: €194,000, included in the overall maximum amount of €194,000 set by the Annual General Meeting.</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, L. 228-92 and L. 228-93 of the French Commercial Code)</i></p>	<p>July 4, 2018 (26 months)</p>	<p>The Board of Directors made no use of this delegation during 2016.</p>
<p>May 4, 2016 (12th resolution)</p>	<p><i>Delegation of authority granted to the Board of Directors 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 responsible for the underwriting of Company equity securities likely to be issued as part of an equity financing facility - Maximum nominal amount: €97,000, included in the overall maximum amount of €194,000 set by the Annual General Meeting.</i></p> <p><i>(Articles L. 225-129 et seq. of the French Commercial Code, and in particular Articles L. 225-129-2, L-225-129-4, L. 225-135, L-225-138 and L. 228-91 of the French Commercial Code)</i></p>	<p>November 4, 2017 (18 months)</p>	<p>The Chief Executive Officer, as delegated by the Board of Directors on October 20, 2016, made use of this delegation on November 17, 2016 and decided to issue 1,850,000 stock warrants in favor of Kepler.</p>
<p>May 4, 2016 (14th resolution)</p>	<p><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></p>	<p>July 4, 2018 (26 months)</p>	<p>The Board of Directors made no use of this delegation during 2016.</p>

	<i>(Articles L. 225-129, L. 225-129-2, L. 228-135, L. 225-135-1 et seq., L. 228-91 and L. 228-92 of the French Commercial Code).</i>		
May 4, 2016 <i>(15th resolution)</i>	<i>Delegation of authority granted to the Board to issue ordinary shares and securities giving access to the share capital of the Company, in the event of a public offering involving an exchange component initiated by the Company - Maximum nominal amount: €194,000, included in the overall maximum amount of €194,000 set by the Annual General Meeting.</i> <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).</i>	July 4, 2018 <i>(26 months)</i>	The Board of Directors made no use of this delegation during 2016.
May 4, 2016 <i>(16th resolution)</i>	<i>Delegation of authority granted to the Board of Directors to increase the share capital, within a limit of 10% of the share capital, as consideration for contributions in kind of equity securities or securities giving access to the share capital of other companies and not part of a public exchange offering - Maximum nominal amount: €194,000, included in the overall maximum amount of €194,000 set by the Annual General Meeting.</i> <i>(Article L. 225-147 of the French Commercial Code).</i>	July 4, 2018 <i>(26 months)</i>	The Board of Directors made no use of this delegation during 2016.
May 4, 2016 <i>(18th resolution)</i>	<i>Delegation of authority granted to the Board of Directors to increase the share capital by the incorporation of premiums, reserves, profits or other items - Maximum nominal amount: €16,000, included in the overall maximum amount of €194,000 set by the Annual General Meeting.</i> <i>(Articles L. 225-129, L. 225-129-2, and L. 225-130 of the French Commercial Code)</i>	July 4, 2018 <i>(26 months)</i>	The Board of Directors made no use of this authorization during 2016.
May 4, 2016	<i>Delegation of authority granted to</i>	November 4,	

<i>(21st resolution)</i>	<i>the Board of Directors to issue and allocate share warrants (BSA) 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 - Nominal ceiling: €16,000.</i>	2017 <i>(18 months)</i>	The Board made use of this delegation on July 26, 2016, and issued, at the price of €0.17 each, a total of 115,000 BSA in favor of 4 non-executive directors, each carrying entitlement to subscribe to one ordinary share with a nominal value of €0.04 at the price of €1.68 each (share premium included) (see the additional reports by the Board of Directors and the statutory auditors).
May 4, 2016 <i>(22nd resolution)</i>	<i>Delegation of authority granted to the Board of Directors to increase the share capital by issuing ordinary shares and/or any securities giving access to other equity securities or to the allocation of debt securities, and/or securities giving access to future equity securities, without preferential subscription rights for shareholders, for the benefit of a certain category of persons meeting pre-determined criteria - Maximum nominal amount: €194,000, included in the overall maximum amount of €194,000 set by the Annual General Meeting.</i> <i>(Articles L. 225-129 et seq. of the French Commercial Code, and, particularly its Articles 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>	November 4, 2017 <i>(18 months)</i>	The Board made use of this delegation on July 12, 2016, and decided to increase the share capital by a nominal amount of €119,205.24 by issuing 2,980,131 shares at the price of €1.49 each (share premium included) (see the additional reports by the Board of Directors and the statutory auditors).

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 History 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.

The proceeds of the operation can be found in point 10.1.1 of this Registration Document.

