Mauna Kea Technologies

A Public Limited Company (*Société anonyme*) with share capital of 1,008,053.52 euros
Registered office: 9 rue d'Enghien
75010 Paris, France
431 268 028 in the Paris Trade and Companies Register

2018 REGISTRATION DOCUMENT

ANNUAL FINANCIAL REPORT

This registration document contains all the information presented in the Annual Financial Report.

AMF AUTORITÉ DES MARCHÉS FINANCIERS

This Registration Document was filed with the *Autorité des Marchés Financiers* (AMF—French Financial Markets Authority) on July 12, 2019 in accordance with Article 212-13 of the AMF General Regulations. It may be used in connection with any financial transaction provided 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).*

TABLE OF CONTENTS

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 S.A.;
- The term “Group” refers to Mauna Kea Technologies SA and its subsidiary.

SECTION 1
1. PERSONS RESPONSIBLE

1.1. Person responsible for the Registration Document

Mr. Robert L. Gershon, Chief Executive Officer 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.

I attest that to my knowledge the financial statements were prepared in accordance with applicable accounting standards and fairly represent the assets, financial position and results of the Company and all entities within its scope of consolidation, and that the management report included herein, whose information is set out in the note 9.2 "Results analysis", presents an accurate picture of the ongoing business, results and financial position of the Company and all entities within its scope of consolidation along with a description of the principal risks and uncertainties.

I received an audit completion letter from the statutory auditors in which they confirm having verified the information on the financial position and financial statements provided in this document and having read this document in its entirety."

July 12, 2019

Robert L. Gershon
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 2017 financial year:
- the management report of the Board of Directors on the consolidated financial statements, the consolidated financial statements and the statutory auditors' report on both appear in Sections 9 and 20 of the Registration Document filed with the AMF on April 27, 2018 under number D. 18-0429;
- the statutory auditors' special report on related party agreements is provided in Section 19.3 of said Registration Document.

2. Regarding the 2016 financial year:
- the management report of the Board of Directors on the consolidated financial statements, the consolidated financial statements and the statutory auditors' report on both appear in Sections 9 and 20 of the Registration Document filed with the AMF on May 31, 2017 under number D. 17-0574;
- 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

Robert L. Gershon
Chief Executive Officer
Address: 9, rue d'Enghien, 75010 Paris, France
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Fax: +33 (0)1 70 08 09 77
Email: investor-dg@maunakeatech.com

SECTION 2
2. STATUTORY AUDITORS

2.1. Main statutory auditors

Exco Socodec,
Member of the Regional Company of Auditors of Dijon
Represented by Mr. Olivier Gallezot
51 Avenue Françoise Giroud, 21000 Dijon

Date of start of first term of office: June 13, 2018.
Duration of the current term of office: six financial years from June 13, 2018.
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.

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, 2022.

2.2. Alternate statutory auditors

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
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		
	2018	2017	2016
Non-current assets	3,956	3,704	3,625
Including intangible assets	1,838	2,100	2,565
Including property, plant and equipment	1,985	1,466	898
Including non-current financial assets	133	138	162
Current assets	15,806	24,043	16,349
Including cash and cash equivalents	8,623	17,453	9,053
TOTAL ASSETS	19,762	27,747	19,974
Equity	7,979	16,744	11,157
Non-current liabilities	6,879	6,850	2,900
Including long-term debt	6,457	6,567	2,640
Current liabilities	4,904	4,153	5,917
Including short-term borrowings and debts	600	386	404
TOTAL EQUITY AND LIABILITIES	19,762	27,747	19,974

Simplified consolidated income statement

Consolidated data audited in €K

	At December 31		
	2018	2017	2016
Total sales of "equipment"	2,683	3,101	4,217
Total sales of "consumables" (probes)	2,812	2,397	2,941
Total sales of "services"	1,265	1,188	1,629
Total sales	**6,760**	6,687	**8,787**
Other income	1,141	1,144	883
Total revenue	**7,901**	7,831	**9,670**
Cost of sales	(2,058)	(2,129)	(2,720)
Gross margin	70%	68%	69%
Total operating expenses	**(19,899)**	**(17,541)**	**(19,660)**
Other operating income and expenses			
Operating Profit (Loss)	**(11,998)**	**(9,710)**	**(9,990)**
Profit before tax	**(12,785)**	**(10,245)**	**(9,744)**
Profit/(loss)	**(12,785)**	**(10,245)**	**(9,744)**
Other comprehensive income	128	(174)	26
Comprehensive income	**(12,657)**	**(10,419)**	**(9,718)**

Simplified consolidated cash-flow statements

Consolidated data audited in €K

	At December 31		
	2018	2017	2016
net cash flows from operating activities	(10,900)	(9,742)	(7,836)
Of which self-financing capacity	(10,874)	(8,607)	(8,635)
Of which change in WCR related to business activities	(26)	(1,136)	799
Net cash flows from investing activities	(1,246)	(735)	(573)
net cash flows from financing activities	3,299	18,913	6,826
Change in cash	**(8,830)**	**8,401**	**(1,567)**

Net cash position

Consolidated data audited in €K	2018	of which < 1 year	of which > 1 year
Financial debts	(7,057)	(600)	(6,457)
Including BPI loans	*(2,766)*		*(2,766)*
Cash and cash equivalents	8,623	8,623	
Net cash balances	**1,566**	**8,023**	**(6,457)**

First Quarter 2019 sales:

The Company reported its quarterly sales for 2019:

	At March 31		
(in € thousands) – IFRS	2019	2018	Change
Total sales of "equipment"	558	373	49%
Total sales of "consumables" (probes)	873	445	96%
o/w pay-per-use program	331	114	189%
Total sales of "services"	284	223	28%
Total sales	1,715	1,042	**65%**

The total sales for the first quarter of 2019 was €1.7 million, up 65% over one year. The sales growth in the first quarter was driven by a 96% increase in consumables sales, 49% of system sales and 28% of service income. The increase from one financial year to another in total consumables sales in the first quarter of 2019 is due to sales under our pay-per-use program, which accounted for approximately 38% of total sales of consumables in the first quarter of 2019, versus 26% in the first quarter of the previous year.

SECTION 4
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 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.
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	The Company's exposure to interest rate risk mainly concerned the debt contracted with IPF Partners, which was fully repaid on June 28, 2019. This debt was subject to the annual interest rate of three-month EURIBOR + 8.5%.
b	Credit and cash management risk	The Group has established policies that insure 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.
	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 business, financial situation, earnings and reputation of the Group.
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 Miniprobes, 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 the end of December 2018, the R&D department had 26 associates and the budget devoted to R&D in 2018 came to more than €4.7 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 other health insurers.

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 miniprobes 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, pulmonology and urology. Confocal miniprobes 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 (AMA) created three new, category I reimbursement codes for endomicroscopy (CPT codes) for the United States. Two of these codes concern gastroenterologists (or endoscopists) and are intended to reimburse procedures performed with Cellvizio in the upper gastrointestinal tract.

The rates of these codes 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-[1]patient). The third code concerns histopathologists.
In March 2015, the 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 CPT code for the upper gastrointestinal tract.

At the date of this Registration Document, the United States is the main 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.

1 Source: Centers for Medicare & Medicaid Services (CMS) 2017, www.cms.gov

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 two sales forces. In France, Germany, England, Belgium, the Netherlands, Luxembourg and the United States, it is marketed by a direct sales force for gastroenterology and pulmonology applications. In other geographical areas, in particular in Asia, certain South American countries and European countries other than the aforementioned countries, the Company wants to adopt an indirect approach through a network of independent distributors who are granted exclusivity by region and industry and market the technology under the Cellvizio brand. In addition, in 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 Europe and 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 2018, 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.
Main partnerships on priority commercial territories:

Partenariats	Siemens	Siemens	Cook Medical	Youhe	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)	Modele experimental	Cystoflex/Uroflex	Tout la gamme autorisee en Chine	Tout la gamme autorisee 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

			Zones géographiques - Partenariats et distributeurs						
	Interventions	Produits	EMEA ventes directes	EMEA Ventes indirectes	Chine	Japon	APAC hors Chine et Japon	Etats-Unis	Amériques hors Etats-Unis
Endoluminal	Interventions bilo-pancréatiques	Aq-Flex / CholangioFlex	Direct	Distributeurs	Youhe	Amco	Distributeurs	Direct	Distributeurs
	Interventions endoluminales	Gastro/Coloflex	Direct	Distributeurs	Youhe	Amco	Distributeurs	Direct	Distributeurs
	Interventions pneumologiques	AlveoFlex/Aq-Flex	Direct	Distributeurs	Youhe	Amco	Distributeurs	Direct	Distributeurs
	Interventions urologiques	UroFlex	Cook Medical Inc.	Cook Medical Inc.	Youhe	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.
Chirurgies	Chirurgie anti-reflux	GastroFlex	-	-	-	-	-	Direct	-
	Chirurgie oncologique	CelioFlex	Direct					Direct	
	Chirurgie urologique	CelioFlex							
	Autres chirurgies	CelioFlex	Direct					Direct	
	Neurochirurgie	En cours		Siemens (investigation clinique) / Direct					
Autres indications	Radiologie interventionnelle	En cours	Siemens (investigation clinique) / Direct						
	Imagerie biomoléculaire	En cours	Siemens - Essai clinique auprès de Cleveland Clinic (Etats-Unis) , UMCG (Netherland) et Royal infirmary						
							Pas de commercialisation ou de partenariat en cours		

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 1,000 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, pulmonology, 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, pulmonology, surgery, interventional radiology, neurosurgery and biomarkers. These are not always identified by the Company as Sponsor, but can result from investigator-initiated 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 "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 sought 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 and its subsidiary Fibertech, 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 became a shareholder in Mauna Kea Technologies as part of a capital increase and held 0.84% of its capital at December 31, 2018.

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;
- 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.

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 framework agreement has been renewed twice (in January 2015 and at the beginning of 2019). It sets a minimum purchase volume for the Company over three years. In exchange, Fujikura guarantees supply, as set out in the agreement, and commits to maintain, barring exceptional circumstances, the maximum price levels for the products and assemblies it supplies to the Company. The products and assemblies may have different definitions and specifications based on the parties' work.

The drafting and execution of this new contract strengthened the partnership between the Company and Fujikura. The Company also maintains regular relations with this supplier, with monthly conference calls between teams, and cross-visits at least once a year.

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 optical 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 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 must 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. The Company put a process in place to select and regularly monitor its critical suppliers and subcontractors and conducts appropriate checks of the components and assemblies it receives to manage this risk.

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 2018 was Shanghai YouHe Medical Technology. 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 28% and 41% of trade receivables as of December 31, 2018 and 2017 respectively.

In 2018, one distributor in the APAC region accounted for more than 17.37% of sales.

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 13485:2016, 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-enticement 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 award 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, 2018, 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 €115,486 thousand, including a net loss of €12,785 thousand for the financial year ended December 31, 2018. 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 8, 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 financing was 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 Company did not fall back on the second tranche which is no longer available.

This financing consisted of 4,000,000 secured bonds with a total value of €4.0 million. The interest on the bonds beared interest at an annual rate equal to the three-month EURIBOR +8.5%. The term was set at 5 years (with deferred principal repayment for the first 18 months). The terms of the bonds contained certain financial covenants.

In November 2018, the Company signed a rider to its subscription agreement signed in February 2017 with IPF Partners, that included two additional tranches of debt, the first of which was for €5.0 million available until the end of April 2019, and another €5.0 million tranche was available until September 2019, both tranches being subject to conditions of attaining a preset level of sales. At December 31, 2018, the Company has fulfilled the conditions necessary to raise the first tranche.

The loans would hace beared interest at an annual rate equal to 3 month Euribor + 8.0%. The first loan tranche had a term of 5 years, with deferred principal repayment for the first 15 months. The second loan tranche had a term of 4 years, with deferred principal repayment for the first 12 months. The issuance of warrants was subject to certain restrictive financial performance conditions, included in the terms and conditions of the contract.

At December 31, the going concern hypothesis was used by the Board of Directors taking into account its cash situation, sales outlooks, the collection of the research tax credit, the granting of a repayable loan and a PERSEE subsidy, and draw-down from tranche C of IPF's €5 million debt in 2019. Within this context the Company considers that it is prepared to meet its commitments through December 31, 2019.

During the first half of 2019, the Company signed a €22.5 million loan agreement with the European Investment Bank. The first tranche of €11.5 million is available on condition that IPFs are repaid, while the subsequent tranches of €6 million and €5 million will be available subject to the achievement of certain milestones, including the Company's commercial progress and its future equity financing activities.

The first tranche of €11.5 million was drawn down on 3 July 2019. This first tranche is repayable at the end of a 5-year period for both the capital and the capitalized interest at a fixed rate of 5%.

Tranche 1 is accompanied by the issuance of share subscription warrants ("BSAs") entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5,75 % of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided by the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of 5 October 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issuance, less a 5% discount, i.e. €1,8856 per warrant. The warrants may be exercised from this day until the twentieth anniversary of the issuance of the warrants, i.e. 3 July 2039.

During the first half of the year, the Company also obtained pre-financing of the research tax credit for an amount of €1.9 million. In parallel, the Company repaid the loan it had contracted with IPF for an amount of €10.7 million. As at the date of this Registration Document, the Group's cash position is sufficient to cover its financing needs over the next twelve months.

The Group is examining various sources of financing with equity, debt or other non-dilutive solutions to ensure continuity of operations beyond that time frame.
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 €(10,900) thousand and €(9,743) thousand for the financial years ended December 31, 2018 and 2017.

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.

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 two tax audits for all taxes of 2009-2010 and 2014-2015, including the Research Tax Credit. No tax adjustments were necessary.

As regards 2018 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 nine to twelve months following the filing of the tax return.

The following table describes the changes in the Research Tax Credit during the 2016-2018 financial years:

(in €k)	12/31/18	12/31/17	12/31/16
Research Tax Credit	1,097	1,096	828

4.4.4. Risks relating to access to public advances

At December 31, 2018, the Company enjoyed the following aid:

At Dec. 31, 2018 (in €k)	Amount granted	Amount Receipt	Amount repaid	Discount effects	Amount still to be repaid
BPI France loans	4,436	3,923	1,020	137	2,766
COFACE loans	1,704	1,704	1,704		
Total aid	**6,140**	**5,627**	**2,724**	**-137**	**2,766**

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, 2018 presented in Section 20.1 "Consolidated financial statements prepared under IFRS for the year ended December 31, 2018" 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):

<u>COFACE advance</u>

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 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 December 31, 2018, the COFACE loan was paid back in full.

Loans received from BPI France (PERSEE project)

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

1/ Immediate repayment in case of judicial liquidation / cessation of activities / dissolution / voluntary liquidation;

2/ A repayment by right and at the sole initiative of OSEO in case of:

- failure by the Company to meet one of its obligations (*) [...],
- irregular situation regarding its tax and social obligations,
- inaccurate or untrue statements;

(*) 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 currency for which the Group is exposed to significant exchange rate risk is the US dollar.

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 €342 thousand as of December 31, 2018;
- a variation in the EUR/USD exchange rate of -10% would have generated a drop in earnings of €418 thousand as of December 31, 2018.

Sales in foreign currencies are broken down as follows:

Foreign currency	Weight of currencies in sales
EUR	42%
USD	53%
Other	5%
Total	100%

4.4.6. Interest rate, credit and cash management risks

Interest Rate Risk

The Company's exposure to interest rate risk mainly concerned the 4,000,000 bonds contracted with IPF Partners. This debt was subject to the annual interest rate of 3 month-EURIBOR + 8.5%. After renegotiation in November 2018, the term was set at 5.5 years (with deferred principal repayment for the first 24 months). All of the debt with IPF Partners was repaid on 28 June 2019 following the financing agreement with the European Investment Bank. The company received the first tranche of €11.5 million under this agreement on July 3, 2019. No interest rate risk is applicable to this new debt.

At December 31, 2018, the Company did not hold any investment securities, whose interest rate changes have a direct impact on the rate of return for these investments and the cash flows generated.

The interest-free repayable BPI loans for a nominal amount of €2,904 thousand are detailed in Note 11 of the consolidated financial statements: Borrowings and financial debts are not subject to interest rate risk.

The Company also set up a new equity financing line with Kepler Cheuvreux, building on the success of the transaction announced on October 6, 2017 which enabled the Company to raise €7.7 million. This system makes it possible to make small successive capital increases based on the needs and under optimized market conditions.

In accordance with the terms of the agreement, Kepler Cheuvreux, acting as financial intermediary and guarantor of the transaction, committed to subscribe to 2,250,000 shares, on its own initiative, following a timetable over a maximum period of 24 months. The shares will be issued based on a volume-weighted average share price over the two trading days preceding each issue, minus a maximum discount of 6.5%. At June 30, 2019, there are 200,000 remaining stock warrants that can be subscribed.

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 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, since 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, 2018, would enable the subscription of 767,313 new shares, thus generating a dilution equal to 3.04% on the basis of the capital existing to date and 2.95% on the basis of the diluted

capital. The dilution in voting rights would come to 2.91% on the basis of the voting rights existing to date and 2.83% 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 and continually changing regulations shaped by efforts to harmonize global standards, in particular the recast of the European Directive on medical devices (EU 2017/745)(22017) approved by the European Parliament in early April 2017 and published in May 2017 with a compliance deadline of May 2020.

The Company has launched an impact assessment of the regulations on the compliance of its products with the new regulation in order to implement the necessary actions. However, compliance with this regulatory process can be long and costly, and there is no guarantee that authorizations will be obtained or of how long it may take to obtain or renew them. If certification or authorization to market the Company's products were refused, their marketing could be delayed or prohibited in the countries involved.

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

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

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

Risks relating to the regulatory environment in Europe – CE marking

2 Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 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

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.

In 2017 the Company renewed its CE certificate which is now valid until December 2020. The new EC marking regulation of Directive 2017/745 should be implemented in 2019 to be effective May 26, 2020.

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 15 applications of existing products in gastroenterology, pulmonology, urology and laparoscopy including robotic-assisted surgery (authorizations K051585, K061666, K111047, K120208, K122042, K123676, K132389, K133466, K141358, K150831, K151593, K160416, K171345, K172844 and K180270).

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 products marketed in China (Cellvizio 100 Series with the new confocal miniprobes designed to observe pancreatic cysts and for urology) and in Japan (confocal 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 the USA and Canada)		€500,000
- Including recall expenses incurred by third parties or the Insured outside of the USA and/or Canada		€500,000
- Including recall expenses incurred by third parties or the Insured in the USA 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	€500,000
Civil liability following a breach of employment law	Insurance	Per year
Defense		
Legal advice		

Liability of corporate officers All de jure and de facto senior managers (Company and Subsidiary)	AIG	€5,000,000
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
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 its 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

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.

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

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 pulmonology.

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

First images of patients made with the Cellvizio®.

2007

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

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

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

2008

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

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

Obtained the "OSEO-Innovative Enterprise" label.

2009

First ever ICCU (International Conference of Cellvizio® Users), a conference for the community of Cellvizio® users held in Miami Beach, Florida (United States) 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 international Digestive Disease Week (DDW) conference.

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.

Influential participation at the international Digestive Disease Week (DDW) conference in Chicago where 36 presentations on the Cellvizio® were given, including two during presidential 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 FDA 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.

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

Obtained a reimbursement rate of $927 from Medicare/Medicaid in the United States for the use of 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.

Marketing authorization for the AQ-Flex™ 19 confocal miniprobe in the United States for use in fine needle aspiration procedures.

Assignment of an OPS code in Germany for the reimbursement of endomicroscopy using Cellvizio® in gastroenterology.

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 reimbursement rate from $927 to $1,013 in early 2014.

Obtained 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.

Obtained 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 confocal miniprobes.

Obtained 510(k) regulatory approval from the FDA for a new Cellvizio® using an infrared wavelength.

French Health Authority authorizes the reimbursement 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 Cellvizio® in the diagnosis of bile duct cancer during endoscopic retrograde cholangiopancreatography (ERCP).

Publication in the United European Gastroenterology (UEG) 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 trial on the use of the Cellvizio® in the scientific journal Breast Cancer Research and Treatment.

Obtained a CPT reimbursement code in the United States for a Cellvizio® biliary application.

Marketing authorization for the Cellvizio® received from the Mexican Health Authority.

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

Obtained CE marking in indications of minimally invasive laparoscopic surgery.

CE marking obtained for interventional radiology.

CE marking obtained for the new perioperative platform Cellvizio® 800.

Regulatory approval obtained in Japan for the AQ-FlexTM 19 confocal endomicroscopy miniprobe.

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.

Obtained regulatory authorization in China to sell the latest generation Cellvizio® 100s as well as for the probes dedicated to pancreatic and urological applications.

Signed a master agreement with Cook Medical for urological applications.

2016

Listed on the OTCQX market in the USA.

Extension of strategic partnership with Fujifilm China.

Exclusive urology partnership with Cook Medical.
Clinical research collaboration with the Scottish company, Edinburgh Molecular Imaging.

FDA authorization for the marketing of miniprobes for near-infrafred surgery.

Endorsement of the Cellvizio® by the American Society of General Surgeons (ASGS).

Increase in reimbursement rates at hospitals (+131%) and ambulatory surgical centers (+86%) in the United States.

Completion of the recruitment of 200 patients for the CONTACT II trial on the diagnosis of pancreatic cysts using fine needle-based confocal laser endomicroscopy (nCLE).

The first study on the contribution of Cellvizio® to pediatric heart surgery is launched.

The CONTACT clinical study confirms the clinical effectiveness of Cellvizio® needle-based endomicroscopy in the diagnosis of pancreatic cysts.

Publication of the results of the PERSEE study in “Surgical Endoscopy” and the “European Journal of Gastroenterology & Hepatology”.

2017

Gastroenterology

Publication of a general overview of the Singapore Gastric Cancer Consortium team in a peer-reviewed journal highlighting the superior performance of endomicroscopy in terms of diagnostic yield improvement in gastric cancer.

Publication of a new study highlighting the strong performance of needle-based confocal laser endomicroscopy (nCLE) in the diagnosis of pancreatic cysts.

Clinical results obtained with confocal laser endomicroscopy highlighted in 27 physician oral presentations on current and emerging applications of Cellvizio® during the Digestive Disease Week (DDW) conference held in Chicago.

Publication of a new study in the World Journal of Gastroenterology, a peer-reviewed journal focused on the field of gastroenterology and hepatology.

Peer-reviewed publication of key multicenter randomized controlled trial demonstrating improved early stomach cancer detection with Cellvizio®: diagnostic yield more than doubled while number of necessary biopsies reduced by half and no change in procedure time.

Publication of a French health economics study showing a significant reduction in clinical costs through the diagnosis of benign pancreatic cysts with Cellvizio®.

Urology

Publication of a new study supporting the use of Cellvizio® in urology for the real-time histological characterization of upper tract urothelial carcinoma (UTUC) lesions.

Pneumonology

Presentation of new data demonstrating the applicability of Cellvizio® in assessing acute lung rejection following transplant at the American Thoracic Society (ATS) annual conference.

Obtained CE marking and authorization in the United States to market the use of CelioFlex™ UHD confocal miniprobes with Cellvizio® during robotic surgery procedures.

Obtained marketing authorization in the United States for the use of Cellvizio® to visualize the internal microstructure of tissues and also identify, among others, cells and vessels and their organization or architecture.

Healthcare cover for procedures using Cellvizio® now provided in Croatia for patients with gastrointestinal, biliopancreatic, respiratory and urinary disorders with reimbursements ranging from €250 to €800.

The FDA validates the cell and vessel identification and their organization or architecture in vivo and in real time with the Cellvizio 100 series and all its confocal miniprobes.

2018

Gastroenterology

Positive assessment obtained from the Korean National Evidence-based Healthcare Collaborating Agency (NECA). New Health Technology Assessment (nHTA) Committee recognizes confocal laser endomicroscopy as "a safe and effective technology in application for esophagus, stomach, bile duct". New Health Technology status enables specific reimbursement codes for Cellvizio® procedures in South Korea, third largest medical market in Asia.

Cellvizio® Demonstrates Superior Identification of Patients at Risk for Esophageal Cancer Compared to Current Diagnostic Standard. The results of the study on 172 patients recruited in 8 non-university centers in the United States were presented at the 2018 World Congress of Endoscopic Surgery organized by the companies SAGES and CAGS.

Discovery of a new structure in the human body. The study conducted on the initiative of researchers who used Cellvizio® to characterize an unknown structure, the "interstitium", up to now never identified by standard histological techniques. According to the publication in Scientific Reports, this discovery may have significance in cancer metastasis and other diseases and could lead to new therapeutic approaches for cancer

20 presentations focusing on Cellvizio®'s clinical value were given during the DDW conference on Barrett's esophagus, Inflammatory Bowel Disease /Syndrome (IBS/IBS), pancreatic cysts and other gastrointestinal diseases.

Publication in Surgical Endoscopy of the positive results of a prospective American multicenter clinical trial on the detection of Barrett's esophagus with Cellvizio® by new users.

Pneumonology

Obtaining U.S. Food and Drug Administration (FDA) 510(k) clearance of the Cellvizio® 100 series F400 and F800 with a new Confocal MiniprobeTM, the CranioFlexTM, to be used during neurosurgical procedures. This marks the 15th U.S. FDA 510(k) clearance of Cellvizio® and the first- ever FDA clearance for CLE applications in neurosurgery.

Publication of a prospective multicenter study that demonstrates the potential of Cellvizio® to aid in the diagnosis of acute cellular rejection in lung transplant patients. Cellvizio's optical biopsy could become a safe and effective alternative to invasive biopsies in transplanted patients.

Publication in Surgical Endoscopy of the positive results of a prospective American multicentric clinical trial on the detection of Barrett's esophagus with Cellvizio®. This publication is additional validation of Cellvizio's superior sensitivity in the detection of Barret's esophagus compared to the standard protocol and the major progress that this represents in terms of identifying individuals at risk for esophageal adenocarcinoma.

The Company presents its Cellvizio need-based endomicroscopy for applications in lung cancer and other lung diseases during the European Respiratory Society (ERS) international congress, the largest gathering of lung disease specialists in the world, held in September in Paris.

First publication on the use of "Tele-Cellvizio" in vivo and in real time between surgeons and histopathologists. The results of the PERSEE trial

involving the teletransmission in real time and the robotic use of the Cellvizio miniprobe are published online in Surgical Endoscopy. Periooperative intraocular confocal endomicroscopy in real time with near-infrared illumination provides additional information in terms of tissue characterization and, in combination with in vivo telepathology, allows interactive collaboration between the surgeon and the histopathologist during surgical procedures.

The results of Contact 2 attained all its primary and secondary clinical evaluation criteria showing a higher diagnostic performance of Cellvizio than the technical standard of care for patient with pancreatic cystic lesions (PCLs). The study showed a very high sensitivity and specificity of the nCLE criteria for the specific diagnosis of single cystic tumors not connected to the pancreas. The systematic addition of the nCLE to standard procedures had a positive impact on therapeutic decisions and offers significant economic benefits for patients and hospitals.

Indebtedness

On May 29, 2019, the Company announced the subscription of a €5 million tranche from IPF Partners as part of the amendment to its debt agreement signed on November 13, 2018.

Following the financing agreement with the European Investment Bank (EIB), the Company received the first tranche of €11.5 million on 3 July 2019.

Tranche 1 is accompanied by the issuance of share subscription warrants (BSAs) entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of 5 October 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issue, less a 5% discount, i.e. €1.8856 per warrant. The warrants may be exercised from this day until the twentieth anniversary of the issuance of the warrants, i.e. 3 July 2039.

In addition, the Company redeemed the non-dilutive bond financing early with IPF Partners. The two bond tranches issued for €4.0 million and €5.0 million respectively in February 2017 and May 2019 were fully repaid on 28 June 2019 for a total amount of €10.7 million. The refinancing of this debt saves €2.0 million in interest over the next five years.

Reimbursement

Mauna Kea Technologies announced the reimbursement coverage of confocal laser endomicroscopy, specifically for Barrett's esophagus, through the creation of a new specific procedural code to be added to the Common Classification of Medical Procedures (CCAM) published in the Official Journal of the French Republic.

The tariffs reimbursed are as follows: 150€ for the endoscopist (Activity 1) and 69€ for anesthesia (Activity 4). This UNCAM's decision will take effect 30 days after its publication.

5.2. Investments

5.2.1. Principal investments made since 2016

Gross Investments (IFRS, in €K)	2018 Financial year 12 months Consolidated	2017 financial year 12 months Consolidated	2016 financial year 12 months Consolidated
Intangible assets	101	185	89
Property, plant, and equipment	1,153	542	427
Non-current financial assets	(5)	(24)	29
TOTAL	**1,249**	**703**	**545**

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 2018, 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, 2018, the investments made have been of the same kind and order of magnitude as those mentioned above during the 2016-2018 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
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 of tissue, or “optical biopsy”. The Company's flagship product, Cellvizio, has received clearance to sell for 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 mainly focuses its efforts on the American market where conditions have improved significantly, in particular due to the reimbursement of procedures in the upper digestive tract.

Furthermore, the implementation of our "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 underway. 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.

Below is a summary of the indications we cover, the confocal miniprobes suitable for these indications, the geographic areas in which we can market them and where we have secured reimbursement codes.

Route of access	Interventions	Interventions	Products	Geographic marketing areas (1) (2)	Geographic areas where repayment rights have been secured
Endoluminal	Digestive endoscopy	Biliopancreatic interventions	AQ-Flex 19	All countries except Korea, Australia & Canada	USA: Upper digestive tract including needle-based access to the pancreas
			CholangioFlex	All countries	Croatia: official rates
		Endoluminal interventions	ColoFlex UHD	All countries	Croatia: official rates
			GastroFlex UHD	All countries	USA: Upper digestive tract France: official rates Croatia: official rates
	Bronchoscopy	Pneumological interventions	AlveoFlex 19	Europe + United States	Croatia: official rates
	Urology	Interventions	CystoFlex F	All countries except Singapore & Taiwan	Croatia: official rates
			UroFlex B		
			CystoFlex UHD R	All countries except Israel, Singapore, China, Korea, Taiwan & Colombia	Croatia: official rates
Surgery	Surgery	Anti-reflux surgery	GastroFlex UHD	All countries	
	Laparoscopic surgery	Oncological surgery	CelioFlex UHD 5	Bangladesh + Chile + Europe + HK + India + USA	
		Urology surgery	CelioFlex UHD 5	Bangladesh + Chile + Europe + HK + India + USA	
		Other surgery	CelioFlex UHD 5	Bangladesh + Chile + Europe + HK + India + USA	
		Robotic surgery	CelioFlex UHD 5	Bangladesh + Chile + Europe + HK + India + USA	
	Neurosurgery	Neurosurgery	CranioFlex	USA only	
Other	Interventional 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, South Korea, Ecuador, Egypt, Europe (Bosnia, Bulgaria, Croatia, France, Greece, Italy, the Baltic Countries, Poland, Czech Republic, Romania, Scandinavia, Serbia), Hong Kong, India, Iran, Israel, Japan, Mexico, Pakistan, Peru, Russia, Singapore, Thailand, Turkey, Uruguay, USA, Venezuela, Yemen.
(2) Authorizations are in the process of being obtained 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 (9 to 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 minimally invasive and perfectly repeatable.
The Company has been awarded 236 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, Miniprobes 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, in particular 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 a large number of medical and surgical sectors in which tissue characterization is required. These include gastroenterology, urology, interventional pulmonology, and surgery. With the recent advent of its new extremely miniaturized (diameter < 1 mm) miniprobe that is able to penetrate a puncture needle, Cellvizio can now access inside organs of the human body and this opens up new possibilities of improved diagnosis for very important pathologies such as pancreatic cancer or lung cancer.

Cellvizio can be used in gastroenterology, pulmonology or urology, where only miniprobes 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, 2018, the Mauna Kea Technologies patents portfolio included 236 national and international patents granted. This policy of innovation and of protecting its intellectual property constitutes a significant barrier to entry for possible competitors. The Company continues to invest in R&D and will continue to maintain a dynamic patent filing policy.
(See Section 11 "Innovation, patents, licenses, trademarks and domain names".)

➢ Very rich and statistically significant clinical validation

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

[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 probe-based confocal laser endomicroscopy in a Barrett's esophagus Surveillance Program. Dig Dis Sci 2013; 58(1):188-93.

There are more than 1,000 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 2017, Dr. Bertrand Napoléon presented new results from the CONTACT clinical trial entitled "Needle-based confocal laser endomicroscopy: the impact on diagnosis and management of pancreatic cystic lesions". The CONTACT clinical trial involved 217 patients in five hospitals and clinics in France. These results followed those published in one of the Endoscopy medical journal's three most widely cited articles in 2016. The new results showed that the use of Cellvizio:

- changed 30% of diagnoses while significantly improving inter-observer agreement on diagnosis from 0.45 to 0.76 and increasing the number of diagnoses with a high degree of certainty from 57% to 79% of cases;
- changed 28% of therapeutic decisions on patients while significantly improving inter-observer agreement on these decisions from 0.36 to 0.64; avoided all forms of monitoring for 42% of patients with a benign cyst and changed the decision between monitoring and surgery for 15% of patients with precancerous lesions.

➢ Marketing authorization obtained

The Group has obtained fifteen 510(k) regulatory authorizations from the United States Food and 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 confocal miniprobes for laparoscopic surgery and interventional radiology, and in October 2015 and August 2017 FDA regulatory authorization in laparoscopic surgery including manual surgery and robotic-assisted surgery. The Group obtained regulatory authorization from the FDA in neurosurgery in 2018.

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 miniprobes 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 confocal miniprobes. They both concern all the current clinical indications covered by Cellvizio, except laparoscopy and interventional radiology: gastroenterology, including the AQ-Flex 19 miniprobe for pancreatic cysts, urology and pulmonology.

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

	Systèmes Cellvizio (1)		Bronchoscopie	Endoscopie Digestive				Urologie			Radiologie Interventionnelle	Chirurgie	
	-		Int. Pneumo.	Interventions endoluminales		Interventions bilio-pancréatiques		Interventions urologiques			Radio Int.	Chirurgie Laparoscopie	Neurochirurgie
	F400	F800	AlveoFlex	GastroFlex	ColoFlex	Cholangio-Flex	AQ-Flex	UroFlex B	CystoFlex F	CystoFlex UHD R	AQ-Flex IR	CelioFlex UHD S	CranioFlex
Europe	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Israel	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Kuwait	En cours		En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours	
Russia	Suspension temporaire		Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire			
Belarus	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Saudi Arabia	En cours		En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours			
Turkey	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Yemen	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Iran	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Pakistan	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Egypt	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Australia	✓		✓	✓	✓	✓	✓	✓	✓	✓			
China	✓		✓	✓	✓	✓	✓	✓	✓	En cours	En cours	En cours	
Hong-Kong	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
India	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Japan	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Korea	✓		✓	✓	✓	✓		✓	✓				
Singapore	✓		✓	✓	✓	✓	✓						
Taiwan	✓		✓	✓	✓	✓	✓						
Thailand	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Bangladesh	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Canada	✓		✓	✓	✓	✓		✓	✓	✓			
USA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Brazil	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Mexico	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Columbia	✓		✓	✓	✓	✓	✓	✓	✓				
Chili	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Venezuela	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Ecuador	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Peru	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Uruguay	✓		✓	✓	✓	✓	✓	✓	✓	✓			

(1) Les Cellvizio F400 et F800 sont différenciés par les longueurs d'onde qu'ils utilisent ; le F800 n'est commercialisable qu'en EU et USA

Légende

✓	Autorisation de commercialisation demandée et obtenue
En cours	Autorisation de commercialisation demandée et en cours de traitement
	Autorisation de commercialisation non demandée

➢ Reimbursement

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 for interpreting images obtained with endomicroscopy. Two of these codes are available to gastroenterologists, the third code was created for use by histopathologists. In early 2016, the American Medical Association (AMA) defined the coverage for procedures in pancreatic cysts and masses (needle-based confocal laser endomicroscopy – nCLE) by assigning one of the codes covering intervention in the upper digestive tract. In March 2015, the 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. This temporary code does not yet give rise to reimbursement.

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 rate also needs to be obtained, as well as payment by government insurers (including Medicare and Medicaid) 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 rate and arranged complete national medical coverage by Medicare/Medicaid and partial coverage by 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 respected 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 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) awarded an OPS code to confocal endomicroscopy. It appeared in the final 2014 list of OPS codes (Operationen- und Prozedurenschlüssel). The allocation and implementation of an OPS code allows the German health authorities to measure the volumes of procedures as well as the related costs of treatment, in order to propose a reimbursement. 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. In a decision dated April 18th 2019 and published in the Official Journal on June 14th 2019, the French National Association of Health Insurance Funds (UNCAM) created the following procedure, in sub-paragraph "07.01.09.01 - Endoscopy of the salivary glands and digestive tract" of Book II of the Social Security Code: "Esophageal endoscopy with confocal laser endomicroscopy-guided biopsy - Pre-therapeutic esophageal mapping with biopsy guided by confocal laser endomicroscopy"1. The tariffs reimbursed are as follows: 150 euros for the endoscopist (Activity 1) and 69 euros for anesthesia (Activity 4). This UNCAM's decision will take effect 30 days after its publication.

In September 2015, the HAS rejected the use of Cellvizio® for the characterization of biliary tract strictures. In the first quarter of 2017, the HAS concluded its review of the Group's last application, filed in 2010, to use Cellvizio® in the colon. The Group is now looking at submitting an application for the use of Cellvizio® in the pancreas.

Summary of reimbursements requested/obtained :

Country	Indication	Product	Competent authority	Year of submission	Description	Pricing
United States	Upper gastrointestinal tract, including access to the pancreas by fine needle	GastroFlex / AQ-Flex	American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS)	2012	Reimbursement code CPT 43206 (esophagus). Esophagoscopy with optical endomicroscopy. Came into force on 01 January 2013.	1483 USD for hospitals, 642 USD for ambulatory surgery centers and 141 USD for physicians (2019 Payment Rates issued by CMS).
		GastroFlex / AQ-Flex	American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS)	2012	Reimbursement code CPT 43252 (upper gastrointestinal tract). Esophagogastroduodenoscopy with optical endomicroscopy. Came into force on 01 January 2013.	2825 USD for hospitals, 1245 USD for ambulatory surgery centers and 178 USD for physicians (2019 Payment Rates issued by CMS).
		-	American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS)	2012	Reimbursement code CPT 88375 for optical endomicroscopic image(s), interpretation and report. Came into force on 01 Janvier 2013.	51 USD for physicians in 2019.
	Biliary ducts (ERCP)	CholangioFlex	American Medical Association (AMA) / Centers for Medicare & Medicaid Services (CMS)	2014	Reimbursement code CPT 0397T (biliary ducts). Endoscopic retrograde cholangiopancreatography (ERCP) with optical endomicroscopy. Came into force on 01 January 2016. Renewed for a period of 5 years.	Based on published rates.
France	Mapping of Barrett's esophagus	GastroFlex	French National Authority for Health (HAS) / National Association of Health Insurance Funds (UNCAM)	2010	Positive appraisal from the HAS to obtain reimbursement of the medical procedure in the mapping of Barrett's esophagus (17 September 2014).	The tariffs reimbursed are as follows: 150 euros for the endoscopist (Activity 1) and 69 euros for anesthesia (Activity 4). 69€ for anesthesia.
	Surveillance of scarred polyps in the colon after resection	ColoFlex	French National Authority for Health (HAS) / UNCAM	2010	No opinion will be released. This assessment has been removed from the HAS Work Program (Q1-2017).	N/A
	Characterization of biliary strictures	CholangioFlex	French National Authority for Health (HAS) / UNCAM	2010	Negative appraisal from the HAS to obtain reimbursement of the medical procedure (22 July 2015). Additional data are needed to provide evidence of the clinical utility of endomicroscopy in this indication.	N/A
Germany	Confocal endomicroscopy in the digestive tract	GastroFlex / CholangioFlex / ColoFlex	German Institute of Medical Documentation and Information (DIMDI)	2013	Code OPS 3-301 added in the medical nomenclature to report any endomicroscopy procedure in the digestive tract, including the biliary or pancreatic ducts. Came into force on 01 January 2014.	Insufficient volume of procedures for pricing and/or G-DRG reimbursement rates (InEK).
United Kingdom	Needle-based confocal laser endomicroscopy for characterising pancreatic cysts	AQ-Flex	National Institute for Health and Care Excellence (NICE)	2015	Negative appraisal from the NICE-MTEP (30 November 2015). Additional data are needed to provide evidence of the clinical utility of endomicroscopy in this indication. Publication of a technology assessment report (MIB) on 26 June 2016.	N/A
China	Endomicroscopy	GastroFlex / CholangioFlex / ColoFlex / AQ-Flex	Chinese Ministry of Health	2016	Pricing was obtained in several regions allowing hospitals to bill patients for the procedures.	Tariffs vary according to the regions.
Croatia	Confocal endomicroscopy	GastroFlex / CholangioFlex / ColoFlex / AlveoFlex / UroFlex / CystoFlex	Croatian Health Insurance Fund (HZZO)	2017	Cellvizio procedures are now covered for patients affected by gastrointestinal, biliopancreatic, respiratory and urinary diseases in the Clinical Hospital Centers.	Additional payments ranging from €250 to €800 according to the indication of the procedures.

The United States and Croatia are the only countries where the Group currently has reimbursement rates.

➢ Installed base of 631 systems sold

The Company chose rapid internationalization at the start of the marketing phase. The installed base of more than 631 systems 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).
Today, the target group is hospital centers specializing in digestive endoscopy, including Community hospitals with a strong activity around gastro-esophageal reflux as well as 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 three and four 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 Youhe Shanghai for gastroenterology and pulmonology applications in China.

The Company is actively searching for new partners to expand its markets and increase its income.
On the back of recent very positive changes in the United States, the Company decided to market its products and services there in the field of gastroenterology, its historic activity and source of the

lion's share of its income, through a direct sales force while continuing to explore potential strategic partnerships.
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 pulmonology in Europe and the United States.

In the EMEA zone at the end of 2018 the team comprised three people: A sales representative for Clinical Sales in northern France, in Belgium, Luxembourg and England. Another who covers southern France and southern Europe as well as an EMEA Sales Director who supervises our sales activities in German-speaking countries; Germany first and foremost. The rest of Europe, the APAC countries and the countries of Latin America are directly managed by the Vice President of International Sales. In total, four people

At the end of December 2018, the U.S. sales team had 20 members. The team is composed of two regional sales managers who oversee twelve sales managers and six clinical support managers. At the end of 2018 a sales director was being recruited to manage the sales teams.

Lastly, in China, development is led by a Business Manager assisted by a head of clinical and technical activities since April 2018.

Overall, at the end of 2018, the Group had a sales force of 26 people.

Main partnerships on priority commercial territories:

Partenariats	Siemens	Siemens	Cook Medical	Youhe	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)	Modele experimental	Cystoflex/Uroflex	Tout la gamme autorisee en Chine	Tout la gamme autorisee 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						

			Zones géographiques - Partenariats et distributeurs						
	Interventions	Produits	EMEA Vente directe: France, UK, Allemagne, Pays-bas, Belgique, Suisse	Vente indirecte: EMEA	Chine	Japon	APAC hors Chine	Etats-Unis	Amériques hors Etats-Unis
Endoscopie	Interventions bilio-pancréatiques	AQ-Flex / CholangioFlex	Direct	Distributeurs	Fujifilm	AMCO	Distributeurs	Direct	Distributeurs
	Interventions endoluminales	Gastro/Coloflex	Direct	Distributeurs	Fujifilm	AMCO	Distributeurs	Direct	Distributeurs
	Interventions pneumologiques	AlveoFlex	Direct	Distributeurs	Fujifilm	AMCO	Distributeurs	Direct	Distributeurs
	Interventions urologiques	UroFlex	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.
Chirurgies	Chirurgie anti-reflux	GastroFlex	-	-	-	-	-	Direct	-
	Chirurgie oncologique	CelioFlex	Direct					Direct	
	Chirurgie urologique	CelioFlex							
	Autres chirurgies	CelioFlex	Direct					Direct	
	Neurochirurgie	En cours		Siemens (investigation clinique)					
Autres voies d'abord	Radiologie interventionnelle	En cours	Siemens (investigation clinique) / Direct						
	Imagerie biomoléculaire	En cours		Essai clinique auprès de Cleveland Clinic (Etats-Unis) , UMCG (Netherland) et Royal infirmary Edinburgh					

Pas de commercialisation ou de partenariat en cours

➢ Conclusion: establish ourselves as the leader in in vivo microscopic imaging

There is no lack of clinical proof regarding the demonstrated contribution of microscopic real-time imaging in vivo. We have now been able to prove that it is possible to obtain reimbursement of these procedures in our priority market, the United States.
We are convinced that the entry of the microscope into the human body marks the advent of a new era of early diagnosis of cancers and other pathologies. Mauna Kea Technologies intends to continue to pursue an ambitious strategy to impose digital optical biopsy as a standard of care.

The Cellvizio value proposal can be applied to many medical sectors in which biopsies are performed. Today the Group continues its commercial strategy in the field of gastroenterology in the United States mainly and is actively studying new applications that will lead to significant market developments.

At the same time, the Research and Development team is continuing its efforts to improve its products and adapt them to other specialties as appropriate.

➢ Highlights of 2018

Cellvizio® obtains positive assessment from the Korean National Evidence-based healthcare Collaborating Agency (NECA).
Cellvizio® obtained a positive assessment from the NECA in March 2018. The safe and effective new technologies assessment committee for applications in the esophagus, stomach and bile ducts. The New Health Technology status enables specific reimbursement codes for Cellvizio® procedures in South Korea, third largest medical market in Asia.

Obtaining the first FDA authorization for confocal laser encomicroscopy applications with Cellvizio® in neurosurgery
In May 2018: Obtained U.S. Food and Drug Administration (FDA) 510(k) clearance of the Cellvizio® 100 series F400 and F800 with a new Confocal MiniprobeTM, the CranioFlexTM, to be used during neurosurgical procedures. This marks the 15th U.S. FDA 510(k) clearance of Cellvizio® and the first-ever FDA clearance for CLE applications in neurosurgery.

Clinical results and conferences – the value of optical biopsy

In April 2018, a new clinical study found that Cellvizio® demonstrates superior identification of patients at risk for esophageal cancer compared to the current diagnostic standard.
The results of the study of 172 patients recruited from 8 non-university centers in the United States were presented to the World Congress of Endoscopic Surgery jointly organized by the American Society of Gastro-Intestinal and Endoscopic Surgery (SAGES) and the Canadian Association of General Surgeons (CAGS).

During the same period, in vivo confocal laser endomicroscopy with Cellvizio® allows the discovery of a previously unknown human structure, the interstitium. The study conducted on the initiative of researchers who used Cellvizio® to characterize an unknown structure, the “interstitium”, up to now never identified by standard histological techniques. The article, titled "Structure and Distribution of unrecognized Interstitium in Human Tissue" was published in Nature Group’s Scientific Reports. According to the publication in Scientific Reports, this discovery may have significance in cancer metastasis and other diseases and could lead to new therapeutic approaches for cancer

In May 2018, 20 presentations focusing on Cellvizio’s clinical value were given at the DDW conference. These papers addressed several topics: Barrett’s esophagus, inflammatory bowel disease (IBD), irritable bowel syndrome, pancreatic cysts and other gastrointestinal diseases.

A multicenter prospective study was published in June 2018, demonstrating Cellvizio®’s potential in diagnosing acute cell rejection in patients with lung transplantation. Cellvizio’s optical biopsy could become a safe and effective alternative to invasive biopsies in transplanted patients.

In September 2018, the positive results of a US prospective multicenter clinical trial on the detection of Barrett's esophagus with Cellvizio® were published in Surgical Endoscopy. This publication is additional validation of Cellvizio's superior sensitivity in the detection of Barrett's esophagus compared to the standard protocol and the major progress that this represents in terms of identifying individuals at risk for esophageal adenocarcinoma.

In October 2018, new results of the PERSEE study on the use of Cellvizio in digestive surgery with live remote transmission to the pathologist were published in Surgical Endoscopy, the official journal of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). This scientific publication, entitled "Intraoperative confocal laser endomicroscopy for real-time in vivo tissue characterization during surgical procedures", reports the study results on 21 consecutive patients undergoing laparoscopic surgery at the Institut Mutualiste Montsouris (IMM) in Paris between 2014 and 2015. During this trial, endomicroscopic images were acquired using a robotic Confocal Miniprobe™, connected to a Cellvizio® system that enabled near-infrared illumination (at a wavelength of 785 nm). A live audiovisual transmission was established between the surgeon and the anapathology laboratory for the real-time interpretation of the optical biopsies by the pathologist, or "Télé-Cellvizio®". The perioperative performance of confocal laser endomicroscopy for the diagnosis of suspicious nodules was assessed using the corresponding surgical histopathology as a reference method.

In November 2018, the results of CONTACT 2, a large multicenter prospective validation study, having achieving its primary and secondary objectives, showed a significantly higher diagnostic performance of nCLE with Cellvizio® compared to standard care methods in patients with cystic lesions of the pancreas. The results were published in the article "Needle-based confocal laser endomicroscopy of pancreatic cystic lesions: a prospective multicenter validation study in patients with definite diagnosis", appearing in the peer-reviewed journal Endoscopy. The study showed a very high sensitivity and specificity of the nCLE criteria for the specific diagnosis of single cystic tumors not connected to the pancreas. It concluded that the systematic addition of the nCLE to standard procedures had a positive impact on therapeutic decisions and offers significant economic benefits for patients and hospitals.

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.

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 miniprobes;
- 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.

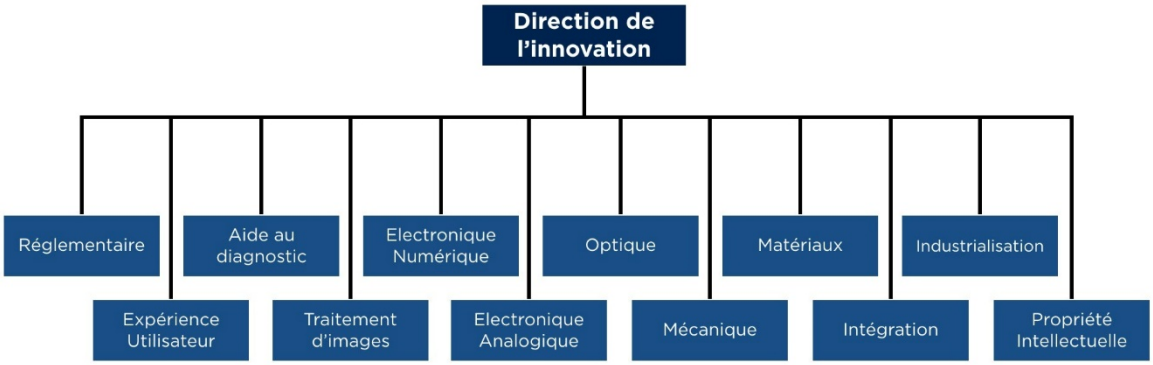
The quality of the study carried out upstream of the Cellvizio's design today enables Mauna Kea Technologies to have a technical platform adaptable for multiple applications with a marginal additional research and development investment.

● A High-Level Multidisciplinary Team

At the end of December 2018, the Research and Development team had 26 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.



- 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. The first 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. Another example is the collaboration with a team from University College in London (UCL), on the increase in Cellvizio image resolution, a collaboration financed by Mauna Kea Technologie through a thesis scholarship granted to that team.

- 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 the R&D department, the production team and the support team are organized;
- 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 the heads of product marketing their feasibility by the R&D teams.

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**

Within this mission, the Research and Development teams are working with product managers and clinical affairs managers to develop new products as part of the company's project management.

Some of the major projects currently under way are:

The new generation of Cellvizio, or **"GEN3**": this program aims to update Mauna Kea Technologies's offer, through new products developed around redesigned 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 is also an opportunity for the R&D Division to rethink the solutions offered by the Company to continue to reduce manufacturing costs while improving durability. This is cross-functional work that relates as much to the system (*capital equipment*) as the miniprobes themselves (the *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 and will be completed at the end of 2019. **"**PERSEE" is an industrial research and development project to develop a flexible, miniature and robotic endomicroscope designed for minimally invasive exploration of the abdominal cavity. The aim is to offer cancer patients the opportunity to select the best treatment strategy for them, whether that be 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 should be completed during 2019. 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 working together to prepare for the launch of the fourth phase, which began in 2016, for an initial period of two years. The Company is currently negotiating an extension of key Stage 4. 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.

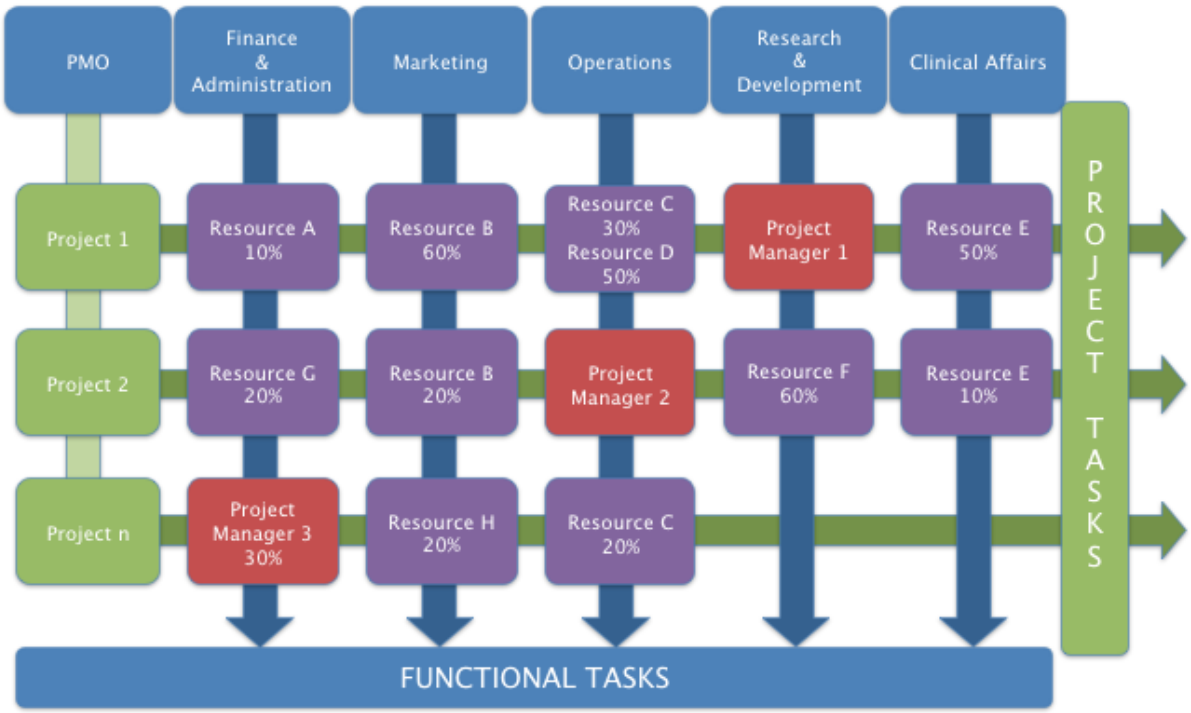
A technological and scientific “roadmap” is established and monitored regularly to ensure overall project coherence and phasing. A project is launched only once the three pillars, namely the expected objective, the calendar and the necessary resources, have been specified and validated. Project advancement 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.