Date	Type of transaction	Number of shares created	Number of shares comprising the capital	Nominal amount (€)	Share capital (€)	Share premium	Issue Price or option price (€)
04/21/2000	Constitution	62 000	62 000	1,00	62 000,00		4,00
07/04/2000	100-for-1-share split	6 138 000	6 200 000	0,01	62 000,00		0,04
09/21/2000	Cash issue of O shares	3 233 100	9 433 100	0,01	94 331,00	1 557 707,58	1,967
2003	Cash issue of O shares	3 820 400	13 253 500	0,01	132 535,00	2 128 344,84	2,268
2004	Cash issue of O shares	3 062 234	16 315 734	0,01	163 157,34	2 774 384,00	3,664
2006	Cash issue of O shares	1 926 978	18 242 712	0,01	182 427,12	2 248 397,93	4,707
2007	Exercise of BSPCE	20 950	18 263 662	0,01	182 636,62	13 747,20	
2007	Cash issue of P shares	8 447 419	26 711 081	0,01	267 110,81	11 730 930,77	3,664
2007	Bond conversions	1 869 477	28 580 558	0,01	285 805,58	2 181 305,76	5,595
2008	Exercise of BSPCE	529 500	29 110 058	0,01	291 100,58	292 179,60	
2008	Cash issue of P shares	6 082 345	35 192 403	0,01	351 924,03	8 446 552,50	5,595
2010	Exercise of BSPCE	5 000	35 197 403	0,01	351 974,03	4 950,00	
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	0,99	
05/25/2011	4-for-1 reverse stock split	- 26 795 835	8 931 945	0,04	357 277,80		NA
07/11/2011	Capital increase	4 346 243	13 278 188	0,04	531 127,52	56 327 309,28	13,00
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 BSA/BSPCE	151 343	13 554 559	0,04	542 182,36	586 536,28	
2012	Exercise of Stock Options	7 187	13 561 746	0,04	542 469,84	28 460,52	
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 Stock Options	34 000	14 026 519	0,04	561 060,76		
2015	Exercise of BSA	70 000	14 096 519	0,04	563 860,76		5,03
2015	Exercise of BSA	70 000	14 166 519	0,04	566 660,76		5,04
2015	Exercise of BSA	70 000	14 236 519	0,04	569 460,76		4,56
05/12/2015	Capital increase	1 189 251	15 425 770	0,04	617 030,80		3,95
2015	Exercise of BSPCE	50 937	15 476 707	0,04	619 068,28		
2015	Exercise of BSA	100 000	15 576 707	0,04	623 068,28		3,11
2015	Exercise of BSA	100 000	15 676 707	0,04	627 068,28		3,15
2015	Exercise of BSA	100 000	15 776 707	0,04	631 068,28		3,15
2015	Exercise of BSA	250 000	16 026 707	0,04	641 068,28		3,08
2015	Exercise of BSA	150 000	16 176 707	0,04	647 068,28		3,08
07/12/2016	Capital increase	2 980 131	19 156 838	0,04	766 273,52	3 887 702,80	1,49
2016	Exercise of BSA	250 000	19 406 838	0,04	776 273,52		3,15
2016	Exercise of BSA	50 000	19 456 838	0,04	778 273,52		3,03
2016	Exercise of BSA	75 000	19 531 838	0,04	781 273,52		2,95
2016	Exercise of BSA	120 000	19 651 838	0,04	786 073,52		3,03
2016	Exercise of BSA	100 000	19 751 838	0,04	790 073,52		2,9
2016	Exercise of BSA	100 000	19 851 838	0,04	794 073,52		2,9
2016	Exercise of BSA	50 000	19 901 838	0,04	796 073,52		2,83
2016	Exercise of BSA	50 000	19 951 838	0,04	798 073,52		2,75
2016	Exercise of BSA	50 000	20 001 838	0,04	800 073,52		2,9

21.2 Memorandum and bylaws

21.2.1 Corporate 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.

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 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.

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 in 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 General 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 (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, in the case of double voting rights or in the case of preferred shares, 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.

Preferred shares do not carry any right to vote at Annual General Meetings. However, beneficiaries of preferred shares will be called to a special meeting under the conditions stipulated by Article L. 225-99 of the French Commercial Code to approve any modification to the rights attached to preferred shares.

Shareholders may, by registered letter with requested return receipt 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 (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, with the exception of preferred shares which do not benefit from any dividend and do not give any entitlement to reserves but entitle holders to the same rights to the liquidation surplus as ordinary 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 indicate 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, with the exception of preferred shares which do not benefit from preferred subscription rights, it being specified, however, that the conversion ratio will be adjusted in order to preserve the rights of their beneficiaries.

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 General 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 General 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. 233-7-1 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 registered 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 General 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.