In 2018, nine activities were managed in the form of transversal projects. Two projects were terminated, including one on the development of a new probe for neurology. Four new projects have been launched: two relating to the Company’s internal organization, and two on product developments or improvements.



6.3. Clinical, regulatory and reimbursement 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).

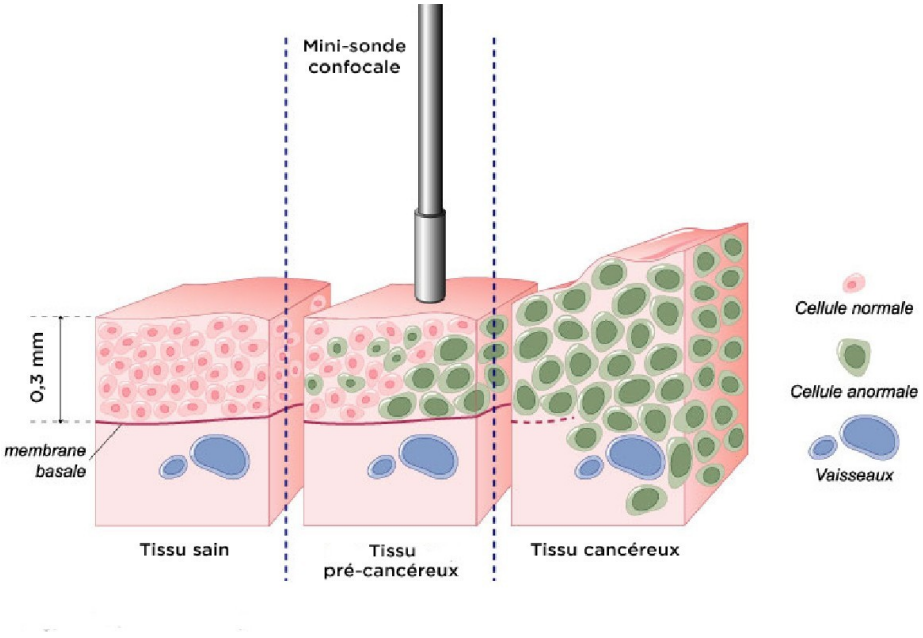


Diagram of cancer cell progression from the mucosa to the surface (progression invisible with endoscopy) and ability of Cellvizio miniprobe to image a precancerous zone.

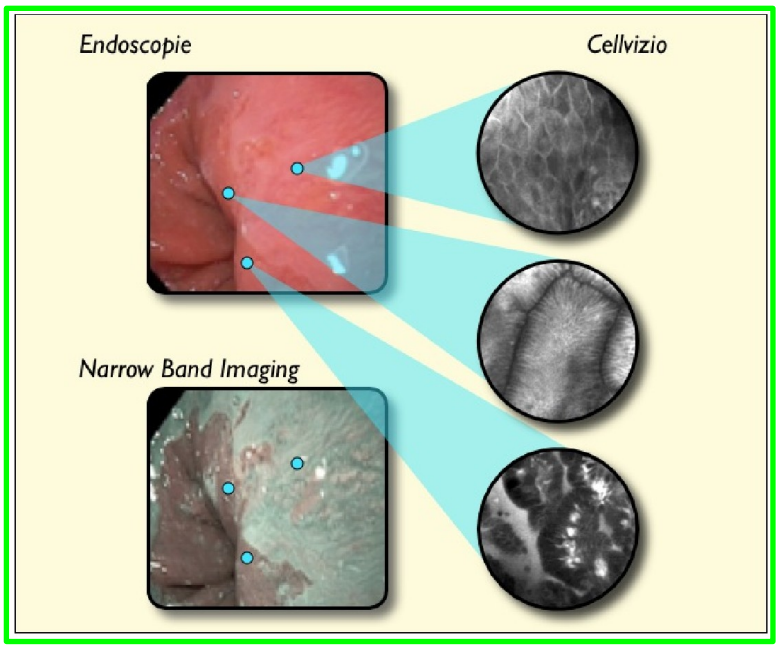
Using a camera located at the end of a flexible, articulated tube - an endoscope - the physician can identify lesions from which samples (biopsies) can be taken for histological confirmation of the macroscopic diagnostic impression.

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 of tissues. 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.

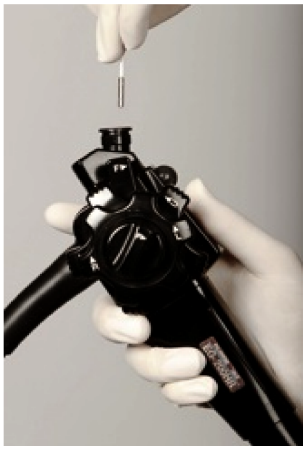
The diagram below shows the essential difference between a standard or improved endoscope and the Cellvizio. The slide on the left shows the macroscopic vision of esophageal mucosa with standard endoscopy, corresponding to actual size x4, and on the lower left with contrast enhancement (narrow band imaging, 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

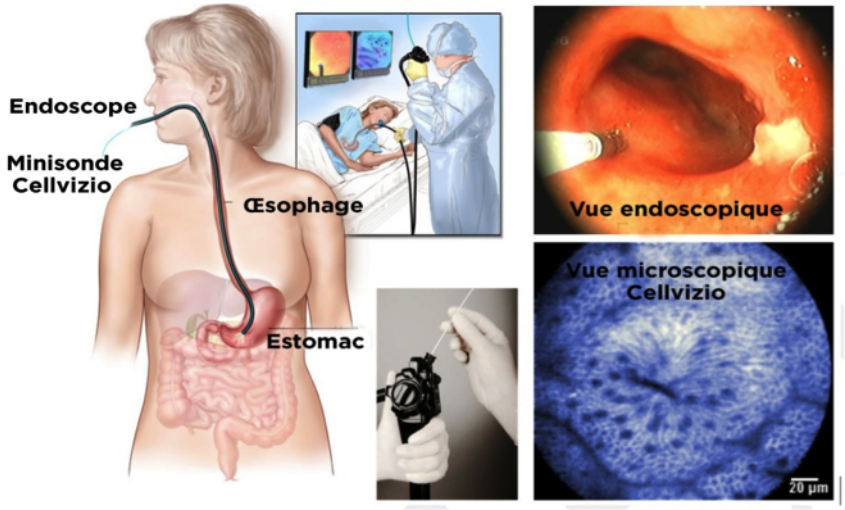
By bringing the microscope to the patient rather than taking a sample (biopsy) from the patient and putting it under a microscope, the Cellvizio combines all the key diagnostic steps in the endoscopic procedure. Indeed, for the first time, the clinician has pertinent real-time cellular information:

- 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,

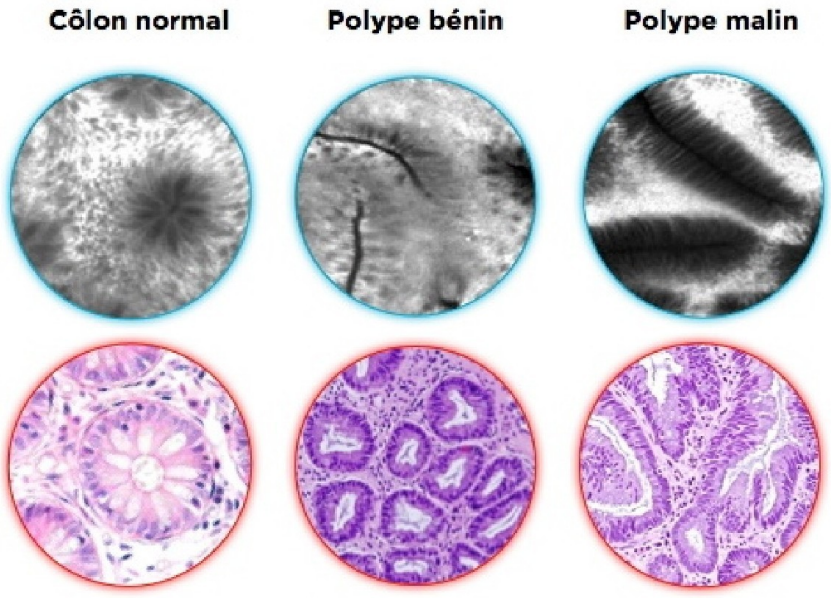
• attracting customers looking for better medical practices,

• optimized yield 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, pulmonology, 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 pulmonology was made.
To date, digestive pathologies accessible by endoscopy are still the indications in which Cellvizio is the most used and the most sold. The Company has obtained regulatory approvals and high level clinical evidence in other applications and is currently studying their potential. From among these, the exploration of the bronchi and targeting of peripheral nodules, potentially malignant, seems to be a very promising avenue. The applications in urology and neurosurgery are others.

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:

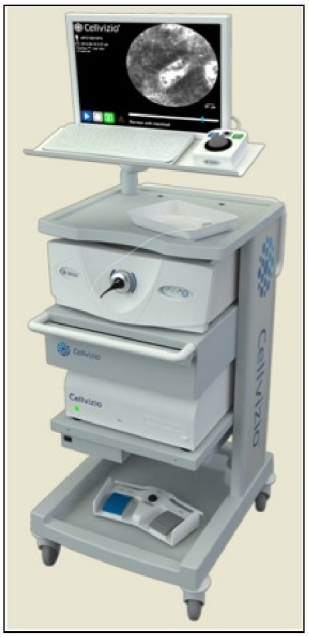
- AlveoFlex probe to access the pulmonary bronchi and alveoli,
- AQ-Flex probe for access to the peripheral nodules through transbronchial needles;

➢ for urological applications:

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

➢ for digestive surgery applications:
- CelioFlex probe for laparoscopy (except for the reproductive organs);

➢ for interventional radiology applications:
- AQ-Flex IR probe.



Unité centrale

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

Example de packaging de mini-sonde

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

During use, the miniprobes must be connected to the Laser Scanning Unit and then inserted into the operating channel of the endoscope like a biopsy forceps would be, for example, to provide the *in vivo* fluorescence microscopic imaging during the endoscopy procedure. They are fully compatible with all the standard equipment being used in endoscopy rooms and, unlike traditional endoscopy, provide deep (up to 150 µm) observation of the mucosa, 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 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 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 1,000 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 in certain countries. 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 (AMA) 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 (CAP) 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 enables 100% of residual lesions to be correctly identified (Shahid et al., Diagnostic accuracy of probe-based confocal laser endomicroscopy in detecting residual colorectal neoplasia after EMR: a prospective study. Gastrointest Endosc. March 2012).

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

Chronic inflammatory bowel diseases

Various studies have shown that Optical Biopsy can be used on patients with inflammatory bowel disease (IBD) to go beyond clinical symptoms by assessing the state of the mucosa at the microscopic level and recommending a suitable treatment protocol. Endoscopic Confocal Microscopy (ECM) was assessed at various stages of the disease in order to:

- identify patients with IBD[5];
- identify patients responding to initial treatment[6,7];
- make aftercare more efficient in terms of dose and duration by:
    - assessing the disease's progression and the patient's response to treatment at the cellular level[8],
    - identifying patients in remission via mucosa scarring[9],
    - anticipating relapses5;
- Detect precancerous lesions and differentiate between Dysplasia Associated Lesion or Mass (DALM) and Adenoma-like Mass (ALM[10,11]).

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.

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[5] Hundorfean G. et al. Confocal Laser Endomicroscopy Provides Potential Differentiation Criteria Between Crohn's Disease and Ulcerative Colitis. Inflammatory Bowel Disease, 2012.
[6] Kiesslich R. et al. Local Barrier Dysfunction Identified by Confocal Laser Endomicroscopy Predicts Relapse in Inflammatory Bowel Disease. Gut, 2012.
[7] Neumann H. et al. Assessment of Crohn's Disease Activity by Confocal Laser Endomicroscopy. Inflammatory Bowel Disease, 2012
[8] Liu J. et al. Increased Epithelial Gaps in the Small Intestines of Patients with Inflammatory Bowel Disease: Density Matters. Gastrointestinal Endoscopy, 2011.
[9] Kiesslich R. et al. Local Barrier Dysfunction Identified by Confocal Laser Endomicroscopy Predicts Relapse in Inflammatory Bowel Disease. Gut, 2012
[10] Kiesslich R. et al. Chromoscopy-Guided Endomicroscopy Increases the Diagnostic Yield of Intraepithelial Neoplasia in Ulcerative Colitis. Gastroenterology, 2007
[11] De Palma G.D. In-vivo Characterization of DALM in Ulcerative Colitis with High-Resolution Probe-based Confocal Laser Endomicroscopy. World Journal of Gastroenterology, 2011.

Other characteristic signs of malignant lesions that are equally specific were presented at UEGW in 2016 and published in 2018 in the endoscopy journal(mucinous cysts and intraductal papillary mucinous tumors of the pancreas). Following these very promising results, new findings presented by Dr. Bertrand Napoléon at the United European Gastroenterology Week (UEGW) in October 2017 showed that the use of Cellvizio:

- changed 30% of diagnoses while significantly improving inter-observer agreement on diagnosis from 0.45 to 0.76 and increasing the number of diagnoses with a high degree of certainty from 57% to 79% of cases;
- changed 28% of therapeutic decisions on patients while significantly improving inter-observer agreement on these decisions from 0.36 to 0.64; avoided all forms of monitoring for 42% of patients with a benign cyst and changed the decision between monitoring and surgery for 15% of patients with precancerous lesions.

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.

Pneumonology

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 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. In May 2017, new data demonstrating the applicability of Cellvizio in assessing acute lung rejection following transplant were presented at the American Thoracic Society's (ATS) international conferencce in 2017. Lead investigator Dr. Cesar A. Keller of Mayo Clinic (Jacksonville, Florida) gave an oral presentation of the clinical study called "Probe-Based Confocal Laser Endomicroscopy in the Diagnosis of Acute Lung Rejection: Results of a Prospective Multicenter Trial". The key findings of the trial were as follows:

- In a follow-up examination of 24 lung transplant patients (16 double and 8 single), Cellvizio imaging was obtained immediately before the biopsy and the images were blindly reviewed by four pulmonologists (one expert and three junior CLE readers), first independently and then after a consensus meeting;
- reproducibility was assessed by calculating the intraclass correlation coefficient (ICC) and Fleiss' kappa and was found to be 0.77 and 0.39 before the consensus meeting and 0.96 and 0.77 after the consensus meeting respectively ($P<0.001$);
- The trial concluded that perivascular cellularity observed with Cellvizio was a feasible and reproducible criterion to assess acute lung rejection *in vivo* even if at this stage, it required a substantial learning curve for image interpretation.

Dr. Keller stated that probe-based endomicroscopy was a potential new tool for providing a less invasive diagnosis of acute lung rejection for transplant patients needing trans-bronchial biopsies. The results of the trial suggested that endomicroscopy could possibly spare patients unnecessary and risky invasive biopsies. He indicated his intention to continue studying this particular application of endomicroscopy in order to improve the therapeutic continuum for lung transplant patients.

This study was also published in the journal "Transplantation" 12.

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 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. ECM is also mentioned in the latest recommendations of the EAU (European Association of Urology) for its potential in diagnosing urothelial tumors13. [13]. Bigger trials are currently in progress to validate this preliminary data.

[12] Transplantation. Feb. 2019;103(2):428-434. doi: 10.1097/TP.0000000000002306. Diagnosis of Acute Cellular Rejection Using Probe-based Confocal Laser Endomicroscopy in Lung Transplant Recipients: A Prospective, Multicenter Trial.Keller CA(1), Khoor A(2), Arenberg DA(3), Smith MA(4), Islam SU(5).
[13] Eur Urol. Jan. 2018;73(1):111-122. doi: 10.1016/j.eururo.2017.07.036. Epub Sep. 1, 2017. Urology Guidelines on Upper Urinary Tract Urothelial Carcinoma: 2017 Update. Rouprêt M(1), Babjuk M(2), Compérat E(3), Zigeuner R(4), Sylvester RJ(5), Burger M(6), Cowan NC(7), Gontero P(8), Van Rhijn BWG(9), Mostafid AH(10), Palou J(11), Shariat SF(12).

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 Cellvizio, was completed at the end of 2015. It 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 started in 2017 and continued in 2018

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;
- traceability, particularly in the context of materiovigilance and proper use;
- relations with health professionals;
- the environment, etc.

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 and ISO 13485:2012 (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 electrics (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 subject to obtaining an approval issued by the Food and Drug Administration (FDA).

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, in 2016 the FDA granted 510(k) authorization for laparoscopic surgery (K160416) and in 2017 for robotic-assisted laparoscopic surgery (K171345).

Following further applications, 510(k) authorization was granted in 2017 by the FDA to visualize and identify cells and vessels and their organization or architecture (K172844). The FDA thus recognized the findings of various studies published that the Cellvizio® series 100 technology and all of its probes make it possible to visualize the internal microstructure of tissues and among other things identify cells and vessels and their organization or architecture. The addition of "cell and vessel identification and their organization or architecture" to the scope of previous approvals (in gastroenterology[14], urology[15] and [16]pulmonology16 during endoscopic, laparoscopic [manual and robotic-assisted] and percutaneous guided imaging surgeries) is a major step for real-time in situ microscopic observation.

[14] http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/WebContent/pdf/in-vivo-executive-summary.pdf
Wallace, M., Lauwers, G., Chen, Y., Dekker, E., Fockens, P., Sharma, P., & Meining, A. (2011). Miami classification for probe-based confocal laser endomicroscopy. *Endoscopy*, *43*(10), 882–891. https://doi.org/10.1055/s-0030-1256632
[15] Chen, S. P., & Liao, J. C. (2014). Confocal Laser Endomicroscopy of Bladder and Upper Tract Urothelial Carcinoma: A New Era of Optical Diagnosis? *Current Urology Reports*, *15*(9). https://doi.org/10.1007/s11934-014-0437-y

The Company also has "accession numbers" used for customs release for systems sent to the United States. Two FDA inspections of the Group's production site, intended to check that the quality system complies with 21 CFR 820 requirements, took place in January 2014 and May 2018.

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) to which 54 countries belong. 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. An audit by South Korea of the Group's manufacturing site, in order to monitor the compliance of the Company's quality system with the Korean regulatory requirements, also took place in February 2018.

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. Annual audits were carried out on the Group's manufacturing site, to verify the compliance of the Company's quality system with the regulatory requirements of Brazil. The last audit took place in March 2018.

Japan

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

[16] Thiberville, L., Salaun, M., Lachkar, S., Dominique, S., Moreno-Swirc, S., Vever-Bizet, C., & Bourg-Heckly, G. (2009). Human in vivo fluorescence microimaging of the alveolar ducts and sacs during bronchoscopy. *European Respiratory Journal*, *33*(5), 974–985. https://doi.org/10.1183/09031936.00083708

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 pulmonology.

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)

	Systèmes Cellvizio (1)		Bronchoscopie	Endoscopie Digestive				Urologie			Radiologie interventionnelle	Chirurgie	
	-		Int. Pneumo.	Interventions endoluminales		Interventions bilio-pancréatiques		Interventions urologiques			Radio Int.	Chirurgie Laparoscopie	Neurochirurgie
	F400	F800	AlveoFlex	GastroFlex	ColoFlex	Cholangio-Flex	AQ-Flex	UroFlex B	CystoFlex F	CystoFlex UHD R	AQ-Flex IR	CelloFlex UHD 5	CranioFlex
Europe	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Israel	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Kuwait	En cours		En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours	
Russia	Suspension temporaire		Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire	Suspension temporaire			
Belarus	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Saudi Arabia	En cours		En cours	En cours	En cours	En cours	En cours	En cours	En cours	En cours			
Turkey	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Yemen	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Iran	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Pakistan	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Egypt	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Australia	✓		✓	✓	✓	✓	✓	✓	✓	✓			
China	✓		✓	✓	✓	✓	✓	✓	✓	En cours	En cours	En cours	
Hong-Kong	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
India	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Japan	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Korea	✓		✓	✓	✓	✓		✓	✓				
Singapore	✓		✓	✓	✓	✓	✓						
Taiwan	✓		✓	✓	✓	✓	✓						
Thailand	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Bangladesh	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Canada	✓		✓	✓	✓	✓		✓	✓	✓			
USA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Brazil	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Mexico	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Columbia	✓		✓	✓	✓	✓	✓	✓	✓				
Chili	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Venezuela	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Ecuador	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Peru	✓		✓	✓	✓	✓	✓	✓	✓	✓			
Uruguay	✓		✓	✓	✓	✓	✓	✓	✓	✓			

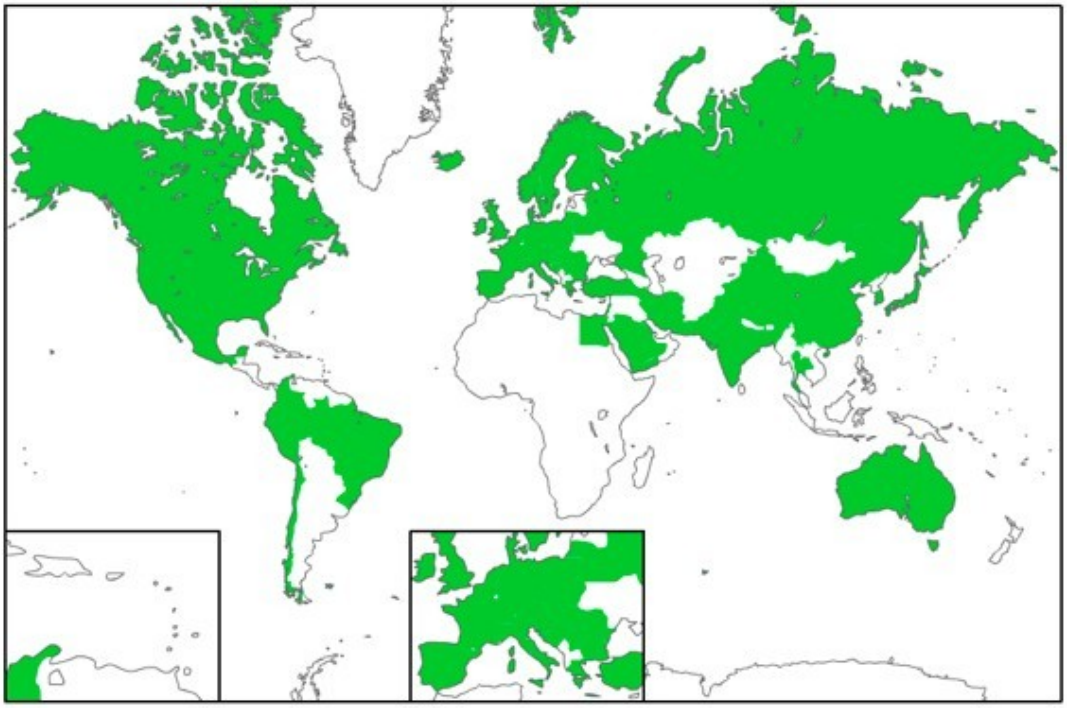
(1) Les Cellvizio F400 et F800 sont différenciés par les longueurs d'onde qu'ils utilisent ; le F800 n'est commercialisable qu'en EU et USA

Légende

✓	Autorisation de commercialisation demandée et obtenue
En cours	Autorisation de commercialisation demandée et en cours de traitement
	Autorisation de commercialisation non demandée

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 which was reviewed and extended during 2018.
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 (e.g. REACH, ROHS, WEEE) 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).

The 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 reimbursement for the Cellvizio® for its main clinical indications.
Accordingly the Reimbursement and Market Access team is working in close collaboration with Clinical & Regulatory Affairs and Marketing & Sales (plus local distributors if necessary), as well as external resources dedicated to the United States, in order to draw up and implement the plan for access to reimbursement in 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 (CAP) to interpret images obtained with confocal endomicroscopy.

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 (ASC). 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 United States. It was increased slightly in 2018 and has remained the same in 2019.

In March 2015, the American Medical Association (AMA) assigned a fourth CPT code linked to the use of endomicroscopy in endoscopic retrograde cholangio-pancreatography procedures (ERCP), an application 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 category III code went into effect in January 2016.

In early 2016, a new milestone was reached when the AMA defined the coverage for procedures in pancreatic cysts and masses (needle-based confocal laser endomicroscopy – nCLE) by assigning one of 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. So far results have been convincing with several insurers announcing 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). 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 Union of Digestive Tract Physicians (SYNMAD) approached the French national health insurance office (UNCAM) which is in charge of studying the scope of applications accepted for reimbursement and the treatment rates. In 2016, representatives from the French National Hepato-Gastroenterology Association (CNP HGE) and the French Digestive Endoscopy Society (SFED) held talks with the French Department for Healthcare Provision (DGOS) on the conditions under which said procedure would be approved and on the official rates set within health care institutions. In a decision dated April 18th 2019 and published in the Official Journal on June 14th 2019, the French National Association of Health Insurance Funds (UNCAM) created the following procedure, in sub-paragraph "07.01.09.01 - Endoscopy of the salivary glands and digestive tract" of Book II of the Social Security Code: "Esophageal endoscopy with confocal laser endomicroscopy-guided biopsy - Pre-therapeutic esophageal mapping with biopsy guided by confocal laser endomicroscopy".

In September 2015, the HAS rejected the use of Cellvizio® for the characterization of biliary tract strictures. In the first quarter of 2017, the HAS concluded its review of the Group's application to use Cellvizio® in the colon. The Group plans to submit a new application for uses in the pancreas and is checking the technical feasibility of an application.

- In Germany

In 2013, an OPS (Operationen- und Prozedurenschlüssel) code was created to document endomicroscopy procedures in the digestive tract, and confocal 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). The allocation and implementation of an OPS code allows the German authorities to measure volumes of procedures as well as the related costs of treatment.

- In Croatia

Since June 2017 the Croatian Health Insurance Fund, which manages Croatia's universal healthcare system, has reimbursed a series of endomicroscopy procedures using Cellvizio® for patients with gastrointestinal, biliopancreatic, respiratory and urinary disorders with reimbursements ranging from €250 to €800. This new coverage shows that various national healthcare systems throughout the world are beginning to recognize the benefits of technology.

In other countries where Mauna Kea Technologies markets the Cellvizio®, efforts are underway to prepare and/or follow up on requests for coverage, notably in the United Kingdom and South Korea. It is interesting to note that in China and Ecuador, there are regional codes for using the Cellvizio®.

- In the United Kingdom

In June 2016, the National Institute for Health and Care Excellence (NICE) published a technological assessment report on the use of Cellvizio® on the pancreas. No immediate recommendation is expected.

- In South Korea

In March 2018, Cellvizio® obtained a positive assessment from the Korean National Evidence-based healthcare Collaborating Agency (NECA). Laser confocal endomicroscopy is recognized as a safe and effective method that can help identify cancerous lesions and target biopsies for patients with suspected dysplasia in the esophagus, stomach, and stenosis of the biliary ducts. This status allows Cellvizio® to be eligible for reimbursement with specific codes, after the decision was made by the Korean Health Insurance Review and Assessment Service (HIRA).

6.4.Marketing and market

6.4.1.Marketing strategy and actions

Since the beginning of 2017, the Company has dedicated a significant portion of its commercial resources to the development of the gastroenterology market in the United States, which it addresses today with a dedicated sales team.
The other target market today is China, for which the Company has a regional distribution partner, Youhe Medical, and dedicated resources.

The elements described below correspond to the Company's organization at the end of 2018.
The Marketing and Product department

With 8 employees, including 3 based in the United States and one in Asia, the Marketing department develops and implements the Group's marketing strategy.

The Marketing department is organized into several areas:

- the Product (upstream marketing);
- lead generation;
- downstream marketing;
- communication and digital marketing;
  key account management, which is dedicated to partner support and development.

Lead generation

Providing sales representatives with a steady stream of new and solid leads is essential to growth.

This is the LeadGen team's goal, using several tools to meet its targets, such as buying databases, inbound marketing and event marketing.

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.
The department is responsible for monitoring the market and customers in order firstly to select the best projects in terms of return on investment and secondly to draft the corresponding functional specifications and monitor technical development efforts.
Once the products are developed, the product management team is responsible for launching them worldwide and providing backing sales support. It is also responsible for the educational and applicational part for each indication.

This includes educating new and potential users through training and educational activities to the physicians among them. The product marketing division monitors users' progress to ensure that they learn quickly.

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

Cellvizio is used via the operating channel of most flexible endoscopes available on the market. However, the Cellvizio does not compete directly with existing product lines in the flexible endoscopy market. Rather than compete with the flexible endoscopy market, the Cellvizio complements existing devices.

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.

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

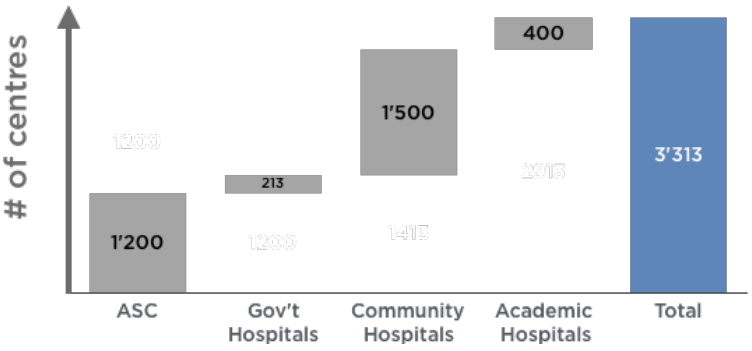
Mauna Kea Technologies' main target in the United States during the next few years includes community hospitals and Ambulatory Surgery Centers.

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 Hospitals 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[17]	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.statista.com/statistics/279322/number-of-hospitals-in-china/
Source: WHO, European Health for All Database, 2007

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.

[17] Source: http://dcc2.bumc.bu.edu/RussianLegalHealthReform/ProjectDocuments/n970.IIIE1.Analysis.pdf

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.

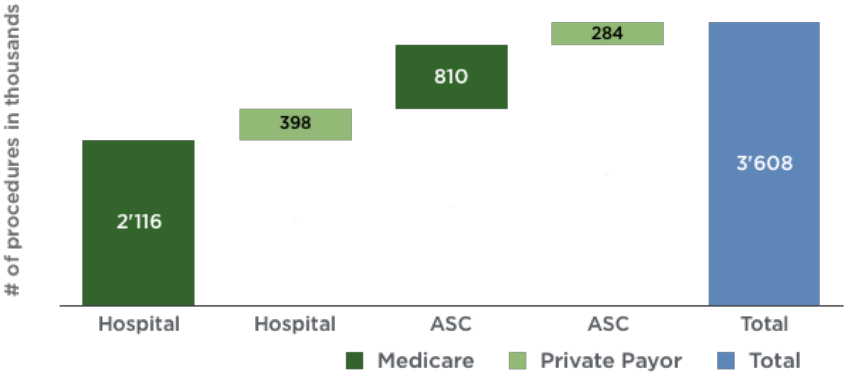
Endomicroscopy is a medical procedure separate from the endoscopy procedure during which it takes place. The Cellvizio's compatibility with the endoscopes and endoscopic tools on the market enables the miniprobe endomicroscopy (with the Cellvizio) to be performed during an endoscopy procedure in order 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'18s 3.6 esophagus, i.e. 3.6 million people, and that 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. November 2012; 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.

18 Source: Gastroenterology – Dec 2005 – Ronkainen et Al

Monitoring colorectal mucosectomy

The number of colonoscopies carried out per year in the United States is growing constantly and is currently around 14.2 million.[19] 60% of colonoscopies are carried out in hospitals as opposed to ambulatory surgical centers, which represent 40% of colonoscopies.[20] 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 Cellvizio.

Pancreatic cysts

From 3 to 10% of the American population has a pancreatic cyst, equivalent to several million patients.21 Today, an estimated 120,000 new cysts are identified each year.22 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), a figure of 50,000 procedures a year in which the Cellvizio could be used to characterize a pancreatic cyst may be reached.

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.

Mauna Kea Technologies has, however, done a strategic repositioning by focusing on the one hand on purely translational preclinical applications (i.e. with short- and medium-term scope in the clinical field) and at the same time by launching a specific program dedicated to clinical applications of optical molecular imaging clinics that are growing rapidly and are an integral part of the incredible emergence of Precision or Customized Medicine techniques.

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

[20] *Source: http://advancingsurgicalcare.com/index.cfm/news/ambulatory-surgery-center-industry-applauds-new-measure-improving-patient-access-to-colorectal-cancer-screenings/*
http://advancingsurgicalcare.com/index.cfm/news/ambulatory-surgery-center-industry-applauds-new-measure-improving-patient-access-to-colorectal-cancer-screenings/

[21] *http://www.ncbi.nlm.nih.gov/pubmed/24091499*

[22] *http://gi.org/guideline/diagnosis-and-management-of-neoplastic-pancreatic-cysts/ and http://www.cdc.gov/nchs/fastats/hospital.htm*

With its unique approach, Mauna Kea Technologies brings to this new market excellent proposals for well-identified and recognized values for the majority of key players. The know-how from both preclinical molecular imaging and in vivo patient histology in a variety of therapeutic areas will make the Cellvizio technique an essential pillar of image-guided precision therapies; the latter can be for example extremely precise image-guided surgery, targeted deposits of therapeutic molecules, or measurements by endomicroscopic imaging of responses of a given patient to micro-doses of drugs to predict the efficacy of the treatments considered. All these applications have been tested in clinical trials including Cellvizio and will constitute important segments for development for Mauna Kea Technologies in the coming years.

6.4.4. Competition

Optiscan/Pentax

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

Owing to a lack of adequate performance (image cadence too slow, diameter too large and rigidity too great), the clinical and commercial development of this system has not met Optiscan's expectations; the company has not been able to finance it themselves and in fact suffered heavy losses (source*:* Optiscan Annual Report 2013). Today, Optiscan has no more agreement with Pentax (since July 2009), which has interrupted the marketing of the product derived from the 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.

Optiscan / Zeiss

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

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

NinePoint Medical

NinePoint 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. 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 benefits of Nvision have thus not yet been demonstrated, even if the procedures may theoretically be reimbursed with the same CPT codes as Cellvizio® (source: NvisionVLE® Imaging System - NinePoint Medical website).

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 pulmonology sectors, in 2013, it obtained marketing agreements for a range of miniprobes 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.

Interventional pulmonology Market

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

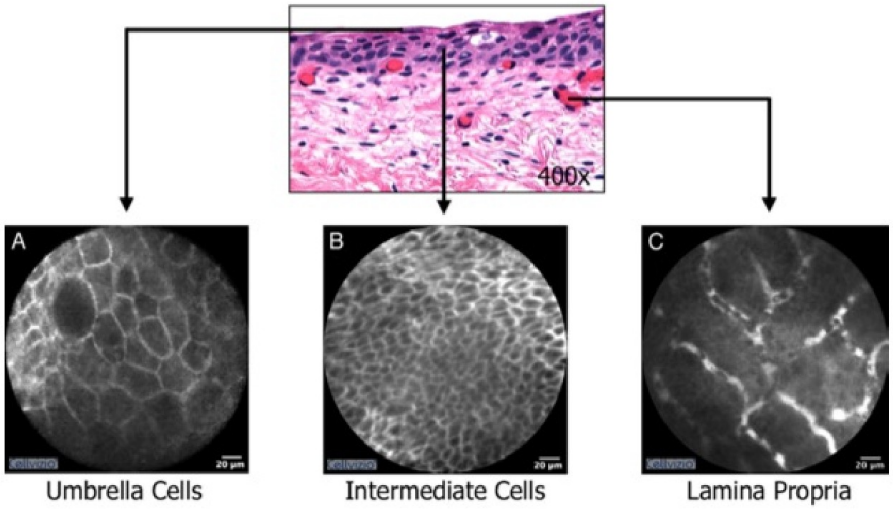
Once the patient exhibits symptoms, the disease is generally quite advanced at the time it is diagnosed and the vital prognosis is quite critical. Most often, however, a peripheral nodule (a small mass, either benign or malignant) is found in the lungs during a routine exam, like a CT scan. The problem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

Several techniques can be used to characterize a pulmonary mass. The most effective, when possible, consists in physically sampling a piece of tissue from the nodule, either via a biopsy through a bronchoscope, sometimes equipped with an electromagnetic navigation device in the pulmonary tract, or by taking a transpleural biopsy with external access. In the first case, the procedure is low risk but the current diagnostic performance of these procedures is low due to sampling errors. In the second case (trans-thoracic access), the procedure is complex for the patient, since it is very invasive, and in the end it is not used much. With the advent of new robotic navigation systems, Cellvizio could make it possible to guide this procedure by inserting the AQ-Flex probe in a transbronchial needle to take biopsies with good diagnostic information, thus improving the efficacy of the procedure and giving the patient faster access to treatment if needed. The recent studies published by the group of Prof. Annema in Amsterdam are in line with this very strong value proposal.

An AlveoFlex confocal miniprobe being inserted into a bronchoscope.

The bronchoscopy market is very similar to the digestive endoscopy market with regard to medical equipment: all healthcare facilities that have an endoscopy unit with 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 is estimated at about 500,000 exams per year in the United States with more than 240 biopsies taken per year. These figures are constantly increasing. This volume, although less than that of digestive endoscopy, is reflected in a potential of several hundred thousand Cellvizio procedures in the pulmonology field, and the associated renewal of several tens of thousands of Confocal Miniprobes per year. Source: Center 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 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.

Cellvizio can be used during diagnostic and therapeutic cystoscopy procedures, as shown by several studies by Prof. Liao of the VA Hospital of Palo Alto (source: Interobserver Agreement of Confocal Laser Endomicroscopy for Bladder Cancer, The Journal of Urology, doi: 10.1089/end.2012.0549, May 2012). Clinical work is in progress to confirm this American data with European results. 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 2018, 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

Since the beginning of 2017, the Company has dedicated a significant portion of its commercial resources to the development of the gastroenterology market in the United States, which it addresses today with a dedicated sales team.
The other target market today is China, for which the company has a regional distribution partner, Youhe Medical, and dedicated resources.

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 2018, earnings through sales of equipment represented 40% of the total sales, with consumables representing 42% and services 18%. 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 stable at €103 thousand in 2018 and 2017. The average sale price of the probes was €6.0 thousand in 2018 and €4.0 thousand in 2017.

In units, the Group sold 26 systems in 2018 against 30 in 2017, and 465 probes in 2018 against 487 in 2017. The Group also placed 55 systems on consignment in 2018 versus 13 in 2017, and replenishment and pay-per-use probes increased from 491 in 2017 to 594 in 2018.

The gross margin recorded for equipment and probes increased slightly. It can vary strongly from one region to another. Overall, for all regions and equipment, it was 70% in 2018, against 68% in 2017 and 69% in 2016.

On the date this Registration Document, the Group had an installed base of 631 units, mainly resulting from equipment sales and, to a far lesser extent, the provision of equipment (fewer than 70 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 uses a sales team based in Paris, assisted by a network of distributors in a certain number of countries, and provides direct marketing in others.

A direct approach in the United States and in France

In these two countries, where the direct approach has priority, the Group has 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 2018 the team consisted of four people.

At the end of December 2018, the US sales team was comprised of 20 people.

A US Director of Sales was being recruited at the end of 2018 to manage sales in the United States.

Finally, in China, the team is composed of two people: a Business Manager and a clinical and technical manager.

In all, the Group had a sales force of 26 people at the end of 2018.
Since 2017, the Company intends to start offering its US 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 chosen in particular to be very active in the main countries of the European Union and Asia – especially China. 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 40 distributors, who have exclusivity in their commercial area. It is under the responsibility of the EVP of Sales & Marketing, USA.
This person is tasked with 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, 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.

As well as providing support for distributors, the Global Sales 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.

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

In early 2016, the sales force in the USA was reorganized into two Eastern and Western divisions.

At the end of 2017 and in early 2018, new sales representatives were recruited to develop the business in the United States.

This sales force is under the direct responsibility of two Regional Sales Managers and a Vice President of Sales who reports directly to the Chief Executive Officer.

4) The impact of "Obama Care" (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 and in 2018 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 strategies

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 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.

In 2017, the Company entered into a distribution agreement with Youhe Shanghai Medical Technology Co. Ltd with the aim of reviving sales of Cellvizio in China.

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.

Main partnerships on priority commercial territories:

Partenariats	Siemens	Siemens	Cook Medical	Youhe	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)	Modele experimental	Cystoflex/Uroflex	Tout la gamme autorisee en Chine	Tout la gamme autorisee 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						

			Zones géographiques - Partenariats et distributeurs						
	Interventions	Produits	EMEA ventes directes	EMEA Ventes indirectes	Chine	Japon	APAC hors Chine et Japon	Etats-Unis	Amériques hors Etats-Unis
Endoluminal	Interventions bilo-pancréatiques	Aq-Flex / CholangioFlex	Direct	Distributeurs	Youhe	Amco	Distributeurs	Direct	Distributeurs
	Interventions endoluminales	Gastro/Coloflex	Direct	Distributeurs	Youhe	Amco	Distributeurs	Direct	Distributeurs
	Interventions pneumologiques	AlveoFlex/Aq-Flex	Direct	Distributeurs	Youhe	Amco	Distributeurs	Direct	Distributeurs
	Interventions urologiques	UroFlex	Cook Medical Inc.	Cook Medical Inc.	Youhe	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.	Cook Medical Inc.
Chirurgies	Chirurgie anti-reflux	GastroFlex	-	-	-	-	-	Direct	-
	Chirurgie oncologique	CelioFlex	Direct					Direct	
	Chirurgie urologique	CelioFlex							
	Autres chirurgies	CelioFlex	Direct					Direct	
	Neurochirurgie	En cours		Siemens (investigation clinique) / Direct					
Autres indications	Radiologie interventionnelle	En cours	Siemens (investigation clinique) / Direct						
	Imagerie biomoléculaire	En cours	Siemens - Essai clinique auprès de Cleveland Clinic (Etats-Unis) , UMCG (Netherland) et Royal infirmary Edinburgh						
							Pas de commercialisation ou de partenariat en cours		

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 miniprobes, the Company decided to subcontract the manufacture of certain models of miniprobes 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 miniprobes from a supplier who is an expert in optical fiber and precision optical assembly. Complete validation of this subcontracting was finalized early in 2013 so that the Group can now pass part of its miniprobe production to this partner, thus ensuring a growth in productivity without further investment. In 2014, this procedure was extended to other stages of miniprobe production. At the end of 2016, the Company had finalized the transfer of the assembly of a new miniprobe 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 miniprobes and, through outsourcing, expect to enlarge its capacity 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.

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

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 in the various countries where they are marketed. 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.
This system was extended in 2018 to mark reusable consumables (confocal miniprobes) directly with a UDI in accordance with FDA requirements. This work also anticipates compliance with the unique identification requirements of the European Regulation DM 2017/745, which will be applicable in 2020.

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 related to the production chain 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..

- The Company regularly audits sensitive suppliers based on an annual schedule drawn up by the Purchasing and Quality Assurance teams and according to evaluation results. In 2018, seven supplier audits were carried out.

6.6.5. Selection of main partner subcontractors

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. The Company implemented an externalization strategy with Fujikura by transferring some of the assembly stages of certain Confocal miniprobe models to benefit from this supplier's industrial expertise.

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

In 2015, the Company also approved a new subcontractor 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.

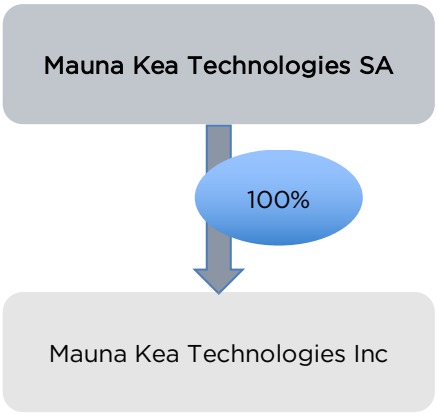
In 2018, the Company hired a new subcontractor for the manufacture and the cabling of the mechanical trolley integrating the components of the Cellvizio 100 Series.

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
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, 2018, it had 26 employees and posted revenues of $3,712 thousand (or €3,141 thousand, at a conversion rate of 1.182) and a net loss of $4,688 thousand (or €3,966 thousand, at a conversion rate of 1.182).

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 2018 financial year, the Company invoiced its subsidiary for the amount of €567 thousand.

c) Financial flows: A Group cash management agreement was reached 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 2018 financial year, the Company invoiced its subsidiary for interest totaling €358 thousand.

SECTION 8
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 m^2 . (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 m^2	03/01/2016	9 years	02/28/2025	98,666
1st floor	115 m^2	Jun. 1, 2005	9 years	N/A	21,915
1st floor + underground parking	223 m^2	Oct. 1, 2000	9 years	N/A	42,495
2nd floor (left-hand side)	115 m^2	Jan. 1, 2005	9 years	N/A	21,915
2nd floor (right-hand side)	223 m^2	Feb. 1, 2004	9 years	N/A	42,495
3rd floor + basement	157 m^2 + 60 m^2 in the basement	Nov. 1, 2008	9 years	Oct. 31, 2017	40,820
4th floor	140 m^2	Nov. 1, 2009	9 years	Oct. 31, 2018	32,240
5th floor	100 m^2 + 20 m^2 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 €401 thousand for the year ended December 31, 2018.

Sub-leasing: During the first quarter of 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.

Offices in the United States: Formerly based at 185 Alewife Brook Parkway in Cambridge, Massachusetts, until February 2017, the subsidiary moved to 24 Denby Road in Allston, Massachusetts. The rental charges recognized in the United States for the 2018 financial year total $68 thousand.

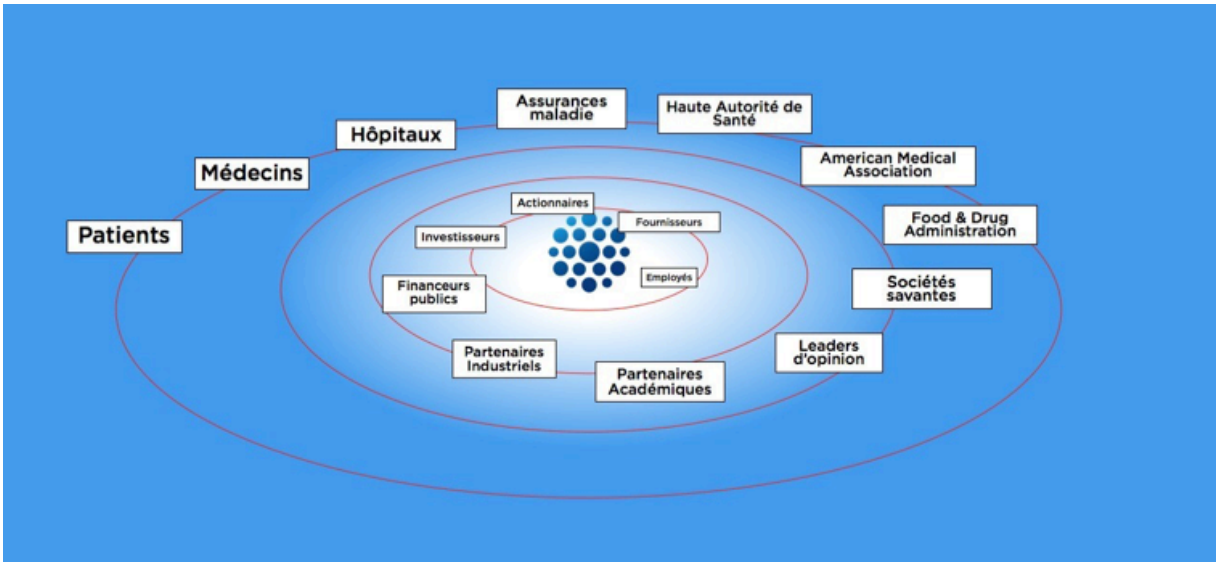
8.1.2. Other tangible assets

The principal property, plant and equipment held by the Company are described in Note 4 to the 2018 consolidated financial statements, appearing in Section 20.1 of this Registration Document.

8.2. Resources and Synergy

Relationships with stakeholders

Mauna Kea Technologies is evolving at the heart of a complex ecosystem that includes many players.



• The ultimate recipients of its products are patients; Physicians, health care institutions and research centers are clients. 631 sites currently have the Cellvizio® technology. The Company has thus developed strong relationships with the medical community, and in particular with opinion leaders, who have experience with our medical devices, and the scientific authority necessary for the adoption of a new medical technology by their colleagues.

•Scholarly societies and professional medical associations have an important influence in obtaining reimbursement codes, or in implementing sound medical practices based on national or international recommendations.

•Healthcare authorities and health insurance organizations issue marketing approvals and reimbursement codes. Mauna Kea Technologies currently markets its products in over 40 countries

•Academic partners with which Mauna Kea Technologies conducts research work.

•Industrial partners, whether customers or suppliers, with which Mauna Kea Technologies has built up strong, lasting partnerships.

•Outside of the medical field, the Company maintains close relationships with both the European and the U.S. financial community. It has a shareholder base of several thousand individual French shareholders, which is the vast majority, and individual European and U.S. institutional investors, general fund managers or healthcare specialists. The Company's shares are also now listed on the OTCQX market in the United States, making it possible for U.S. investors to buy shares in dollars by means of American Depositary Receipts (ADRs).

•Lastly, the Company's employees share, maintain, and develop the values of Mauna Kea Technologies.

8.3. Societal impact

8.3.1. Medical environment

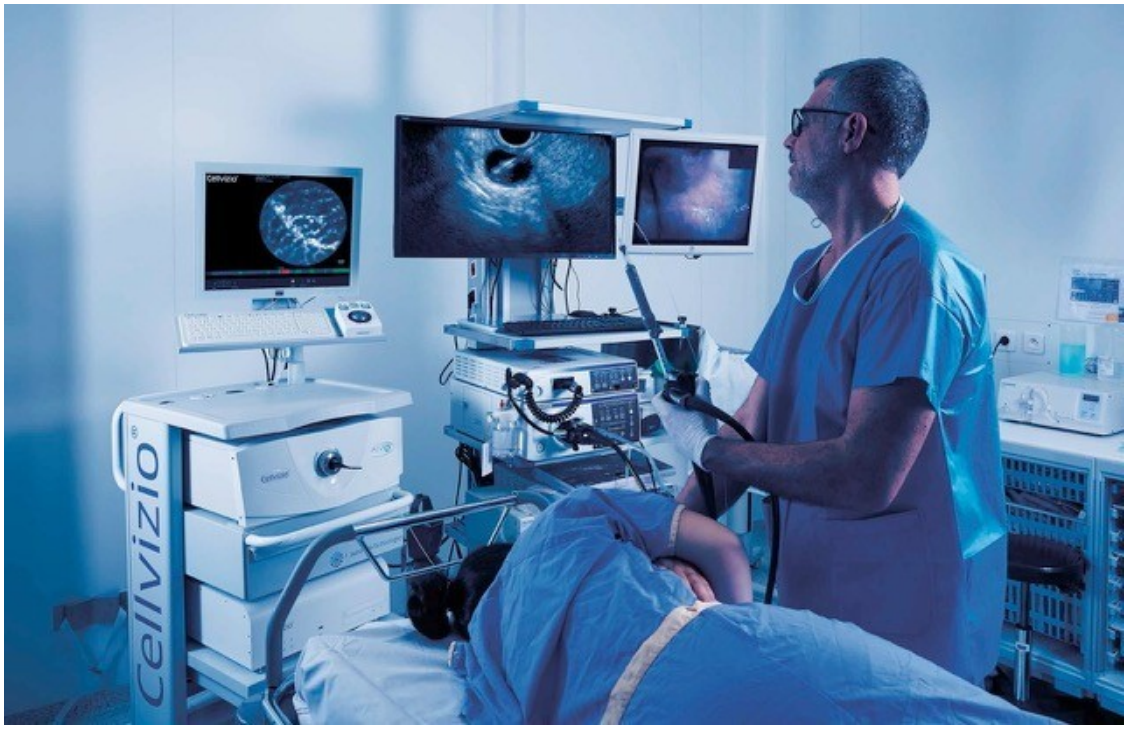
Patients are at the heart of its business activity and its aim is to give users the means to eliminate diagnostic and treatment uncertainties when tracking tissue, cellular and even molecular organization.
With this approach, Mauna Kea Technologies is developing a range of medical and clinical evidence using various resources, including an exhaustive review of the scientific literature on the technology and its clinical applications.

Carrying out clinical investigations

These are aimed at providing sufficient proof to demonstrate the safety, efficiency, and benefits of medical devices for the health economy. Mauna Kea Technologies is the sponsor of several clinical trials in line with the international standard ISO 14155. A rigorous process is followed: for each trial, a clinical study plan (protocol) is submitted to the ethics committees and the competent national authorities upon which the participating study centers depend, and according to their local legislation.

The protocol describes in detail the nature of the trials carried out, and is committed to demonstrating the pertinence of the study, by giving priority to the potential benefit for the patient and the associated risks.
The patients who participate in the trial receive an information notice, which specifies the nature of the trial in which the physician proposes to include them, the risks involved, and the benefits of the clinical evidence, which may be concluded from this trial.
They thus co-sign an "informed" consent with their investigator-physician, and keep a copy.

Only the data that is pertinent to the clinical demonstration is gathered during the clinical trials. All personal and/or sensitive patient data is processed in compliance with the laws and regulations in force pertaining to data protection, management, and processing. Identifying information is removed from all data gathered for a specific patient, and is sometimes coded, in order to guarantee respect of their privacy.