As an extension of the original contract signed in 2010, the Company early in 2015 renewed its supply contract for laser fibers and assemblies with Fujikura, a Japanese corporation which is the Company's sole supplier of laser fibers.

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.

In December 2015, the Company signed a multi-year worldwide marketing partnership agreement with Cook Medical covering urological applications of its unique Cellvizio platform. Cook Medical is a privately-held group with more than 11,000 employees and headquarters in Bloomington, Indiana. As one of the best known and respected players in the field of medical devices and supplies, Cook Medical is also a world leader in urology applications.

The marketing agreement with Cook Medical, our exclusive urology partner, was a great success during the first half of 2016. However, this partnership encountered some difficulties towards the end of the year, related to regulatory and administrative issues. The Group is working hard with Cook Medical to identify suitable solutions.

On February 1, 2016, following the recent approval of Cellvizio 100 by the Chinese FDA, the company decided strategic partnership with Fujifilm China. Fujifilm will commercialize Cellvizio for gastroenterological and pulmonary applications in China and will integrate the Cellvizio platform into its commercial offers for advanced endoscopy systems.

SECTION 23
THIRD PARTY INFORMATION, STATEMENTS BY EXPERTS AND
DECLARATION OF INTERESTS

N/A.

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) and on the AMF website (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).

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

Advanced mosaic: optimized treatment of a succession of adjacent images used to reconstruct wide field maps of a mucosa;

Autofluorescence: light which is generated naturally by biological tissues, for example, under the action of illumination. Endoscopic imaging through autofluorescence therefore consists of analyzing this light in order to enhance, for instance, the detection of precancerous lesions;

Barrett's Esophagus: see Endo-brachy-esophagus (EBO);

Biliary and/or pancreatic duct strictures: shrinkage of the natural ducts, whether pancreatic or biliary;

Biopsy: mechanism that consists of taking a sample from the organism in order to carry out a microscopic examination;

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);

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 transport the Laser beam to the area to be observed, inside human anatomic tracts, through other standard endoscopic devices (colonoscope, gastroscope, bronchoscope, cholangioscope, etc.), a catheter or even a needle;

Cystoscopy (or endourology): an endoscopic medical examination used to examine the inner wall (mucosa) of the bladder via the urethra and possibly the ureters; This examination also enables therapeutic intervention;

Distal lesion: lesions situated at the farthest tip of a given organ (esophagus, biliary tract, etc.);

Distal tip: The farthest tip of a mini-probe, for instance. The distal tip of the confocal mini-probes contains optical micro lenses;

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).

Dysplastic lesion: precancerous lesion;

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;

EGD (Esophagogastroduodenoscopy): upper endoscopy used to examine the esophagus, stomach and duodenum;

Endo-brachy esophagus (EBO or Barrett's Esophagus): complication of gastroesophageal reflux which, if it is not treated, can evolve into esophageal cancer;

Endomicroscopy: endoscopic procedure using a device which provides visualization of tissues at microscopic level;

Endoscopic Confocal Microscopy via miniprobe (ECM): endomicroscopic procedure using a miniprobe which is compatible with standard endoscopes; The only ECM system available is the Cellvizio;

Histology: a branch of biology and medicine that studies biological tissues;

Histopathology: technical, human and veterinary medical specialty, which focuses on the study of macroscopic and microscopic lesions in pathological tissues sampled from a living or dead subject;

Learned Society: society or organization formed by groups of experts who, through their work and discussion, ensure the progress of knowledge in their field of activity;

Metaplasia: transformation of a cellular tissue. Reversible phenomenon not disturbing the tissue's functions;

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;

Multicenter clinical trials: clinical trials that take place in several different places simultaneously;

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;

Nodules: abnormal, rounded, and palpable formations on or under the skin, which can be benign or malignant. Some nodules can be cancerous tumors;

Optical biopsy: see endomicroscopy;

Optoelectronics: combination of optical and optoelectronic 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;

Randomized clinical trial: clinical trial of a new treatment during which participants are assigned at random to the control group or the experimental group;

Resection: surgical ablation of part of an organ or a pathological tissue such as a tumor;

System for spectroscopic interrogation of colorectal polyps: optical technology used to investigate the nature of a polyp by analyzing the light backscattered by the polyp tissues;

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.);

Transpleural route: route of access across the pleura, i.e. the space between the lungs and the thoracic wall;

Transurethral resection: this procedure takes place via the natural routes with no abdominal opening. 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;

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;

White light endoscopy: traditional endoscopy.

LIST OF CLINICAL PUBLICATIONS

Clinical publications are available on the Company's website at the following link:
<http://www.maunakeatech.com/en/content/clinical-evidence>