Mauna Kea Technologies makes regular visits to the study sites in order to ensure compliance with the protocol, and each year sends an analysis to the ethics committees, pursuant to local legislation and requirements.

All investigators and/or their institutions draw up a specific agreement for each trial with the Company, in order to reiterate their independence, the respective duties of the parties, and the terms of compensation, in compliance with local legislation and the principle of transparency. They thus maintain their full freedom of expression regarding the technology and its performances.

Mauna Kea Technologies has also identified experts in different specialties to support it in decision-making and validation of clinical evaluations of its products: the Medical Advisory Board comprised of expert doctors - opinion leaders - which helps to define the Company's clinical development strategy.

Monitoring the use of medical devices after they are placed on the market

In order to manage such activities, Mauna Kea Technologies remains attentive to its clients and to their feedback on the use of its products, by providing input to the continuous process of improvement.
As part of its monitoring of activities connected to the Quality Management System (QMS), internal audits are regularly performed, in order to check the conformity and effectiveness of the key activities of the Company, such as Post-Market Surveillance (PMS) or materials vigilance. These audits are performed by auditors who are independent from the activity being audited.

Within the context of product use in a medical environment, a specific process of Post-Market Surveillance and of materials vigilance has been put into place. This makes it possible to gather data on incidents presenting a potential risk to patient or user health connected to the use of our products. The incidents are analyzed, in liaison with the physician-users, in order to decide whether the incident should be reported to the national health authorities. In 2018, there were no incidents reported to the competent authorities pursuant to the applicable European directive or any national legislation. Two events were reported to US authorities: a dysfunction and a potential adverse event by a hospital. The potential adverse event had no consequences on the patient's health.

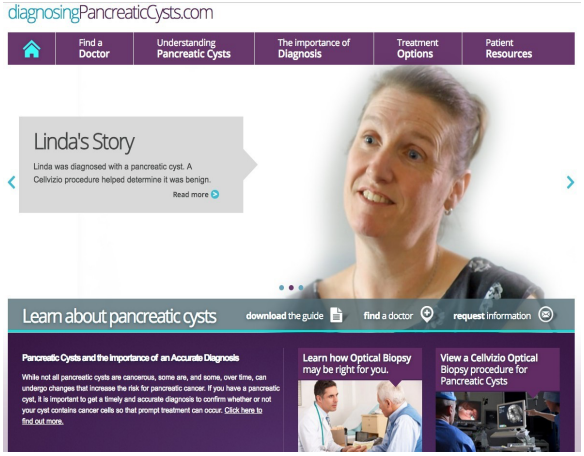
Maintaining information for healthcare professionals

In 2017, the Company completely revamped its e-learning site, cellvizio.net, aimed at healthcare professionals to make it easier to use and enriched with the latest information.
Mauna Kea Technologies regularly sends out newsletters and also encourages its users to undertake continuous training in the form of workshops and support for symposia, on-site training when equipment is installed, supporting users in their initial procedures and providing tutoring by expert users. A new smartphone application called Cellvizio was developed in 2017 and enables product images to be viewed.

Providing information to patients

In 2013, Mauna Kea Technologies launched two websites dedicated to the following indications:

Pancreatic Cysts



Barrett's esophagus

http://diagnosingpancreaticcysts.com

http://diagnosingbarretts.com.

The objective of these American and British patient use websites is to provide information on these illnesses, their diagnostic method, and the potential contribution of optical biopsy.
There one can find patient testimonials, specialist search engines by country, as well as treatment options for these pathologies.

Endomicroscopy with Cellvizio® has the benefit of being able to reassure the patient in the numerous cases where the cells are healthy, because it eliminates an anxiety-provoking wait of several days to several weeks for the pathology examination results.

The sites are therefore an aid for the patients and their family, but also very useful for general practitioners and specialists.

8.3.2. Regulatory environment

The national competent authorities and notified bodies develop, validate, and check that the standards and regulations are applied by manufacturers of medical devices according to their classification.

Within the European Union and partner countries, Mauna Kea Technologies works with G-Med on the CE marking of its class IIa devices.

The Food and Drug Administration (FDA) in the USA, the CFDA in China, Anvisa in Brazil, Health Canada in Canada, and MHLW in Japan are the main authorities that validate the compliance of its devices.

510(k) regulatory authorizations

In April 2014 Mauna Kea Technologies obtained a double authorization: one Class 1 authorization for the use of Cellvizio® technology and one Class 2 (NINSHO) authorization for the endoscopic use of the Cellvizio® confocal miniprobes. Both relate to all of the current clinical indications of Cellvizio®: gastroenterology, urology, and pulmonology.

Each time it significantly modifies its devices, whether in technical terms or in terms of their potential use, including any new application, Mauna Kea Technologies files an application with the competent authority. In the United States the Company has obtained 15 regulatory 501(k) agreements from the Food & Drug Administration. In 2018, the Company obtained the first FDA authorization for confocal laser encomicroscopy applications with Cellvizio® in neurosurgery.

8.3.3. Market access environment

Once it has registered its technology with the competent authorities in countries where its devices are to be marketed, the Company must ascertain the reimbursement codes in most countries so that patients or users can be covered or reimbursed once the medical treatment has taken place.

In March 2012, the Company obtained the creation of three so-called CPT® codes of Category I, specifically granted by the American Medical Association (AMA) for endomicroscopy in the upper digestive tract. The creation of these codes is a strong recognition of the interest of doctors and the healthcare system in optical biopsy and in the products of Mauna Kea Technologies in the United States. In spring of 2015, a CPT of Category III was obtained, for the use of endomicroscopy in bile ducts.

Cellvizio® procedures can now be reimbursed by public and private insurance companies in the United States thanks to the CPT codes obtained. The inclusion of the procedure by Medicare and a number of payers relates to some 100 million American citizens. In November 2016, Medicare published the 2017 reimbursement rates, and the rates for the Optical Endomicroscopy code rose 131% for hospitals and 86% for ambulatory surgical centers, a major event for the Company. In this context, the Company launched new initiatives in the United States to accelerate the adoption of the Cellvizio technology® in the United States: the consignment of the Cellvizio® and Minisondes® systems according to contractual agreements with healthcare institutions and users and with fee-for-service billing. In 2019 these repayments were all maintained or even slightly increased.

At the same time, initiatives were taken in order to obtain reimbursement codes for the use of Cellvizio® in other European countries (France, Germany, Italy, and the United Kingdom).

Data from clinical trials is analyzed for medico-economic evaluation of the product taking into account current practices and the impact of the introduction of Cellvizio® in patient management. These analyses will help us expand into other countries. Studies conducted by the Company have enabled the development of economic models demonstrating the clinical and economic benefits of the technology.
In comparison with standards, including conventional biopsy, some models and publications have concluded that it offers the advantage of avoiding taking physical biopsies on areas identified as healthy using digital optical biopsy; taking into account for example that 90% of physical biopsies are negative in screening for Barrett's Esophagus, that corresponds to several million tissue removals which could be avoided, and potential savings for healthcare systems of several hundreds of millions of euros, as presented during the Symposium organized by Mauna Kea Technologies with approximately one hundred experts in digestive pathology, which can be found in the book, "Endomicroscopy in digestive pathology", coordinated by Drs. Coron and Rahmi.
Applied to pancreatic cysts as a diagnosis tool, endomicroscopy allows practitioners to avoid operating on patients who do not require it but who would have undergone it on a conservative basis. As this figure could exceed 40%, the use of endomicroscopy also means a reduction in the overall costs of treating pancreatic cysts by avoiding difficult and costly surgery.
In 2017, a new study, conducted under the direction of Claude Le Pen, Professor of Healthcare Economics at l'Université Paris-Dauphine, demonstrates the potential for substantial reduction in clinical costs in France through the use of Cellvizio® in the diagnosis of pancreatic cysts. "A Health Economic Evaluation of Needle-Based Confocal Laser Endomicroscopy For The Diagnosis Of Pancreatic Cysts" was published on October 9, 2017 in Endoscopy International Open, an open access scientific journal specializing in gastrointestinal endoscopy. It assesses the economic value of the diagnosis of benign cysts using confocal needle-mediated endomicroscopy (EUS-FNA + nCLE), compared to the EUS-FNA-guided biopsy puncture which is the reference method today.
Several clinical trials have shown that real-time visualization of specific types of cells by optical biopsy using Cellvizio® allows for a safer and more accurate diagnosis. Professor Le Pen measured the value of using Cellvizio® in terms of total cost of procedures and hospitalization valued at public and private rates.
This evaluation was carried out from the point of view of the public payer using the pricing of the official nomenclatures for health insurance.
The study demonstrates that the Cellvizio® fine needle puncture provides significant cost savings by reducing the risk of misdiagnosis through better accuracy, namely:

• a 23% reduction in the total number of surgical procedures, associated with a 13% reduction in clinical costs (public sector) and 14% (private sector);
• a reduction in the number of surgical procedures helping to save the life of 4 out of 1,000 patients.

Finally, since 2017, the Croatian Health Insurance Fund, which manages the universal medical protection system in Croatia for approximately 4.2 million people, reimburses a series of procedures using Cellvizio®.

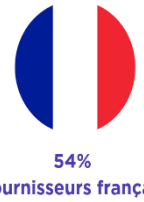
8.3.4. Economic environment

Convinced that, in France it must encourage the emergence from start-up to success to generate economic value and jobs, the French government created the Initiative French Tech at the end of 2013. "French Tech" means all those who work in or for French start-ups in France or abroad: entrepreneurs primarily, but also investors, engineers, large groups, associations, media outlets, public operators, research institutes committed to the growth of start-ups on the one hand and their international influence on the other.
The philosophy of French Tech is: to rely on initiatives of the members of French Tech to develop what already exists, and to create a snowball effect. It is a shared ambition, driven by the State, but supported and built with all of the players.

In the vocabulary of French Tech, a start-up is a young company with a global ambition in search of an economic model that will ensure strong and rapid growth or taking risks through exploring new products or services, those which succeed become very rapidly international enterprises, with several hundred, even thousands, of employees.
It was thus completely natural that since 2014, Mauna Kea Technologies has been an active player in French Tech, with its Founder and CEO, Alexandre (Sacha) Loiseau, regularly participating in conferences, open days, and other initiatives.

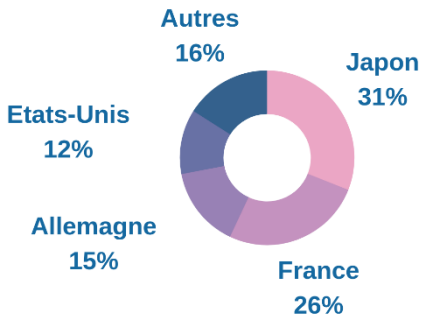
8.3.5. Subcontracting and suppliers

Mauna Kea Technologies maintains privileged relationships with its suppliers. It worked during this year with 135 suppliers for its production and research and development purchases, particularly in the optical, electronic and mechanical categories. 54% of the suppliers used were French, a figure that is again declining compared to previous years.



The Company uses subcontracting for the integration of Cellvizio® electromechanical boxes, the manufacture of certain probes as well as the translation of user documents with the same French, Japanese and British subcontractors for many years.

The main countries it works with are Japan and France with respectively 31% and 26% of the volume of purchase, then Germany and the United States with 15% and 12%. It is noted that these trends have been relatively stable for several years, with priority given to building long-term supplier partnerships. These countries are not deemed to be at risk with respect to work conditions. Its principal supplier, which represents 28% of production purchases, is a shareholder of the Company; a contract was entered into with it for the transfer of probe production.



Suppliers are monitored throughout their relationship with Mauna Kea Technologies: from the sourcing phase, where strategic suppliers are selected based on objective criteria shared by all, to monitoring their performance through an annual evaluation of the 50 most critical suppliers and to a supplier audit program conducted by auditors trained in the exercise and compliance with standards and regulations. In 2018, seven supplier audits were carried out.

Mauna Kea Technologies has been tracking supplier payment indicators for several years. In 2018, the average payment period was 47 days, stable compared to 2017, 59% of invoices were paid late which is a marked improvement compared to 2017 (-16 points), with an average delay down slightly to around 26 days. These improved results are partly due to the 2018 awareness campaign conducted with production and research and development suppliers to explain our accounting processes and to negotiate fairer terms of payment for all.

Finally, the good practices acquired thanks to ADEME's support in 2017 for more responsible purchasing continue to be applied on a daily basis, for example with an effort to select suppliers locally or the sharing by all employees of the same ethics.

8.3.6. Educational environment

The Company has a partnership policy with certain schools. The Company regularly receives students of different levels at its premises to present its activities. These days of exchanges make it possible for the Company to present open internships, but also for the students to present their projects and their professional aspirations.

In the same way, the Company works very closely with the Université Technologique de Compiègne, in the context of exchanges with former students.

Mauna Kea Technologies also contributes to the professionalization program offered by business schools, engineering schools and universities (Specialized Masters), providing internships or work-study placements to students who are integrated into Company functions (quality, clinical affairs, research and development).

8.3.7. Industrial and academic environment

Mauna Kea Technologies is growing in a competitive sector; it therefore emphasizes protection of its confidential and proprietary information, in order to ensure its technological advancement. The Company does, however, promote interactions with its technological environment, in the framework of partnerships and collaborative projects, but also with players in the market in which it operates, in the framework of its strategic development.
Various types of confidential information are communicated by the Company: scientific, technical, financial or clinical data. Such exchanges are systematically covered by confidentiality agreements.
Models, specifically developed in accordance with the needs of Mauna Kea Technologies, are utilized in order to maintain the confidentiality of information exchanged with the various partners. They are mainly utilized outside of any contractual partnership.

8.3.8. Ethical environment

Fairness and ethical business conduct are part of the basic principles of Mauna Kea Technologies' activities. Clinical affairs comply with the rules of ethical business conduct through the anonymity of patient data used during clinical trials, and the software incorporated into the products is developed in conformity with ISO Standard 62304.

Pursuant to the transparency laws (Sunshine Act) that govern relations between industry and healthcare professionals, Mauna Kea Technologies has set up internal processes for gathering the necessary information and raising awareness among its personnel who are in contact with healthcare professionals.
In France, for example, within the framework of the Bertrand Act of May 29, 2011 as amended in 2016 relating to the transparency of benefits granted by businesses producing or marketing products which have a healthcare-related or cosmetic end use for humans, the following information must be made public:
•the existence of agreements entered into with health professionals and other similar persons (with the exception of agreements governed by Articles L. 441-3 and L. 441-7 of the French Commercial Code),
• the total benefits granted for which the amount is equal to or greater than €10.
Such information is centralized on a single website which is managed by the Ministry of Health.

Lastly, the Company has organized every year since 2009 the ICCU event (International Conference of Cellvizio® Users). 2015 saw the seventh edition of this event. In response to the success of this event, an independent scientific committee was created for the selection and revision of the scientific works submitted for public presentation.

Thus, the different presentations or posters were selected in full independence, under the aegis of a Scientific Secretariat comprised of 18 experts representing the various specialties, which may be found during this event.

An education committee was also set up to coordinate the specialized or “Post-Graduate Course”, intended for physicians wishing to improve their skills, particularly in the interpretation of confocal endomicroscopic images.

Changes to the Code of Ethics of the medical devices industry mean that Mauna Kea Technologies can no longer organize this event. On the other hand, the creation in the United States in October 2016 of a Learned Society: “International Society for Endomicroscopy – IS4E” by a group of practitioners who advocate for technology and its benefits to patients will help to continue fruitful exchanges within the scientific community and users (www.IS4E.org). Two events were organized in 2017 by this new Company to discuss setting up annual conferences dedicated to endomicroscopy.

Finally, the Company scrupulously complies with the rules of independence with respect to healthcare professionals, in order to guarantee that their product-purchasing decisions will always be made in the interest of the patient, thanks in particular to a code of conduct. The latter defines the conduct to be adopted vis-à-vis healthcare professionals, based upon the latest versions of the Advamed and MEDTECH codes of ethics published in 2016 with effect from January 1, 2017 regarding relationships between industry and healthcare professionals. The single international code for all staff is expected to be available in 2018 in both English and French. In this respect, compliance training for new hires is already being disseminated.

8.3.9. Working environment at Mauna Kea Technologies

Job creations

In addition to the jobs created directly by Mauna Kea Technologies, which had 70 employees at its head office in France at the end of 2018 and 29 in its subsidiary and representation offices, the Company has forged a network of privileged relationships with certain French and European but also Japanese suppliers, with which it develops, designs, and manufactures its products.

Employment and integration of disabled workers

The Company has set up a partnership with a Workforce Support Service Establishment (ESAT); it thus employs handicapped workers in printing assignments.

Expenses incurred were €2,001 in 2018 versus €1,289 in 2017, a relative increase in these expenses, the result of the trust that has been acquired and renewed for several years in our partner.

Anti-discrimination and gender policy

The Company does not discriminate in hiring, whether in terms of origin, religion, age, or gender: all profiles are examined with equal scrutiny. We base our decisions exclusively on what profile is best suited to the competencies being sought.

Policy of gender parity and gender distribution

Scope France	12/31/18	12/31/17	Change
Women executives	38%	34%	+11.76%

The proportion of women executives has increased this year to 38% of the Company's workforce. The mostly male workforce is explained by the technical and mechanical precision of the Company's core business. Mauna Kea Technologies employees mainly have technical profiles and therefore we have a preponderance of male employees as a result.

Wage increases for Male/Female Employees

In €, Scope - France	12/31/18	12/31/17	Change
Average	5,083.34	5,293.06	-3.96%
Men Average	5,582.44	6,182.64	-9.71%
Women Average	4,360.96	3,983.06	+9.49%

Wage increases for Male Executives/Female Executives

In €, Scope - France	12/31/18	12/31/17	Change
Executive Average	5,789.52	5,874.36	-1.44%
Average, Male executive	6,304.86	6,823.69	-7.60%
Average, Female executive	5,033.67	4,480.02	+12.36%

Employee assessment: The Performance and Development review

More than a simple performance evaluation, the Performance and Development review aims to create a true dialog between the employee and the manager on development goals in the Company.

It begins by an employee balance sheet, prepared by the employee, who can broadly express what he or she likes about his/her position, his or her professional aspirations, and his or her development goals. It contains a paragraph, "Growing with the business", one of the four Company values, with the employee being given free rein to express him or herself.

The employee is then asked to express him or herself on his or her performance, its adequacy with respect to Company values, and a self-evaluation of competencies required for the position. He or she then proposes objectives for the following year.
The manager then holds an interview on the basis of this employee balance sheet, and analyzes the progress observed on the development areas set the preceding year. The manager also sets, in agreement with the employee, developmental actions for the following year, based on the gaps noted.
These actions are the basis for the Company's training plan.

Compensation policy and its evolution

Compensation is reviewed annually, in line with the employees' performance, assessed during Performance and Development reviews.

Taking into account the financial position of the Company, no profit sharing or incentive agreement has been put into place. Target-based bonuses are paid to all employees, with a portion linked to the Company's results, and the other on the basis of individual objectives.

Other compensation components:

- Since its inception, the Company has implemented a supplemental health and retirement plan; mutual insurance is covered 70% by the employer, and the retirement plan, 100%. It is worth noting that the health insurance plan offers a very good level of coverage;
- Employees benefit from restaurant vouchers, with the employer assuming 53% of the cost. The face value is €9.

Lastly, all employees of Mauna Kea Technologies have for many years been connected with its performance through the allocation in France of Founders' warrants (BSPCE), Preference Shares connected with a Bonus Shares Grant or stock options in the United States.

Labor relations

Elections for employee representatives took place in March 2015; taking into account the size of the Company, the elected persons were grouped into a Sole Employee Representative Body.

The organization of work hours is made on the basis of industry-wide agreements. (National Agreement of March 3, 2006 of the National Convention of Engineers and Executives in Metallurgy, and National Agreement of July 10, 1970, as amended, on Monthly Payment of Wages).

The staff representatives were elected before the Rebsamen Act and a Committee for Health, Safety, and Working Conditions has also been created. This body meets quarterly, in accordance with the legislation.

The elections of the Social and Economic Committee, which will bring together Staff Delegates, Works Council and Health, Safety and Working Conditions Committee in the same occasion, are planned for 2019.

Health and safety

The Company prepared a Single Document, in accordance with the legal provisions. This document was totally redefined in 2012, and a detailed action plan was implemented with the Committee for Health, Safety, and Working Conditions. It is monitored at each quarterly meeting of the Committee for Health, Safety, and Working Conditions.

It is worth noting:

- 2 two work accidents were reported in 2018 representing seven days of absence;
- the Company owns an external defibrillator: the Company's First Aid workers have been trained in the use of this device, as well as around ten employee volunteers.

Employees who are exposed to contamination risks (because of frequent presence in hospitals) attend doctor visits, reinforced by blood-work analysis. Some employees also wear a radiation-protective dosimeter, to be worn in the operating room.

8.3.10. Knowledge of our environment

Intelligence gathering involves the collection of information and the reinforcement of knowledge on the environment outside of the Company, making it possible for the Company to anticipate change and to assist in strategic decision-making. It is therefore a key factor in the survival and evolution of a business, especially in the field of innovation. Moreover, in a competitive sector, an effective Product Development activity goes beyond the four walls of a business and explores what is being developed and marketed on the outside. The intelligence-gathering activity thus also extends the objective of promoting in-house innovation.

In addition to participating in and actively contributing to multiple technical or medical conferences, in fields as varied as bio-photonics, the Computer-Vision, or medical and biomedical research, Mauna Kea Technologies uses its internal social networks (Google+, Slack) to disseminate and share, sometimes in near real-time, the information collected by its teams during such events.

This effort, which is complementary to and inherent in innovation, constantly trickles through all the Company's Product Development activities.

8.4. Environmental Footprint

8.4.1. To reduce the environment footprint of products all throughout the life cycle

Starting from the product design phase, the Company takes into account all European regulations pertaining to the environment (for example, REACH, ROHS, DEEE, etc.) whose objective is to:

limit waste and its hazards;

promote reuse and recycling;

- improve conditions for disposal and control,
- limiting or prohibiting the use of certain hazardous materials.

These regulations and their requirements are completely integrated into the Company's quality-control system. Specific procedures, under the joint responsibility of Quality and R&D engineers, have been established in order to guarantee that no substance, which is hazardous to the environment, is incorporated into its products.

A REACH and RoHS regulations monitoring process has been implemented since 2014. Mauna Kea Technologies now systematically requires new documentation of the supplier's commitment to comply with these standards. In 2017, in view of the many changes in the REACH regulation, a new in-depth review of all the parts included in the nomenclature of our products was conducted by a working group composed of an R&D engineer specialized in medical device vigilance, a regulatory manager and a buyer. The suppliers were again surveyed in order to prove their compliance with the REACH and RoHS regulations. The Company is now compliant with RoHS regulations and has obtained proof of REACH compliance for 98% of its product components.

In addition, Mauna Kea Technologies called upon an approved eco-entity (Recylum) for the recycling of its products at the end of their useful life. Products reaching the end of their useful life are collected by the company, sorted and stored with a view to recycling, as required by the regulations in force.

Finally, thanks to the support of ADEME in 2017 and a stated desire to reduce our environmental impact, new packaging has been designed for one of our products and the share of recyclable materials increased from 87% to 98% of the total weight. Previously, some of the product and packaging was shipped from the United Kingdom. The logistics scheme has been simplified and greenhouse gas emissions have decreased by 97% for the packaging of this product.

8.4.2. Decrease the environment footprint of the company

Production and marketing activities

The activities of Mauna Kea Technologies do not implement hazardous products or contribute to any significant pollution. Mauna Kea Technologies has "clean" manufacturing, based upon optical and mechanical processes, which use very little chemical product.
With respect to waste management, the soiled residue from production (disinfecting wipes, gloves, adhesive residues, etc.) presenting an infectious risk are stored in a special container. This container is collected by a specialized company (EDC, GC Group), which reduces the infectiousness of the waste to the level of household garbage.

The Company is committed to reusing products at the end of their useful life for trials and tests, for example, destructive tests or durability tests on our probes, or by recovering components for the production of models or prototypes during new product design.

Mauna Kea Technologies is committed to controlling the use of resources

Taking into account the number of employees and of its operations, the Company has little impact on its environment. Nevertheless, daily actions are performed in order to limit this footprint.
For example, in 2012, it renewed its pool of printers, and introduced a badge-recognition system, which enabled it to limit unnecessary printing and paper waste. It also implemented selective sorting in all offices at the beginning of 2017 and made all employees aware of the process.

Greenhouse gas emissions

The Company has a fleet of two low-emission vehicles with CO2 levels below 130 gCO2/km.

The electrical consumption is as follows: it was 172,814 kWh in 2017 versus 182,705 kWh in 2016 for the main site, respectively 11,181 kg CO2 equivalent versus 11,821 kg CO2 equivalent (*). After an increase in consumption between 2015 and 2016 due to the development of a new floor for production, there was a 5.41% decrease in consumption between 2016 and 2017.
(*) 64.7 g of CO2 equivalent per kWh, source ADEME Electricity 2016 - average mix

The Company has also identified significant greenhouse gas emissions in view of its activity: Transported merchandise upstream and downstream of the logistics supply chain, business travel as well as work/home commutes. A more in-depth study must be conducted to quantify these various items and to analyze the possible drivers to reduce greenhouse gas emissions.

SECTION 9
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, 2018, and to refer to the notes to the 2017 consolidated financial statements contained in Section 20 of this Registration Document. The 2015 and 2016 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 2018 consolidated financial statements of Mauna Kea Technologies, approved by the Board of Directors on March 19, 2019, 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		
	2018	2017	2016
Total sales of "equipment"	2,683	3,101	4,217
Total sales of "consumables" (probes)	2,812	2,397	2,941
Total sales of "services"	1,265	1,188	1,629
Total sales	**6,760**	**6,687**	**8,787**
Other income	1,141	1,144	883
Total revenue	**7,901**	**7,831**	**9,670**
Cost of sales	(2,058)	(2,129)	(2,720)
Gross margin	70%	68%	69%
Total operating expenses	**(19,899)**	**(17,541)**	**(19,660)**
Other operating income and expenses	0	0	0
Operating Profit (Loss)	**(11,998)**	**(9,710)**	**(9,990)**
Profit before tax	**(12,785)**	**(10,245)**	**(9,744)**
Profit/(loss)	**(12,785)**	**(10,245)**	**(9,744)**

9.2.1. Sales and other operating income

Full Year 2018 Sales

(in € thousands) – IFRS	2018	2017	Change %
1st quarter	1,042	1,599	(35%)
2nd quarter	1,665	1,686	(1%)
3rd quarter	1,933	1,852	4%
4th quarter	2,120	1,550	37%
Total Sales	**6,760**	**6,687**	1%

Full Year 2018 Sales by Category

(in € thousands) – IFRS	2018	2017	Change %
Systems	2,683	3,101	(13%)
Consumables	2,812	2,397	17%
including "pay-per-use"	*890*	*650*	*37%*
Services	1,265	1,188	6%
Total Sales	**6,760**	**6,687**	**1%**

Total sales for the 2018 financial year were €6.8 million, up 1% from 2017. The growth in sales for financial year 2018 is mainly due to a 17% increase in sales of consumables and a 6% increase in service income, offsetting the 13% decline in system sales over the period. The decline in system sales in 2018 from 2017 was due to the Company's strategic decision to shift the business model towards placing the units on a pay-per-use consignment, versus the direct systems sales model, which prevailed in the previous year. The Company placed 55 new Cellvizio systems within its "pay-per-use" (PPU) program in 2018, up 323% from 2017.
The new systems placements in 2018 resulted in a 37% increase in sales of "pay-per-use" consumables.

Full Year 2018 Sales by Geography with split by activity (Clinical / Preclinical)

(in € thousands) – IFRS	FY 2018	FY 2017	Change
United States & Canada [23]	**3,582**	**3,142**	**14%**
Clinical	3,181	3,117	2%
Preclinical	400	25	1,516%
Asia-Pacific	**1,599**	**1,952**	**(18%)**
Clinical	1,407	1,229	14%
Preclinical	191	722	(74%)
EMEA	**1,544**	**1,283**	**20%**
Clinical	1,001	816	23%
Preclinical	543	467	16%
Latin America	**36**	**310**	**(88%)**
Clinical	36	310	(88%)
Preclinical	0	0	n/m
Total Clinical Sales	**5,626**	**5,473**	**3%**
Total Pre-clinical Sales	**1,135**	**1,214**	**(6%)**
Total Sales	**6,760**	**6,687**	**1%**

[23] Sales in the United States and Canada were previously reported with sales for the Latin America region under the Americas heading.

9.2.2. Operating Expenses

Consolidated data audited in €K	2018	2017	Change
Cost of sales	(2,058)	(2,129)	(3%)
Gross margin	70%	68%	
Research & Development	(4,653)	(4,265)	9%
Sales & Marketing	(9,097)	(7,586)	20%
Administrative Expenses	(3,953)	(3,350)	18%
Share-based payment transaction expenses	(138)	(210)	(34)%
Total operating expenses	**(19,899)**	**(17,541)**	**13%**

Operating expenses amounted to €19,899 thousand for the year, compared with €17,541 thousand in 2017, representing an increase of 13%. The main contributing factor was the increase in sales and marketing expenses. As a result of this increase and the 1% increase in sales, the operating loss for 2018 was €11,998 thousand, compared with a loss of €9,710 thousand in 2017 including €786 thousand in other operating income and expenses.

Cost of products sold and gross margin

The cost of goods sold came to €2,058 thousand for 2018 versus €2,129 thousand for 2017, representing 30% and 32% of sales, respectively. Gross margin was 70% in 2018, versus 68% in 2017. This 2-point increase reflects the favorable product mix in 2018, as well as control of production costs.

Research and Development Costs

Throughout fiscal year 2018, the Research and Development team continued its work on the next generation of systems. The development costs of this product have not been capitalized in the accounts, the research still very upstream in the development process.

In 2018, Research and Development expenses amounted to €4 thousand, versus €4,265 thousand for 2017.

In 2018, the annual portion of capitalized development expenses was zero. The company maintains a high level of R&D expenses mainly attributed to research and development in the fulfillment of projects led from several years.

Marketing and Sales Costs

Marketing and sales expenses are currently the largest overhead. These expenses increased by 20%, from €7,586 thousand in 2017 to €9,097 thousand in 2018.
This item remains the largest overhead for the Company, representing 46% of all operating expenses in 2018.
This items include the sales and marketing expenses, but also clinical research expenses, logistic and supply expenses directly linked to sales.

In marketing, at year-end 2018 the Group had a team of eight people 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.

At the end of 2018, the sales teams were comprised of:

- 4 people in the EMEA region
- 20 people in the United States;
- 2 people in China

In total, at the end of 2018, the Group had a sales force of 26 people led by a sales manager for the EMEA and APAC zones, and by two regional sales managers for the United States, from December 7 to 31, 2017.

Administrative expenses
The administrative expenses basically consist of employee benefits expenses, operating costs relating to the head office in Paris, and external expenses such as audit, attorney and consultant fees.

The administrative expenses were up by 18% on 2017, from €3,350 thousand in 2017 to €3,951 thousand in 2018.

Share-based payments

As with previous fiscal years, the Group continued to issue stock options to its US employees, and also warrants to its independent board directors. As the Group is no longer allowed to issue founders' warrants (BSPCE), the Group in 2016 and 2018 implemented preferred share plans whose terms and conditions were voted and approved by the shareholders at the General Meeting of October 5, 2018.
The share-based payments in 2018 amounted to €138 thousand, compared with €210 thousand in 2017.

9.2.3. Composition of net income

The operating expenses amounted to €19,899 thousand for the year, compared with €17,541 thousand in 2017, representing a decline of 13%. The main contributing factor was the increase in sales and marketing expenses.

As a result of this increase and the 1% increase in sales, the operating loss for 2018 was €(11,998) thousand, compared with €(9,710) thousand in 2017.

After taking into account a financial loss of €786 thousand for the year to December 31, 2018, compared with a loss of €535 thousand at December 31, 2017, the Company's net loss comes to €12,785 thousand, compared with a net loss of €10,245 thousand for the year ended December 31, 2017.

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.
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.

9.2.5. Earnings per share

The loss per issued share (weighted average number of outstanding shares during the year) came respectively to €0.51 and €0.49 per share for the financial years ended December 31, 2018 and 2017.

9.3. Balance sheet analysis

9.3.1. Non-current Assets

Consolidated data audited in €K	2018	2017	Change
Intangible assets	1,838	2,100	-14%
Property, plant, and equipment	1,985	1,466	26%
Non-current financial assets	133	138	-4%
Non-current assets	**3,956**	**3,704**	6%

Non-current assets were €3,956 thousand at December 31, 2018, 6% more than the €3,704 thousand at December 31, 2017.

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

The increase in the item is in part due to a decrease in intangible assets due to the amortization of patents and development costs and to a reclassification concerning the activation of PLM (Product Life Management) for €207 thousand. In part it is due to transfers of property, plant and equipment relating to systems placed in consignment.

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, 2018" of this Registration Document.

9.3.2. Current assets

Consolidated data audited in €K	2018	2017	Change
Inventories & Work in progress	2,456	1,969	25%
Trade receivables	1,643	2,034	-19%
Other current assets	3,019	2,462	23%
Current financial assets	64	125	-49%
Cash and cash equivalents	8,623	17,453	-51%
Current assets	**15,806**	**24,043**	-66%

Current assets amounted to €15,806 thousand at December 31, 2018, versus €24,043 thousand at December 31, 2017.

Negative net cash flows relating to operating activities are financed with the Group's cash. This translated into a decrease in the outstanding amount of cash and current financial instruments, which stood at €8.6 million at December 31, 2018, versus €17.5 million at December 31, 2017.

Cash and outstanding amount in cash represented 55% of current assets at December 31, 2018.

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 Research Tax Credit receivable at December 31, 2018 was €1,097 thousand versus €1,096 thousand at December 31, 2017. (See Note 7.2 to the consolidated financial statements presented in Section 20.1 "Consolidated financial statements prepared according to IFRS for the financial year ended December 31, 2018" of this Registration Document).

9.3.3. Equity

Consolidated data audited in €K	2018	2017	Change
Issued capital	1,008	974	3%
Share premium	91,753	87,973	4%
Reserves	(72,072)	(61,896)	15%
Foreign currency translation on reserves	74	(61)	218%
profit/(loss)	(12,785)	(10,245)	25%
Total equity	**7,979**	**16,744**	**-48%**

The net changes in Group equity are mainly due to the annual deficits recorded in 2017 and 2018, 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	2018	2017	Change
Non-current liabilities			
Long-term loans and borrowings	6,457	6,567	-2%
Non-current provisions	422	283	49%
Total non-current liabilities	**6,879**	**6,850**	4%

Long-term loans and borrowings include refundable grants from BPI (formerly OSEO) at December 31, 2018, as well as financing from IPF Partners.

At December 31, 2018, the Company benefited from the €2.8 million BPI loan. The COFACE loan was repaid in full in the second half of 2018.

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	2018	2017	Change
short-term loans and borrowings	600	386	55%
Trade payables	2,087	1,663	25%
Other current liabilities	2,216	2,104	5%
Total current liabilities	**4,904**	**4,153**	**18%**

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.

SECTION 10
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 "P preferred shares"), as well as by significant conditional advances granted by OSEO and 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 €2.9 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 2016 and December 2016 relating to the line of financing established with the intermediary Kepler Cheuvreux, for a total amount of €2.5 million net;
- a €7 million bond issue with IPF Partners, a fund specialized in alternative financing for European growth companies in the healthcare sector.This financing was comprised of two loan tranches. The Company has only drawn the first tranche of €4.0 million, which was issued in February 2017. The second tranche for the remaining €3.0 million was available for the following 12 months;
- drawdowns between January 2017 and December 2017 relating to the line of financing established with the intermediary Kepler Cheuvreux, for a total amount of €15.5 million net;
- drawdowns in January 2018 relating to the line of financing established with the intermediary Kepler Cheuvreux, for a total amount of €3.8 million net.

Summary of drawdowns by Kepler Cheuvreux

	BSA 2016-2	BSA 2017-1	BSA 2017-2
Date of General Meeting	May 04, 2016	May 3, 2017	May 3, 2017
Date of Chairman's decisions	Nov. 18, 2016	Sep 19, 2017	Dec 1, 2017
Number of authorized share warrants (BSA)			
Total number of BSA issued	1,850,000	2,100,000	2,250,000
Total number of shares that may initially be subscribed	1,850,000	2,100,000	2,250,000
of which the number that may be subscribed by corporate officers	0	0	0
Number of beneficiaries who are not corporate officers	1	1	1
Start date for exercise of the BSA	Nov. 18, 2016	Oct. 6, 2017	Dec 1, 2017
BSA expiration date	Nov. 18, 2018	Oct. 6, 2018	Dec. 1, 2018
BSA issue price	€3.0000		
Number of shares subscribed at December 31, 2018	1,850,000	2,100,000	2,050,000
Cumulative number of BSA canceled or void as of December 31, 2018	0	0	0
BSA remaining at December 31, 2018	0	0	200,000
Number of shares that may be subscribed for as of December 31, 2018	0	0	200,000

In accordance with the terms of the agreement, Kepler Cheuvreux, acting as financial intermediary and guarantor of the transaction, committed to subscribe to 24 shares, on its own initiative, following a timetable over a maximum period of 24 months. The shares will be issued based on a volume-weighted average share price over the two trading days preceding each issue, minus a maximum discount of 6.5%.

Changes in the composition of the share capital during the year

	Number of shares	Nominal value (euros)	Issued capital (euros)
Shares comprising the share capital at the beginning of the financial year	24,347,338	0.04	973,893.52
Exercise of BSAs	850,000	0.04	34,000,000
Exercise of Stock Options	4,000	0.04	160.00
Shares comprising the share capital at the end of the financial year	25,201,338	0.04	1,008,053.2

10.1.1. Capital financing

The following table summarizes the principal capital increases, in value, between the Company's creation date and December 31, 2018:

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)
05.2015	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
2017	15.6	Exercise of BSA by Kepler Cheuvreux
2018	3.8	Exercise of BSA by Kepler Cheuvreux
Total	125.6	

10.1.2. Financing through loans

The Company did not take out any new borrowing in 2018.

On February 8, 2017, Mauna Kea Technologies announced a debt financing agreement with IPF Partners, containing two tranches for a total amount of €7.0 million, tranche A of which was exercised for €4.0 million in February 2017. The second tranche of €3.0 million has not been exercised.

In November 2018, the Company signed an amendment to the existing agreement, which included two additional tranches of debt, a first tranche of €5.0 million was available until the end of April 2019, and another tranche of €5.0 million was available until September 2019, both tranches being subject to predefined sales level conditions. At December 31, 2018, the Company fulfilled the conditions necessary to raise the first tranche. In addition, the amendment modified the repayment schedule for tranche A exercised in February 2017, which would have begun from June 2019 and no longer from December 2018.

At December 31, 2018, the renegotiation of the IPF bond issue led, under IFRS 9, to reduce the debt by €41 thousand in exchange for a financial product.

The loans would have beared interest at an annual rate equal to 3 month Euribor + 8.0%. The first loan tranche had a term of 5 years, with deferred principal repayment for the first 15 months. The second loan tranche had a term of 4 years, with deferred principal repayment for the first 12 months. The issuance of the warrants was subject to certain restrictive financial performance conditions, included in the terms and conditions of the agreement.

During the first half of 2019, the Company signed a €22.5 million loan agreement with the European Investment Bank. The first tranche of €11.5 million available on condition of repayment of the IPF, while the subsequent tranches of €6 million and €5 million, will be available subject to the achievement of certain milestones, including the Company's commercial progress and its future equity financing activities.

The first tranche of €11.5 million was drawn down on 3 July 2019. This first tranche is repayable at the end of a 5-year period for both the capital and the capitalized interest at a fixed rate of 5%. In parallel, the Company repaid the loan it had contracted with IPF for an amount of €10.7 million.

Tranche 1 is accompanied by the issuance of share subscription warrants (BSAs) entitling the holder, in the event of exercise, to subscribe for a maximum of 1,450,000 shares of the Company (i.e. 5.75% of the share capital on a non-diluted basis) subject to the legal and contractual adjustments provided for in the documentation. These warrants were issued on the basis of the fourth resolution (private placement) adopted by the Extraordinary General Meeting of 5 October 2018. The exercise price of the warrants is equal to the weighted average of the volumes of the last three trading days preceding their issue, less a 5% discount, i.e. €1.8856 per warrant. The warrants may be exercised from this day until the twentieth anniversary of the issuance of the warrants, i.e. 3 July 2039.

10.1.3. Financing by repayable advances

The Company has received three conditional advances that were the subject of an agreement with BPI France (formerly OSEO) as well as a loan from COFACE.

Summary of advances received:

At Dec. 31, 2018 (in €k)	Amount granted	Amount Receipt	Amount repaid	Discount effects	Amount still to be repaid
BPI France loans	4,436	3,923	1,020	-137	2,766
COFACE loans	1,704	1,704	1,704		
Total paid	**6,140**	**5,627**	**2,724**	**-137**	**2,766**

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, 2018 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	
	2018	2017
net cash flows from operating activities	(10,900)	(9,742)
Of which self-financing capacity	(10,874)	(8,607)
Of which change in WCR related to business activities	(26)	(1,136)
Net cash flows from investing activities	(1,246)	(735)
net cash flows from financing activities	3,299	18,913
Net foreign exchange difference	16	(35)
Change in cash	(8,830)	8,401

10.2.1 cash flows from operating activities

The cash consumption relating to operating activities for the financial years ended December 31, 2018 and 2017 came to €10,900 thousand and €9,742 thousand respectively.

The cash consumption relating to operating activities rose by 12% during 2018. This increase was due to the reversal of positive impacts on the WCR in 2018 (-€26 thousand in 2018 vs. -€1,136 thousand in 2017) and the new "pay-per-use" business model implemented in the United States which is more capital-intensive than direct sales.

10.2.2 Cash flows relating to investment activities

Outside the "pay-per-use" model, the Company's production activity does not require large tangible fixed investments due to the use of subcontracting for part of the production. However, the final manufacturing tasks – assembly, control and validation – are performed in-house.
These investments in property, plant and equipment, in particular systems placed on consignment, demonstration devices, prototypes and office equipment, came to €1,153 thousand and €542 thousand respectively for the financial years ended December 31, 2018 and 2017.

On the other hand, the Company activated intangible assets in the course of the 2017 and 2018 financial years, mainly patent and other intangible asset expenses. In this respect, the Company invested €101 thousand and €185 thousand respectively for the 2018 and 2017 financial years. In 2018, the 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 €3,299 thousand and €18,913 thousand for the 2018 and 2017 financial years.

In 2018, the cash flow from financing activities of €3,299 thousand mainly came from BSA warrants exercised for €3,780 thousand.

In 2017, the cash flows from financing activities of €18,913 thousand mainly consisted of exercised BSAs for €15,496 thousand and the bonds issued to IPF for €3,900 thousand.

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
11. INNOVATION, PATENTS, LICENSES, TRADEMARKS AND DOMAIN NAMES

Research and development costs are recognized in accordance with the IAS 38 standard. These costs are described in Note 1.4 to the 2018 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 the end of December 2018, the Group had a total of 40 inventions protected by patent registration, grouped in 34 families of separate patents. At that date, these 40 inventions had resulted in 236 patents being granted. Twenty-six patents 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.

11.2.2Nature 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
Endoscopy	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		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
OCT-OA	11	01/22/2004	DAT	WO2005/080911	High-resolution in vivo 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, in vivo eye tomography system equipped with said device
Active targeting (CIP)	13	01/22/2004	TOM	US 7,658,495	Aiming procedure and device for eye examination, in vivo eye tomography system equipped with this device (Continuation *in part*)
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 in vivo fibered confocal fluorescence imaging system, in situ in vivo fibered confocal fluorescence imaging procedure and system
Mosaicing	21	08/02/2017	MOS	FR 2 904 927	Image mosaicing procedure, including motion distortion and tissue deformation cancellation option, for fibered confocal 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	Optical procedure and probe for in vivo imaging of biliary or pancreatic duct mucosa, and procedure to selectively treat a biliary or pancreatic duct mucosa tissue sample
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 micropositioner	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
Smart Review (continuation)	39	05/23/2014	EV3	US 15/997,802	Characterization method of images acquired with a medical video device
Smart Review (continuation)	39	05/23/2014	EV4	US 15/997,915	Characterization method of images acquired with a medical video device
Smart Review (continuation)	39	05/23/2014	EV5	US 15/997,936	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:

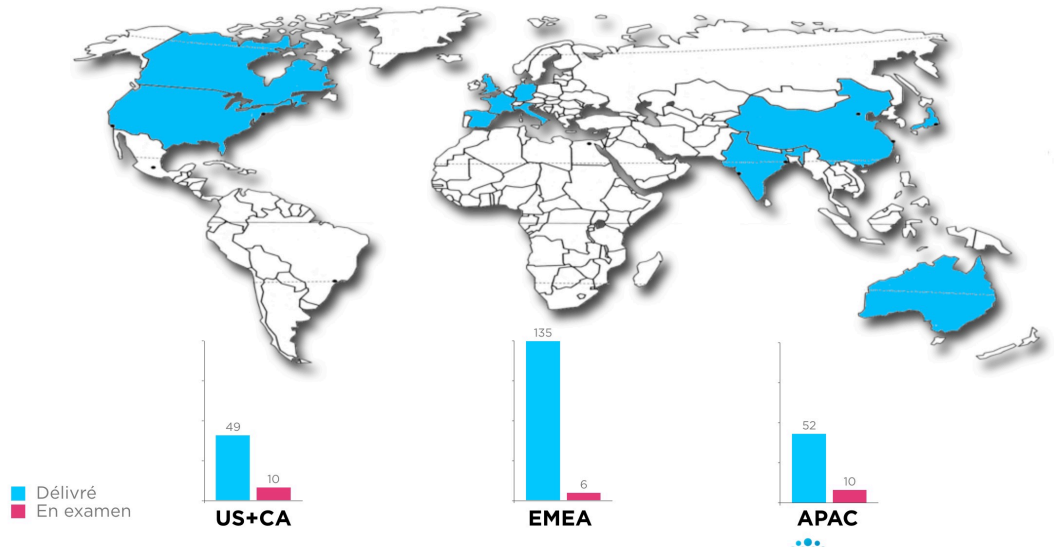
- alveolar imaging;
- biliary duct imaging;
- solid organ imaging; and
- deep intra-cerebral imaging of animals.

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 chart gives the distribution by number of the various patent applications/patents issued according to world regions and according to their status.



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 endomicroscopic 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.

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
12. TRENDS

12.1 Principal trends since the end of the last financial year

First Quarter 2019 Sales

The Company shipped 13 Cellvizio systems in the first quarter, including 7 systems placed under the Company's pay-per-use program, an increase of 63% compared to 8 systems in the first quarter 2018 including 5 systems placed under consignment. Shipped consumable probes unit volume was 195 units, an increase of 85% compared to 106 probes sold in the first quarter of 2018. Recurring sales generated by probes within the framework of the consignment program increased by 189% compared with 2018 (€331 thousand in 2019 versus €114 thousand in 2018).

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

N/A.

SECTION 13
13. PROFIT PROJECTIONS OR ESTIMATES

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

SECTION 14
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.

On October 10, 2018 the Board of Directors appointed, with effect from October 22, 2018:

- Mr. Alexandre Loiseau as Chairman of the Board of Directors and Chairman of the Strategic Committee;
- Mr. Christopher McFadden as member of the Board of Directors and Chairman of the Compensation and Appointments Committee;
- Mr. Robert L. Gershon as CEO and member of the Board of Directors;
- Mr. Christophe Lamboeuf as Deputy CEO while maintaining his role as Chief Financial Officer;
- Ms. Molly O'Neill as Chairwoman of the Audit Committee.

Mr. Jean Luc Boulnois resigned from his position as a member of the Board of Directors and Chairman of the Audit Committee.

At its meeting of March 19, 2019, the Board of Directors deemed that four of its members satisfied all the criteria, namely Messrs. Christopher McFadden and Joseph Devivo, and Mses. Jennifer F. Tseng and Molly O'Neill.

Every year, the Board of Directors will assess, on a case-by-case basis, the status of each member vis-a-vis the aforementioned criteria.

Terms of office

The members of the Board of Directors are appointed by the Ordinary General Meeting for a term of three years. This term is tailored to the specific requirements of the Company. The renewal of directors' terms of office is not staggered, as recommended by the MiddleNext Code (recommendation No. 9). In fact, all members' terms of office are scheduled to end at the same time.

Ethics

The internal rules and code of ethics were approved by the Board of Directors. These documents outline the rules which must be followed by the members of the Board, in accordance with recommendation No. 1 of the MiddleNext Code.

Director selection

At the time of appointment or renewal of the term of office of each director, details of their experience, expertise and list of appointments held is set out in the Registration Document and shared at the Annual General Meeting. This information is available online on the Company's website, as suggested in the MiddleNext Code, under recommendation No. 8. The appointment and/or renewal of each director shall be the subject of a specific resolution submitted to the shareholders' vote.

The applicable rules are statutory and are in accordance with the law.

Preparation and Organization of tasks undertaken by the Board

The Company's Board of Directors has a set of internal rules, in accordance with recommendation No. 7 of the MiddleNext Code. This document, approved by the Board of Directors at its meeting of May 25 and amended by the Board of Directors at its meeting of March 21, 2017, is available on the Company's website.

In compliance with recommendation No. 2, these internal rules, in the clause entitled "Disclosure of interest" on the prevention of conflicts of interest, state that a director who finds him or herself in a situation of conflict of interest, is obliged to inform the members of the Board as such and to determine whether he/she should abstain from voting and/or taking part in Board discussions.

In compliance with recommendation No. 4 of the MiddleNext Code, outside of Board meetings and when in the interest of the Company, the directors must regularly be provided with all important information relating to the Company, that is likely to have an impact on the commitments and financial position thereof. They may ask for any further explanations or additional information, and more generally, may request access to any information they deem useful.

To take an effective part in the Board's work and deliberations, each member of the Board is provided with whatever additional documents he or she thinks useful. Such requests are made to the Chairman or, when appropriate, to any senior executive of the Company (Chief Executive Officer or Chief Operating Officer).

Each member of the Board is authorized to meet with the Company's senior executives, so long as he or she first informs the Chairman of the Board and the Chief Executive Officer.

The Board is regularly informed by the Chief Executive Officer of the Company's and the Group's financial position, cash position, financial commitments and significant events.

Finally, any new member of the Board may ask to receive training in particular aspects of the Company or Group, their lines of business and their business segments.

The members of the Board are convened by letter, fax or email at least five (5) days before each meeting.

The Board may also be convened by any other means, even verbally, if all the Board members in office are present or represented at the meeting.

All documents or drafts of documents that could be informative to the members about the meeting agenda and any matters brought before the Board are sent, handed or made available to the members of the Board within a reasonable time before the meeting.

Moreover, whenever it meets, the Board is informed about the Company's financial position, cash position and commitments.

In accordance with Recommendation 11 of the MiddleNext Code, once a year the Board discusses the way it functions and, at least once every three years, undertakes a formal assessment, where appropriate with an outside consultant.

The purpose of this assessment, moreover, is to make sure that the important questions are suitably prepared and debated, and to measure the contribution of each member to the Board's work, chiefly in regard to his or her qualifications and degree of involvement.

Report on the Board's activities during the 2018 financial year

The minutes of each meeting are prepared by the Chief Executive Officer, then approved by the Chairman, who submits them for approval at the next meeting. They are copied into the minutes register following signature by the Chairman and one Director.

During the 2018 financial year, the Board of Directors met 12 times: on January 25, February 28, March 22, May 4, May 30, July 24, September 19, October 2, 10 and 17, and November 12 and 28. All meetings were chaired by the Chairman of the Board. The directors' attendance rate was close to 82%.

As set out in recommendation No. 14 of the MiddleNext Code, the majority of issues are addressed at the meetings of the Board. Nevertheless, the issues relating to the assumption of an accident and the sudden unavailability of the director were not addressed during 2018 and will be added to the agenda of the next Board meeting.

Prior to Board meetings, the directors are sent all documents required to enable them to prepare for the issues to be discussed.

In accordance with recommendation No. 11 of the MiddleNext Code, in 2018, the Board performed a self-assessment of its composition, organization and the way it operates. A questionnaire was sent to the members of the Board, the results of which will be presented by the Chairman at the next meeting.

Lastly, in accordance with recommendation No. 12, the directors must offer minority shareholders the opportunity to meet with them and discuss the operation of the Company. In 2018, this took place at the General Meetings held in Paris on May 30, June 13, October 5, and December 19.

At December 31, 2018, the Company's Board of Directors was comprised of six directors. No non-voting Board members were appointed on this day.

Name or company name	Role	Date of appointment	Expiration of term of office	Committee
Alexandre Loiseau	Chairman of the Board of Directors	Appointed as director by the OGM of May 3, 2017 Appointed Chairman of the Board of Directors on October 10, 2018 with effect from October 22, 2018	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019	Member and Chairman of the Strategic Committee Member of the Compensation Committee
Chris McFadden	Independent director	OGM of 5/3/2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019	Compensation Committee – Member and Chairman of the Audit Committee
Joseph Devivo	Independent director	OGM of 5/3/2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019	Member of the Audit and Strategic Committees
Jennifer F. Tseng	Independent director	OGM of 5/3/2017	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019	Member of the Compensation Committee
Molly O'Neill	Independent director	OGM of 30/05/2018	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019	Member and Chairman of the Audit Committee
Robert Gershon	Independent director	Coopted by the Board of Directors of October 10, 2018 with effect from October 22, 2018 – Ratified by the OGM of December 19, 2018	At the close of the Annual General Meeting held to approve the financial statements for the year ending December 31, 2019	N/A

Mr. Jean Luc Boulnois resigned from the Board of Directors and from his position as Chairman of the Audit Committee at the Board of Directors meeting of October 10, 2018, with effect from October 22, 2018

In accordance with recommendation No. 1 of the MiddleNext Code, the executive directors do not hold more than two other appointments as directors in listed companies outside the Board's group.

The CEO uses the Company's registered office as his professional address.

The professional addresses of the other directors are as follows:

- Mr. Alexandre Loiseau is domiciled at Mauna Kea Technologies;
- Mr. Robert L. Gershon is domiciled at Mauna Kea Technologies;
- Christopher McFadden is domiciled at Kohlberg Kravis Roberts 555 California Street, 50th Floor, San Francisco, CA 94104, United States;
- Joseph DeVivo is domiciled at InTouch Health, 7402 Hollister Ave., Goleta, CA 93117, United States;
- Jennifer F. Tseng is domiciled at Boston Medical Center, 88 East Newton Street, C-500, Boston, MA 02118, United States;
- Ms. Molly O'Neill is domiciled at Proteus Digital, 2600 Bridge Pkwy, Ste. 101, Redwood City, CA 94065, 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.

Balanced gender representation

On the date of this report, two of the six members of the Board of Directors are women. The Company is in compliance with the law of January 27, 2011 on balanced gender representation on boards of directors, the Board being comprised of less than eight members, therefore the difference between the number of directors of each sex shall not be greater than two.

14.1.2Other corporate positions as of December 31, 201

Name and roles held within the Company	Main roles held in all Companies	Other appointments held in all companies
Alexandre Loiseau, Chairman of the Board of Directors	Chief Executive Officer of Mauna Kea Technologies until October 22, 2018	MDoloris SA, member of the Strategic Committee
Robert L. Gershon Robert L. Gershon, Director and CEO since October 22, 2018	Mauna Kea Technologies – Chief Executive Officer as of October 22, 2018	N/A
Christopher McFadden, independent director, Chairman of the Board of Directors through October 22, 2018	Kohlberg Kravis Roberts, Managing Director	- Foundation Radiology Group, independent director - InnovaTel Telepsychiatry, director - Reliant Rehabilitation, Board of Directors observer - Athena Health, Board of Directors observer - Healthcare Staffing Services, Board of Directors observer

Joseph DeVivo - independent director	InTouch Health, Chief Executive Officer	- ALSAC/St. Jude, director - AdvaMed, Director
Jennifer F. Tseng – independent director	Boston University School of Medicine, Chief and Chair of the Surgery Department	N/A
Molly O'Neill – independent director	St George's University, Director of growth and strategy	- Qure Medical, director - Rocky Vista University Boards, director

14.1.3 Director biographies

Alexandre (Sacha) Loiseau, Ph.D.
Chairman of the Board
Chairman of the Strategic Committee

Sacha Loiseau founded Mauna Kea Technologies in May 2000 and was its CEO for 18 years.

Co-inventor of the Cellvizio confocal laser endomicroscopy platform, he oversaw and raised more than €120 million to finance the development of Mauna Kea since its creation, taking the company public on the Euronext stock market in July 2011.
In 2013, Sacha was appointed co-leader of the Industrial Plan on Medical Devices and New Health Care Equipment, then a member of the "Medicine of the Future" steering committee. Sacha helped found MedTech, the French association of business leaders in innovative medical technologies in France, and has served as its Vice President since June 2016.
Sacha 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. He is a graduate of the École Polytechnique in Paris and has a Ph.D. in Astrophysics and Space Instrumentation from the Université Paris-Diderot. He has authored many scientific articles, is cited as an inventor on seven patents and was a 2018 Marius Lavet award winner.

Robert L. Gershon
Chief Executive Officer
Member of the Board of Directors

Robert L. Gershon has more than 30 years of experience in the field of medical technologies.

Robert is a seasoned executive with more than 30 years of experience in managing business strategies and general management at medical technology companies. Rob was CEO of Bovie Medical (NYSE: BVX) from December 2013 to December 2017, where he successfully led the commercialization of new technologies, repositioned the company's product portfolio and improved its financial profile. Previously, he held management positions at Henry Schein Inc. and Covidien (now Medtronic). Rob has an MBA from J.L. Kellogg Graduate School of Management of Northwestern University and a BSBA from American University in Washington, D.C.

Christopher D. McFadden
Member of the Board
Chairman of the Compensation and Appointments Committee

Christopher McFadden is the Senior Managing Director at Kohlberg Kravis Roberts (KKR), a global investment fund.

Prior to joining KKR, Mr. McFadden founded Canyon Healthcare Partners, a healthcare private equity firm and was a Senior Advisor to Athyrium Capital Management. Previously, he was a Managing Partner at Health Evolution Partners and a Managing Director at Goldman Sachs, where he was a member of the Americas Special Situations Group (AmSSG) focused on healthcare private investing. Mr. McFadden serves as Chairman of InnovaTel Telepsychiatry and as a Board Member for ValueCentric.

Joseph DeVivo
Member of the Board

Joseph DeVivo is Chief Executive Officer of InTouch Health, Inc.

Mr. DeVivo previously served as CEO and a member of the Board of Directors of AngioDynamics, Worldwide President of Smith & Nephew Orthopedics, CEO and a member of the Board of Directors of RITA Medical Systems, Operations Director and a member of the Board of Directors of Computer Motion Incorporation (CMI), Vice-President and CEO of U.S. Surgical/Davis a division of Tyco International Healthcare representing $350 million. Joseph received his B.S. in Business Administration from the E. Claiborne Robins School of Business at the University of Richmond.

Jennifer F. Tseng
Member of the Board

Jennifer F. Tseng is Head and Chairwoman of Surgery at Boston University School of Medicine.

Dr. Tseng is a renowned oncologist and gastrointestinal surgeon whose practice focuses on the upper gastrointestinal tract. She has led research groups at Beth Israel Deaconess Medical Center in the fields of oncology, gastroenterology, endocrine and breast problems, as well as melanomas, sarcomas, and other malignant tumors.
Dr. Tseng is a graduate of Stanford with a medical doctorate from the University of California in San Francisco as well as a Master's in Public Health from Harvard T.H. Chan School of Public Health. She did her internship in General Surgery at Massachusetts General Hospital then conducted research in molecular medicine at Harvard Medical School/Children's Hospital of Boston and in surgical oncology at the University of Texas MD Anderson Cancer Center in Houston.

Molly O'Neill
Member of the Board
Chairman of the Audit Committee

Molly O'Neill, Chief Growth and Strategy Officer of St. George's University, Grenada.

Over the past 30 years Ms. O'Neill has held senior leadership roles at Tenet Healthcare Corporation, Ascension Health Care Network, Duke Medicine and Partners Healthcare in Boston. From 2015 to 2017 she was Chief Commercial Officer of Proteus Digital Health. Earlier in her career she worked at Gambro Healthcare as Vice President of Disease Management & Business Development. During her career she has demonstrated an exceptional ability to bring clinical value to patients and all stakeholders in the healthcare sector. Molly received her B.Sc. in Journalism and her M.S. in Health Care Administration from Virginia Commonwealth University/Medical College of Virginia.

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
15. COMPENSATION AND BENEFITS

15.1 Compensation of directors and executives

In accordance with the provisions of Article L. 225-373-3 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.

15.1.1 Executive compensation

The Company applies all of the recommendations of the MiddleNext Code on executive and non-executive pay.

For the 2018 financial year, 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 March 21, 2019. These objectives took into account the Company's sales growth.

At its meeting on March 19, 2019, the Board of Directors, acting on the proposal from the Compensation Committee dated February 6, 2019, examined the level of achievement of these targets and decided to pay the Chief Executive Officer the variable compensation corresponding to those targets, subject to the Company's performance.

Executive corporate 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 incentive policy, the Company awarded bonus preferred shares to Company employees and stock options to employees of its subsidiary, on October 10, 2018 and July 19, 2017.

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

Restrictions imposed by the Board in respect of the exercise of options granted or sale of bonus shares granted to executives.

The executive corporate officer does not hold any options or share warrants.

In accordance with the provisions of Article L. 225-197-1 of the French Commercial Code, the Chief Executive Officer must hold in registered form, until the termination of his duties, 10% of the shares awarded by the Board of Directors, within the limit of a number of shares whose cumulative value does not exceed one year of total gross compensation.

Approval of the elements of compensation due or granted to the Chairman and the Chief Executive Officer for 2018

In accordance with Article L. 225-100-II of the French Commercial Code, the fixed, variable and exceptional elements of compensation granted or still to be granted for the 2018 financial year to the Chairman and the Chief Executive Officer by virtue of their offices, as approved by the Board of Directors in line with the principles and criteria approved by the General Meeting on December 19, 2018 under its second and fourteenth resolutions and set out in the "Compensation of executive

corporate officers" section above, will be submitted for shareholder approval at the General Meeting called to approve the financial statements for the 2018 financial year.

Principles and criteria for determining, allocating and granting the fixed, variable and exceptional elements of total compensation and benefits in kind due to the Chairman, the Chief Executive Officer and the Deputy CEO for 2019.

Pursuant to Article L. 225-37-2 of the French Commercial Code, the Board of Directors submits to the approval of the General Meeting the principles and criteria applicable to the determination, distribution and allocation of variable, and exceptional elements of the total compensation and benefits of any kind attributable to the President and Chief Executive Officer resulting from the exercise of their mandate for the 2019 financial year and constituting the compensation policy relating to them.

These principles and criteria, adopted by the Board of Directors on the recommendation of the compensation Committee, are set out below:

For Mr. Alexandre Loiseau, Chairman of the Board of Directors:

Compensation elements	Principles	Criteria for determination
Fixed compensation	The chairman receives a fixed compensation payable in 12 monthly installments	The gross annual amount of this compensation, which takes into account the additional significant tasks entrusted by the Board of Directors to its new Chairman, was set at €236,740, less the directors' fees paid to him during the same period.
Attendance fees	The Chairman receives attendance fees.	As for every director, the Chairman may receive attendance fees, the amount of which is decided by the Board, within the limit of the budget approved by the General Meeting) and the principles adopted by the Board of Directors. The Board, based on its his attendance and the time devoted to his office, including, where applicable, within the committee or committees set up by the Board.
Benefits in kind	Provision of a vehicle GSC Insurance	

In addition, the Chairman may be granted the option to subscribe, for valuable consideration, to share warrants subject to presence conditions.

For Mr. Robert L. Gershon, Chief Executive Officer:

Compensation elements	Principles	Criteria for determination
Fixed compensation	The CEO receives a fixed compensation payable in 12 monthly installments	The gross annual amount of this fixed compensation was set at 395,000 euros for the financial year 2018 For 2018, this compensation will be paid prorata temporis (period from October 22 to December 31, 2018).
Variable compensation	The Chief Executive Officer receives a variable compensation up to 100% of his fixed compensation, if 100% of the objectives have been attained.	This variable compensation is based half on Company objectives and half on objectives set by the Board of Directors on the recommendation of the Compensation Committee. These objectives are not made public for reasons of confidentiality.

In addition, the CEO may be granted share subscription options and bonus shares, subject to conditions of attendance and performance.

Finally, Robert L. Gershon may claim a severance compensation under the following conditions:

In the event of dismissal not caused by gross or serious misconduct or resignation caused by a significant reduction of its awards or compensation, or following a change of control of the Company, Robert L. Gershon would receive, provided that he has attained the objectives on which his normal bonus is based (up to 100% of his fixed compensation) by more than 50%, (i) a monthly indemnity equal to his salary for 12 months following his departure, (ii) the pro rata of his annual bonus until the date of his departure (calculated by reference to the level of achievement of the Company's objectives for the last fully completed financial year, if the departure is during the first half-year, or the current financial year if during the second half-year, and (iii) an amount equivalent to the cost of maintaining his medical insurance for 12 months. The schedule for exercising his options would continue in this case for 12 months following his departure as if he had not left the Company.

Granting this severance compensation was authorized by the Board of Directors meeting on October 10, 2018, in accordance with the provisions of Article L. 225-38 of the French Commercial Code.

In accordance with the provisions of Article L. 225-42-1 of the French Commercial Code, this indemnity was published on the Company's website and will be submitted for approval by the Ordinary General Meeting, based on a special report by the statutory auditors, to be held in 2019 to deliberate on the financial statements for the financial year ended December 31, 2018.

It is recalled, to the extent necessary, that no payment of any kind whatsoever may be made before the Board of Directors acknowledges, on or after termination of his duties, compliance with the above conditions.

For Mr. Christophe Lamboeuf, Deputy CEO:

It is recalled that all of the compensation received by Mr. Christophe Lamboeuf is for his salaried CFO duties:

Compensation elements	Principles	Criteria for determination
Fixed compensation	The CEO receives a fixed compensation for his salaried CFO duties payable in 12 monthly installments	The gross annual amount of this fixed compensation was set at €185,000.
Variable compensation	The Chief Executive Officer receives a variable compensation for his salaried CFO duties up to 30% of his fixed compensation, i.e. €55,500, if 100% of the objectives have been attained.	Such variable compensation is based on corporate objectives set by the Remuneration Committee.
Benefits in kind	Provision of a vehicle	

In addition, the Deputy CEO may be granted share subscription options and/or bonus shares, subject to conditions of attendance and performance.

We ask you to approve the principles and criteria as set out in this report as well as the resolutions pertaining to them:

"Ninth resolution
Approval of the principles and criteria for determining, allocating and granting the fixed, variable and exceptional elements of total compensation and benefits in kind due to Alexandre Loiseau as Chairman of the Board of Directors (ex ante vote),

The Annual General Meeting, ruling under the quorum and majority conditions required for ordinary general meetings,

having reviewed the Board of Directors report,

approves the principles and criteria for determining, allocating and granting the fixed, variable and exceptional items of total compensation and benefits in kind presented in the aforementioned report and due to Mr. Alexandre Loiseau for the 2019 financial year as Chairman of the Board of Directors, as such principles and criteria are described in the Board of Directors report."

"Tenth resolution
Approval of the principles and criteria for determining, allocating and granting the fixed, variable and exceptional elements of total compensation and benefits in kind due to Robert L. Gershon as Chief Executive Officer,
The Annual General Meeting, ruling under the quorum and majority conditions required for ordinary general meetings,

having reviewed the Board of Directors report,

approves the principles and criteria for determining, allocating and granting the fixed, variable and exceptional elements of total compensation and benefits in kind presented in the aforementioned report and due to Mr. Robert L. Gershon for the 2019 financial year in his capacity as Chief Executive Officer, as such principles and criteria are described in the Board of Directors report."

"Eleventh resolution

Approval of the principles and criteria for determining, allocating and granting the fixed, variable and exceptional elements of total compensation and benefits in kind due to Mr. Christophe Lamboeuf as Chief Executive Officer,

The Annual General Meeting, ruling under the quorum and majority conditions required for ordinary general meetings,

having reviewed the Board of Directors report,

approves the principles and criteria for determining, allocating and granting the fixed, variable and exceptional elements of total compensation and benefits in kind presented in the aforementioned report and due to Mr. Christophe Lamboeuf for the 2019 financial year in his capacity as Chief Executive Officer, as such principles and criteria are described in the Board of Directors report."

In accordance with Article L. 225-100 of the French Commercial Code, the amounts resulting from the implementation of these principles and criteria will be submitted for shareholder approval at the General Meeting called to approve the financial statements for the 2019 financial year.

Summary table of compensation and options and shares granted to each executive corporate officer		
Alexandre Loiseau (Chairman of the Board of Directors as of October 22, 2018)	Financial year ended 12/31/2018 (in euros)	Financial year ended 12/31/2017 (in euros)
Compensation due for the period (detailed in Table 2)	34,241	N/A
Valuation of options granted during the period	N/A	N/A
Valuation of performance shares granted during the period	N/A	N/A
Alexandre Loiseau (Chief Executive Officer until October 22, 2018)	Financial year ended 12/31/2018 (in euros)	Financial year ended 12/31/2017 (in euros)
Compensation due for the period (detailed in Table 2)	214,805	256,605
Valuation of options granted during the period	N/A	N/A
Valuation of performance shares granted during the period	373,050	N/A
Robert L. Gershon (Chief Executive Officer – as of October 22, 2018)	Financial year ended 12/31/2018 (in euros)	Financial year ended 12/31/2017 (in euros)
Compensation due for the period (detailed in Table 2)	65,979	N/A
Valuation of options granted during the period	481,286	N/A
Valuation of performance shares granted during the period	N/A	N/A

Summary of compensation for each executive corporate officer				
Alexandre Loiseau (Chairman of the Board of Directors)	Amounts due for the year ended 12/31/2018 (in euros)		Amounts due for the year ended 12/31/2017 (in euros)	
	Amounts due	Amounts paid	Amounts due	Amounts paid
-fixed compensation	31,692	31,692	0	0
-variable compensation	0	0	0	0
-exceptional compensation	0	0	0	0
-attendance fees	14,200	0	0	0
-benefits in kind	2,550	2,550	0	0
TOTAL	48,442	34,242	0	0
Alexandre Loiseau (Chief Executive Officer)	Amounts due for the year ended 12/31/2018 (in euros)		Amounts due for the year ended 12/31/2017 (in euros)	
	Amounts due	Amounts paid	Amounts due	Amounts paid
-fixed compensation	165,575	165,575	205,000	205,000
-variable compensation	39,899	36,900	36,900	45,850
-exceptional compensation	0	0	0	0
-attendance fees	0	0	0	0
-benefits in kind	12,330	12,330	14,705	14,705
TOTAL	217,804	214,805	256,605	265,555
Robert L. Gershon (Chief Executive Officer)	Amounts due for the year ended 12/31/2018 (in euros)		Amounts due for the year ended 12/31/2017 (in euros)	
	Amounts due	Amounts paid	Amounts due	Amounts paid
-fixed compensation	65,979	65,979	0	0
-variable compensation	0	0	0	0
-exceptional compensation	0	0	0	0
-attendance fees	0	0	0	0
-benefits in kind			0	0
TOTAL	65,979	65,979	0	0

Stock options granted during the financial year to each executive corporate officer by the issuer and by any company group						
Name of the executive corporate 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
Robert Gershon	11/12/2018	Purchases	€481,286	600,000	€2.59	2019-2022
TOTAL			€481,286	600,000	€2.59	

Stock options exercised during the financial year by each executive corporate officer				
Alexandre Loiseau (Chairman of the Board of Directors)	Plan No. and date	Number of options exercised during the period	Exercise price	Year of grant
N/A				
Robert L. Gershon (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 corporate 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 options according to the method used for the consolidated financial statements	Acquisition date	Vesting date	Performance conditions
Alexandre Loiseau	10/10/2018	4,500	€373,050	10/10/2019	10/10/2021	yes
Christophe Lamboeuf	10/10/2018	1,200	99,480€	10/10/2019	10/10/2021	yes

Bonus shares vesting during the period for each executive corporate 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 executive officers:

Executive corporate officers	Employment contract		Supplementary pension plan		Compensation or benefits due or likely to be due owing to termination or change of role		Compensation for non-compete clause	
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, 2019							
	Yes	No	Yes	No	Yes	No	Yes	No
Robert L. Gershon, (Chief Executive Officer)		X		X		X		X
Date on which term of office began:	October 22, 2018							
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, 2019							

Executive corporate officers	Employment contract		Supplementary pension plan		Compensation or benefits due or likely to be due owing to termination or change of role		Compensation for non-compete clause	
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, 2019							
	Yes	No	Yes	No	Yes	No	Yes	No
Christophe Lamboeuf (Deputy CEO)	X			X		X		X
Date on which term of office began:	October 22, 2018							
Date on which term of office expired:								

15.1.2 Directors' fees and other compensation received by non-executive corporate officers

Table on directors' fees and other compensation received by non-executive corporate officers				
Members of the Board of Directors	Directors' fees paid for the year ended 12/31/2018 (in euros)	Directors' fees paid for the year ended 12/31/2017 (in euros)	Plans awarded in 2018	Plans awarded in 2017
Christopher McFadden				
-attendance fees	74,581	81,000		
-other compensation				
-value of BSA granted (1)			11,200	
TOTAL	74,581	81,000	11,200	
Joseph DeVivo				
-attendance fees	42,778	45,500		
-other compensation				
-value of BSA granted (1)				
TOTAL	42,778	45,500		
Molly O'Neill				
-attendance fees	33,556	0		
-other compensation				
-value of BSA granted (1)			7,500	
TOTAL	33,556	0	7,500	
Jennifer F. Tseng				
-attendance fees	35,584	30,400		
-other compensation				
-value of BSA granted (1)			9,000	
TOTAL	35,584	30,400	9,000	

(1) €0.3 per share warrant in February 2018, and €0.28 per share warrant in November 2018

Jean-Luc Boulnois resigned from his role as director as of October 22, 2018.

The Board of Directors meeting of May 25, 2016 set the principles for distributing directors' fees between its members as follows:

- 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 €30,000 pro rated to their attendance rate at Board meetings;
- the Chairmen of the Audit and Compensation Committees are each allocated €10,000 per year for this role;
- the members of the Audit and Compensation Committees other than the Chairmen are allocated €8,000 for this role.

Directors receive no special pension, termination benefit or non-compete compensation.

It is recalled that the General Meeting of May 3, 2017 set the budget for directors' fees at €245,000 for the 2017 financial year as well as for each subsequent financial year, until otherwise decided by the Ordinary General Meeting.

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	05/03/2017	10/05/2018
Date of the Board of Directors' meeting	09/01/2014	07/26/2016	02/28/2018	11/12/2018
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	55,000	40,000
Start date for exercise of the options	09/01/2015	07/26/2017	02/28/2019	11/12/2019
Expiration date	09/01/2024	07/26/2026	02/28/2028	11/12/2028
Issue price	€0.61	€0.16	€0.30	€0.28
Exercise price	€6.12	€1.68	€3.12	€2.76
Exercise procedures (where the plan consists of several tranches)	In thirds every 3 years	In thirds every 3 years	In thirds every 3 years	In thirds every 3 years
Number of shares subscribed at 12/31/2018	N/A	N/A	N/A	N/A
Cumulative number of stock options canceled or invalid	60,000	25,000	0	0
Stock options remaining at year-end	60,000	90,000	55,000	40,000

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) 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)	N/A			

Historical bonus preference share grants					
Information on bonus preference shares granted					
Date of General Meeting	05/04/2016	05/04/2016	05/04/2016	10/05/2018	10/05/2018
Date of the Board of Directors' meeting	07/26/2016	11/15/2016	10/17/2017	10/10/2018	11/12/2018
Total number of bonus shares granted	7,765	570	2,340	5,700	1,375
Share vesting date	07/26/2017	11/15/2017	10/17/2018	10/10/2019	11/12/2019
Expiration of the holding period	07/26/2019	11/15/2019	10/17/2020	10/10/2021	11/12/2021
Number of shares subscribed for					
Cumulative number of shares canceled or invalid	1,850	350	1,990	na	na
Bonus preference shares remaining at year-end	5,915	220	350	5,700	1,375

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), share warrants and free performance shares (AGAP) issued by the Company to its corporate officers and executives, whether subscribed for by the beneficiaries or not during the 2018 financial year:

Beneficiaries		BSA	Founders' warrants (BSPCE)	Stock options	AGAP
Alexandre Loiseau	Chief Executive Officer until October 22, 2018 then Chairman of the Board of Directors as of that date				4,500
Joseph DeVivo	Director				
Jean-Luc Boulnois	Director				
Christopher McFadden	Independent director, Chairman of the Board of Directors through October 22, 2018	40,000			
Jennifer F. Tseng	Director	30,000			
Molly O'Neill	Director	25,000			
Robert Gershon	Chief Executive Officer as of October 22, 2018			600,000	
Christophe Lamboeuf	Deputy CEO as of October 22, 2018				1,200

The exercise of each share warrant entitles the holder to one new share; the exercise of each preference share entitles the holder to a maximum of 100 new shares.

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
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 the 2018 financial year, the Company's Board of Directors met 12 times: on January 25, February 28, March 22, May 4, September, October 7, 10 and 17, and November 12 and 28. All meetings were chaired by the Chairman of the Board. The directors' attendance rate was 82%.

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 of Directors meeting of October 10, 2018, with effect from October 22, 2018, Mr. Alexandre Loiseau was appointed Chairman of the Board of Directors representing the Company with respect to third parties. As part of his appointment, he was assigned specific tasks, in particular for the 2019 financial year:
- Serve as a resource and assist the Executive Director, at his request, in operational or strategic initiatives as well as in the transition to his position
- Serve as a resource and assist the team in charge of developing the application in interventional pneumology and assist in the coordination of various initiatives
-Serve as a resource and assist the product development manager on the product roadmap
- Assist the team in charge of intellectual property to strengthen the Company's position in this field
- Help maintain high-level relationships with opinion leaders in multiple fields as well as strategic partners and/or suppliers
- Serve as a resource on various strategic initiatives including development in China
- Serve as a resource on obtaining reimbursement in France for various applications

At the Board of Directors meeting of October 10, 2018, with effect from October 22, 2018, Mr. Robert L. Gershon was appointed CEO. The Chief Executive Officer is not subject to any limit of powers implemented by the Board of Directors. He is assisted in his duties by a Deputy CEO, Mr. Christophe Lamboeuf, who is vested with the same powers as the CEO and is also the Company's Chief Financial Officer.

Mr. Christophe Lamboeuf succeeded Mr. Olivier Regnard as Chief Financial Officer as of April 5, 2018. He was then appointed Deputy CEO, while maintaining his role as CFO, at the Board of Directors meeting of October 10, 2018 with effect from October 22, 2018. With 25 years of experience in finance, accounting and operations, he is directly in charge of the Finance, Information Systems, Human Resources and Operations departments at the Group level.

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.

16.2 Specialized committees - Corporate governance

In accordance with recommendation No. 6 of the MiddleNext Code, the Board of Directors decided to set up three specialized committees: the Audit Committee, the Compensation Committee and the Strategic Committee.

16.2.1 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:

-Molly O'Neill, Chairwoman and independent director, appointed by the Board of Directors meeting of October 10, 2018;

-Chris McFadden, independent director, appointed by the Board of Directors of 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 legal audit 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 met five times during the 2018 financial year: January 24, March 23, July 26, September 18, and December 18.

16.2.2 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, the other financial rights, including those in the event of retirement, of the members of the Board of Directors. The committee proposes compensation amounts and structures, in particular, rules for determining the variable portion, taking into account the Company's strategy, objectives and results as well as market practices, and
  · the bonus share and stock option plans and any other similar profit-sharing arrangement, in particular, the personal awards 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 June 11, 2014, March 21, 2017 and October 10, 2018 are:

- Mr. Chris McFadden, Chairman of the Compensation Committee and independent director;
- Alexandre Loiseau;
- Ms. Jennifer F. Tseng, 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 twice during the 2018 financial year: on February 6 and July 26.

16.2.3 Strategic Committee

The Strategic Committee constituted by the Board of Directors of October 10, 2018 is responsible for making recommendations to the Board on the Company's strategic approaches.

It is comprised of two members: Messrs. Alexandre Loiseau and Joseph Devivo.

The Strategic Committee did not meet in 2018.

16.3 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. Executive power				
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			
II. Supervisory power				
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			

16.4 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 the 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 (the French [24]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;
-safeguard the Company's decision making and processes to promote the achievement of its objectives;
-ensure the Company's actions are consistent with its values;
-engage the employees around 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 May 31, 2017 which will be updated in 2019.

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. Co-ordination between risk management and internal control

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.

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

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[25]27 (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 proper 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) The 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 2018, 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.

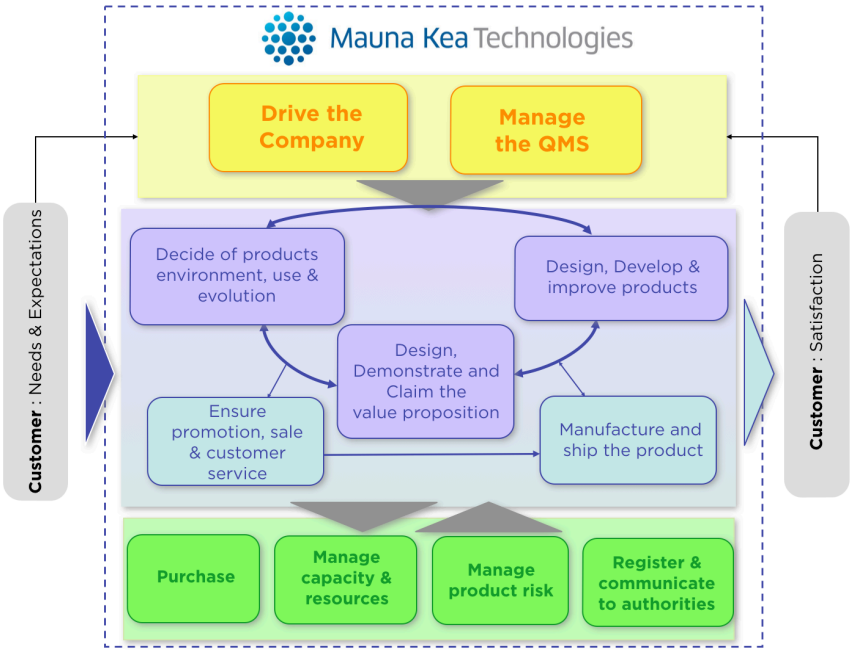
Procedures relating to operational processes

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

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

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

SECTION 17
17. EMPLOYEES

17.1 Human resources

17.1.1 Presentation of employees

Permanent contract **workforce** **Executive workforce**

The workforce is almost exclusively on permanent contracts. The headcount is highly qualified, and consists primarily of executives. The Company mainly hires people with high-level education and skills, and also invests significantly in training new employees, with a view to retaining them.

17.1.2 Number and workforce distribution

Distribution of average annual workforce by category:

	12/31/18	12/31/17	Change
Permanent contract	95.4	81	+17.78%
Fixed-term contract	1.3	2.5	-48.00%
Apprentices	2.8	3.4	-17.65%
Total workforce	99.5	86.8	+14.63%
Executives	86.8	72.9	+19.07%
Non-executives	12.7	14	-9.29%

Breakdown of the average annual workforce by gender:

	12/31/18	12/31/17	Change
Men	61.6	55.5	+10.99%
Women	37.9	31.3	+21.09%
Total workforce	**99.5**	**86.9**	**+14.50%**

Distribution of the annual average workforce by geographical region:

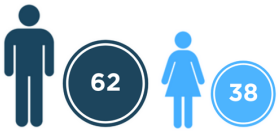
	12/31/18	12/31/17	Change
France	72.1	67.9	+6.19%
Europe excluding France	0	0	0%
America	24.5	15.8	+55.06%
Asia-Pacific	2.9	3.1	-6.45%
Total workforce	**99.5**	**86.9**	**+14.50%**

Entries and departures:

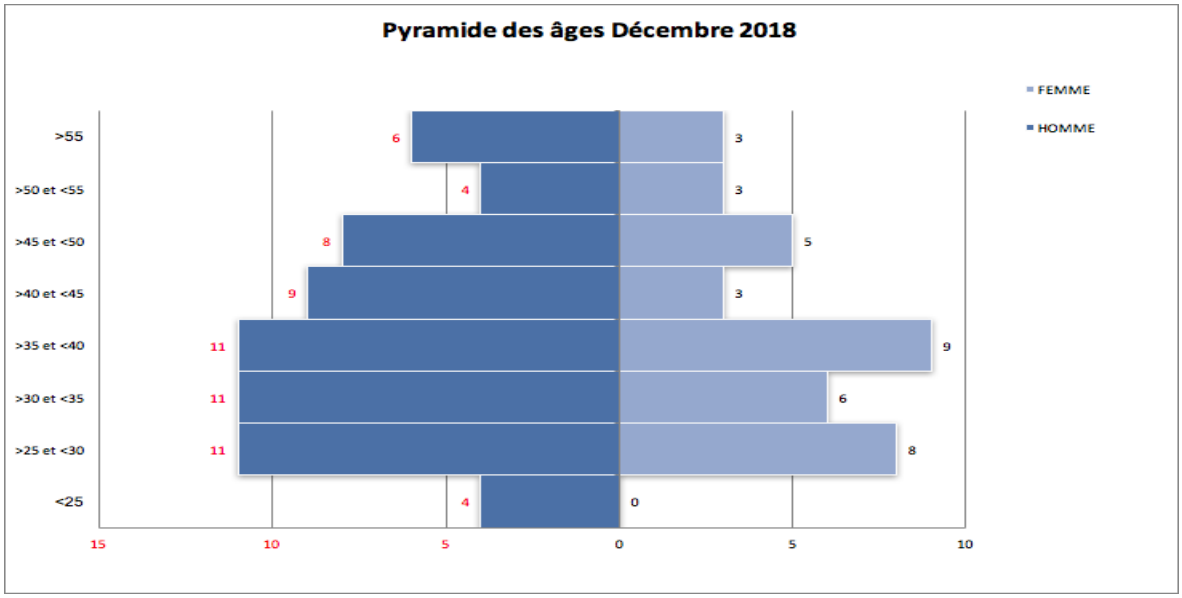
Number of new hires	2018	2017
Permanent contracts	36	33
Fixed term contracts	1	7
Apprentice/intern	0	5
Total	**37**	**45**

Departure by reason	2018	2017
Redundancies/dismissals	1	1
Voluntary departure	19	20
End of fixed-term contract	1	2
Other	6	6
Total	27	**29**

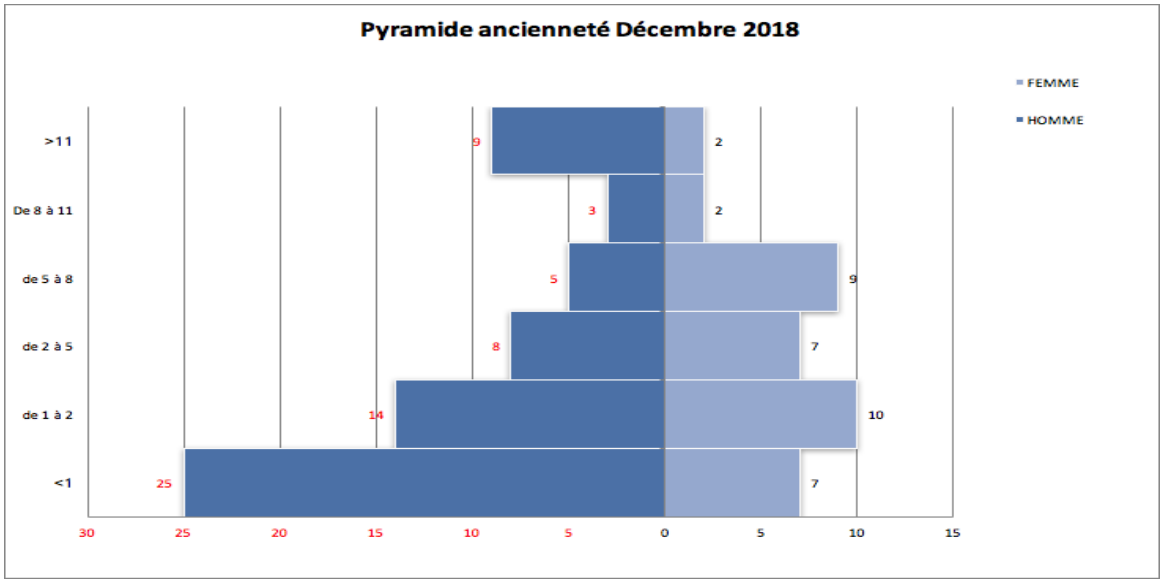
In 2018, Mauna Kea Technologies supported its development ambitions in the United States with a massive recruitment plan for commercial profiles, which accounts for a significant share of workforce growth over 2018.



In France, recruitment has occurred in both operational functions and management functions, with the same stabilization and strengthening objective.
Although Mauna Kea has more men than women, the latter are well represented in all functions of the Company. Their representation rose slightly from the previous year.



29% of employees are over age 45 and 23% are under 30, with proportions that remain stable from year to year and demonstrate the Company's ability to attract talent from all levels of experience and maintain a broad diversity of age in its workforce.



The 2018 length of service pyramid shows the impact of recruiting at the beginning of the year: the 0-2 year bracket now makes up 56% of the workforce and confirms the Company's ability to attract new talent. Accordingly, the median bracket (two to eight years of service) declined a bit in terms of proportion, and its gender distribution has grown in favor of women.

Moreover, the number of employees with more than eight years of service is growing slightly, a sign of employees' commitment and consistent adherence to the Company's values.

There was also a decline in departures in the less than one year bracket. The improved Human Resources process implemented in 2018 has begun to bear its fruits. Stabilizing Mauna Kea Technologies' teams remains a Human Resources priority.

17.1.3 Organization of work hours

The majority of employees work on a daily contract basis, pursuant to the contractual framework, which allows them a contractual number of rest days (9 in 2018).
Other employees work on a basis of 36 hours and 50 minutes per week, thus benefiting from 9 rest days pursuant to French working time legislation (RTT).

The majority of employees work full time: Throughout 2018, only 1.4 employees were part-time.

Absenteeism (excluding paternity and maternity leave)

Scope - France only Excluding work-study students	2018	2017
Number of sick days / total number of hours theoretically worked	1.22%	2.33%

There was less absenteeism due to fewer long-term absences. This remains well below the national average observed by specialized firms (Ayming reports 4.72% average absenteeism in 2018 in France).
Increased access to teleworking, paid paternal leave and the allocation of rest days in 2014 has helped boost this indicator.

17.1.4 Values shared by employees

Working at Mauna Kea Technologies is much more than the simple performance of assigned tasks. The Company expects from each employee a faultless work ethic: honesty, openness, good humor and respect are the key values shared by all on a daily basis. Motivation, initiative, and creativity are also expected, at the cost, if necessary, of risk-taking, mistakes, or actions being called into question, but always attentive to new proposals. Innovation does not follow a straight and well-trodden path. To innovate, it is essential to know how to take risks, explore, make mistakes, question oneself, listen, and change.

Employees have now jointly defined and share a system of values, which make for a strong business. This system relies upon four pillars:

- passion for performance;
- thinking outside the box;
- the willingness to grow with the business;
- team solidarity.

These four values structure and provide direction to the work and daily exchanges between employees, as does the quality-control policy, of which they form an integral part.

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
	In numbers	% of the capital	
Alexandre Loiseau	511,740	2.03%	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 2016 at the rate of 1 preference share for 100 new shares 4,500 Preference Shares 2018 at the rate of 1 preference share for 100 new shares
Christopher McFadden			30,000 BSA 2014 40,000 BSA 2016 40,000 BSA 2018
Joseph DeVivo			25,000 BSA 2016
Jennifer F. Tseng			30,000 BSA 2018
Molly O'Neill			25,000 BSA 2018
Robert Gershon			600,000 2018 stock options
Christophe Lamboeuf			1,200 Preference Shares 2018 at the rate of 1 preference share for 100 new shares

17.3 Employee participation in Company share capital

At December 31, 2018, Group employees held 26,775 shares and 53,550 voting rights, or 0.11% of the Company's capital and 0.20% of its voting rights.

17.4 Profit-sharing and participation agreements

N/A.

SECTION 18
18. PRINCIPAL SHAREHOLDERS

18.1 Breakdown of the capital and voting rights

Changes in the breakdown of the capital and voting rights

Shareholders	12/31/2018						12/31/2017					
	number of shares	of the capit	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM	number of shares	of the capit	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM
Alexandre Loiseau	511 740	2,03%	1 023 480	3,89%	1 023 480	3,89%	511 740	2,10%	1 023 480	4,10%	1 023 480	4,10%
Subtotal Board of Directors	**511 740**	**2,03%**	**1 023 480**	**3,89%**	**1 023 480**	**3,89%**	**511 740**	**2,10%**	**1 023 480**	**4,10%**	**1 023 480**	**4,10%**
Seventure (nominatif)							99 006	0,41%	198 012	0,79%	198 012	0,79%
Seventure (*)												
Callpers (*)												
Inocap												
The Capital Group Companies, Inc (*)												
Subtotal major shareholders	**0**	**0,00%**	**0**	**0,00%**	**0**	**0,00%**	**99 006**	**0,41%**	**198 012**	**0,79%**	**198012**	**0,79%**
Other registered	636 769	2,53%	1 250 193	4,75%	1 250 193	4,76%	619 644	2,55%	619 644	2,48%	619 644	2,48%
Other free float	24 014 010	95,29%	24 014 010	91,22%	24 014 010	91,35%	23 098 801	94,87%	23 098 801	92,55%	23 098 801	92,62%
Own shares	38 819	0,15%	38 819	0,15%	0	0,00%	18 147	0,07%	18 147	0,07%	0	0,00%
Total shares comprising the share capital	**25 201 338**	**100,00%**	**26 326 502**	**100,00%**	**26 287 683**	**100,00%**	**24 347 338**	**100,00%**	**24 958 084**	**100,00%**	**24 939 937**	**100,00%**

Shareholders	12/31/2016						12/31/2015					
	number of shares	of the capit	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM	number of shares	of the capit	number of theoretical voting rights	% of theoretical voting rights	voting rights exercisable at AGM	% voting rights exercisable at AGM
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												
Seventure (nominatif)	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 (*)	110 892	0,55%	110 892	0,51%	110 892	0,51%						
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%**

(*) 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.

At December 31, 2018, the following shareholders were eligible for double voting rights:

Shareholders	Double voting rights
ALEXANDRE LOISEAU	1,023,480
FUJIKURA	424,882
CREDIT AGRICOLE LUXEMBOURG	229,238
IPERIUM INTRENATIONAL	154,994
Various individuals and legal entities	417,734
TOTAL	2,250,328

Statutory restrictions on the exercise of voting rights and the transfer of shares or clauses brought to the Company's attention in application of article L. 233-11 of the French Commercial Code

N/A

Direct or indirect stakes in the Company's share capital of which it is aware by virtue of Articles L. 233-7 and L. 233-12 of the French Commercial Code

See section 15.1.1 below: "Restrictions imposed by the Board in respect of the exercise of options granted or sale of bonus shares granted to executives".

18.4 Participation of shareholders in Annual General Meetings

In accordance with recommendation No. 12 of the MiddleNext Code, the Board hereby reports on its shareholder relations.

The last Ordinary General Meeting was held on December 19, 2018 at the Company's head office in accordance with Article 19 of its bylaws. Shareholders present or represented by proxy accounted for 18% of the Company's share capital and 20% of its voting rights (according to the number of shares making up the capital minus Treasury shares). Shareholders were able to vote by absentee ballot or proxy or attend the Meeting in person. The ordinary resolutions were all adopted with more than 87% of votes.

The last Extraordinary General Meeting was held on October 5, 2018 at the Company's head office in accordance with Article 19 of its bylaws. Shareholders present or represented by proxy accounted for 25% of the Company's share capital and 28% of its voting rights (according to the number of shares making up the capital minus Treasury shares). Shareholders were able to vote by absentee ballot or proxy or attend the Meeting in person. All resolutions were approved by a majority of more than 79% (except for Resolution 18 which was rejected and which the Board of Directors had advised voting against).

The terms for taking part in general meetings are set out in Article 19 of the bylaws, available online at www.maunakeatech.com.

The right to participate in the meetings shall be governed by applicable legal and regulatory provisions, and shall in particular be subject to the registration of the securities under the name of the shareholder or the proxy registered on the shareholder's behalf two (2) 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 intermediary.
Any shareholder unable to attend a meeting in person may select one of the following three options on each occasion under the legal and regulatory conditions in force:

- 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.

18.5 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.

18.6 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.

18.7 Statement of pledges

On the date of the Registration Document, as part of the debt contracted with IPF Partners in February 2017, the Company is subject to pledges on all of its bank accounts and part of its fixed assets.

SECTION 19
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 and commitments prepared for the financial year ended December 31, 2018

EXCO Socodec
51, avenue Françoise Giroud – Parc Valmy – BP 16601
21066 Dijon Cedex
S.A.R.L. au capital de € 3 200 000

Commissaire aux Comptes
Membre de la compagnie régionale de Dijon

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

Commissaire aux Comptes
Membre de la compagnie régionale de Versailles

Mauna Kea Technologies
Annual General Meeting held to approve the financial statements for the year ended December 31, 2018

Statutory auditors' report on related party agreements and commitments

To the Annual General Meeting of Mauna Kea Technologies,

In our capacity as statutory auditors of your Company, we hereby present to you our report on 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 justifying why they benefit the Company. We are not required to give our opinion as to whether they are beneficial or appropriate or to ascertain the existence of other agreements and commitments. It is your responsibility, in accordance with Article R. 225-31 of the French Commercial Code (Code de commerce), to assess the relevance of these agreements and commitments prior to their approval.

We are also required, where applicable, to inform you in accordance with Article R. 225-31 of the French Commercial Code (Code de commerce) of the continuation of the implementation, during the year ended December 31, 2018, of the agreements and commitments previously approved by the Annual General Meeting.

We performed those procedures which we deemed necessary in compliance with professional guidance issued by the French Institute of Statutory Auditors (Compagnie nationale des commissaires aux comptes) relating to this type of engagement.

Agreements and commitments submitted for approval to the Annual General Meeting

We hereby inform you that we have not been notified of any agreements or commitments authorized and concluded during the year ended December 31, 2018 to be submitted to the Annual General Meeting for approval in accordance with Article R. 225-38 of the French Commercial Code (Code de commerce).

Agreements and commitments previously approved by the Annual General Meeting

We hereby inform you that we have not been notified of any agreements or commitments previously approved by the Annual General Meeting, whose implementation continued during the year ended December 31, 2018.

Dijon and Paris-La Défense, April 16, 2018

The Statutory Auditors

French original signed by

EXCO SOCODEC	ERNST & YOUNG et Autres
Olivier Gallezot	Cédric Garcia

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

20.1 Consolidated financial statement

Consolidated financial statement prepared in accordance with IFRS as December 31, 2018

STATEMENT OF FINANCIAL POSITION
(Amounts in thousands of euros)

ASSETS	Note	12/31/2018	12/31/2017
Non-current Assets			
Intangible assets	**3**	1 838	2 100
Property, plant, and equipment	**4**	1 985	1 466
Non-current financial assets	**5**	133	138
Total of non-current assets		**3 956**	**3 704**
Current assets			
Inventories & Work in progress	**6**	2 456	1 969
Trade receivables	**7**	1 643	2 034
Other current assets	**7**	3 019	2 462
Current financial assets	**8**	64	125
Cash and cash equivalents	**9**	8 623	17 453
Total of current asets		**15 806**	**24 043**
TOTAL OF ASSETS		**19 762**	**27 747**

EQUITY AND LIABILITIES	Note	12/31/2018	12/31/2017
Equity			
Issued capital	**10**	1 008	974
Share premium	**10**	91 753	87 973
Reserves		(72 072)	(61 896)
Foreign currency translation on reserve		74	(61)
Profit / (loss)		(12 785)	(10 245)
Total of equity		**7 979**	**16 744**
Non-current Liabilities			
Long-term loans and borrowings	**11**	6 457	6 567
Non-current provisions	**12**	422	283
Total of non-current liabilities		**6 879**	**6 850**
Current liabilities			
Short-term loans and borrowings	**11**	600	386
Trade payables	**13**	2 087	1 663
Other current liabilities	**13**	2 216	2 104
Total of current liabilities		**4 904**	**4 153**
TOTAL OF EQUITY AND LIABILITIES		**19 762**	**27 747**

COMPREHENSIVE INCOME STATEMENT
(Amounts in thousands of euros)

	Note	12/31/2018	12/31/2017
Operating Revenue			
Sales	**15**	6 760	6 687
Other income	**15**	1 141	1 144
Total of revenue		**7 901**	**7 831**
Operating Expenses			
Cost of sales		(2 058)	(2 129)
Gross margin		*70%*	*68%*
Research & Development	**18**	(4 653)	(4 265)
Sales & Marketing	**18**	(9 097)	(7 586)
Admnistrative expenses	**18**	(3 953)	(3 350)
Share-based payments	**17**	(138)	(210)
Total of expenses		**(19 899)**	**(17 541)**
Current operating profit		**(11 998)**	**(9 710)**
Financial revenue	**19**	116	205
Financial expenses	**19**	(902)	(740)
Profit before tax		**(12 785)**	**(10 245)**
Income tax expense	**20**		
Profit / (loss)		**(12 785)**	**(10 245)**
Other comprehensive income			
Items that will not be reclassified to profit or loss			
Actuarial differences on defined benefit plans	**12**	(7)	0
Total of items that will not be reclassified to profit or loss		**(7)**	**0**
Items that will be reclassified subsequently to profit or loss			
Exchange differences on translation of foreign operations		135	(174)
Total of items that will be reclassified subsequently to profit or loss		**135**	**(174)**
Other comprehensive income for the year, net of tax		**127**	**(174)**
Comprehensive income		**(12 657)**	**(10 419)**
Weighted average number of shares outstanding (in thousands)		25 201	21 123
Basic earnings per share (EUR/share)		**(0,51)**	**(0,49)**
Weighted average number of potential shares (in thousands)	**23**	27 222	24 224

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	**12/31/2016**	**800**	**72 382**	**(72)**	**(52 322)**	**113**	**(9 744)**	**11 157**
Allocation of the profit / (loss)					(9 744)		9 744	
Capital transactions		174	15 591					15 765
Share-based payment transactions					210			210
Treasury shares transactions				(13)	44			31
Comprehensive income as of *	12/31/2017				0	(174)	(10 245)	(10 419)
Equity as of *	**12/31/2017**	**974**	**87 973**	**(84)**	**(61 812)**	**(61)**	**(10 245)**	**16 744**
Allocation of the profit / (loss)					(10 245)		10 245	
Capital transactions		34	3 780					3 815
Share-based payment transactions (1)					138			138
Treasury shares transactions				(135)	74			(61)
Comprehensive income as of	12/31/2018				(7)	135	(12 785)	(12 657)
Equity as of	**12/31/2018**	**1 008**	**91 753**	**(219)**	**(71 853)**	**74**	**(12 785)**	**7 979**

CASH-FLOW STATEMENT
(Amounts in thousands of euros)

	Note	12/31/2018	12/31/2017
Cash flows from operating activities			
Profit / (loss)		(12 785)	(10 245)
Elimination of amortisations, depreciations and provisions		1 130	1 074
Share-based payment transaction expense and revenue	**17**	138	210
Other items excluded from the auto-financing capacity		643	339
Revenue and expenses related to the discounting of repayable advances	***11/19***	*67*	*68*
Revenue and expenses related to the bond	***11/19***	*71*	*70*
Net financial interest paid	***19***	*481*	*386*
Other non-cash items		*24*	*(185)*
Capital gain or loss from asset sales		(0)	15
Auto-financing capacity		**(10 874)**	**(8 607)**
Change in WCR related to business activities		(26)	(1 136)
Inventories & Work in progress		*(313)*	*(255)*
Trade receivables		*433*	*(25)*
Other current assets		*(557)*	*291*
Trade payables		*419*	*(1 176)*
Other current liabilities		*(8)*	*29*
Net cash flows from operating activities (A)		**(10 900)**	**(9 743)**
Cash flows from investing activities			
Purchase of property, plant and equipment and intangible assets	**3/4**	(1 254)	(727)
Proceeds from sale of property, plant and equipment and intangible assets		1	2
Change in loans and advances granted		7	(10)
Other cash flows from investing operations			
Net cash flows from investing activities (B)		**(1 246)**	**(735)**
Cash flows from financing activities			
Proceeds from exercise of share options	**10**	3 804	15 496
Proceeds from issue of shares	**10**	10	
Repurchases and resales of treasury shares			31
Net financial interests paid	**19**	(357)	(276)
Other cash flows from financing operations	**11**	(158)	3 662
Net cash flows from financing activities (C)		**3 299**	**18 913**
Net foreign exchange difference (D)		16	(35)
Change in cash (A) + (B) + (C) + (D)		**(8 830)**	**8 401**
Cash at the beginning of the period	**9**	17 453	9 053
Cash at the end of the period	**9**	8 623	17 453
Change in cash		**(8 830)**	**8 401**

(1) changes in WCR are presented in the notes to the current assets and liabilities and did not include foreign exchange differences summarized on line (D)

NOTES TO THE FINANCIAL STATEMENTS

Mauna Kea Technologies is a medical device design and sales company whose mission is to eliminate uncertainties in diagnosis and treatment and to improve patient care for the widest possible range of medical indications. In becoming a global player in real-time cellular diagnostics, the Company's prime objectives are to constantly improve the quality of care provided to patients and efficiency of healthcare professionals and systems. The Company's flagship product, Cellvizio, has received clearance to sell for a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, Canada, Brazil and Mexico.

Highlights of the financial year

On November 13, 2018, the Company signed an amendment to its subscription agreement dated February 3, 2017 with IPF Partners, a provider of alternative financing solutions. The amendment provides the option for the Company to subscribe two new tranches of €5 million each.

The first tranche for €5.0 million is available until April 2019, and another tranche of €5.0 million is available until September 2019. Both tranches would be subject to conditions for achieving pre-defined revenue levels. As at December 31, 2018, the Company met the necessary conditions to raise the first tranche.

The loans would bear interest at an annual rate equal to 3 month Euribor + 8.0%. The first loan tranche has a term of 5 years, with deferred principal repayment for the first 15 months. The second loan tranche has a term of 4 years, with deferred principal repayment for the first 12 months. The issuance of warrants is subject to certain restrictive financial performance conditions, included in the terms and conditions of the contract.

Note 1 : Accounting principles

1.1 Accounting principles applied by the Group

The financial statements are presented in thousands of euros. Rounding may in some cases cause insignificant variances in totals.

They were approved by the Board of Directors at its meeting of March 19, 2019. 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 going concern assumption was adopted by the Board of Directors taking into account the following elements:

- the cash position at 31 December 2018 of €8.6m;
- sales prospects (including those resulting from signed partnerships);
- the receipt of the 2017 research tax credit of €1.1 million in 2019;
- the granting of a repayable advance and a PERSEE grant of €0.6 million in 2019;
- the drawdown of Tranche C of IPF's €5 million debt in 2019 (see Note 11).

In this context, the Company considers that it is in a position to meet its commitments until December 31, 2019.

This financial information was prepared on the basis of the principles underlying all the standards and interpretations adopted by the European Union whose application is mandatory at December 31, 2018. 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, 2018 and applied for the first time by the Company this financial year are:

- Amendments to IAS 40 “Transfers of investment property”;
- Amendments to IFRS 2 "Share-based payments" ;
- Amendments to IFRS 4: Applying IFRS 9 Financial Instruments with IFRS 4 Insurance Contracts
- IFRS 9 - Financial instruments
- IFRS 15 - Revenue contracts with customers
- IFRIC 22 — Foreign Currency Transactions

IFRS 9 - Financial instruments

Principle
IFRS 9 changes the conditions for the recognition of hedging operations and the main accounting categories of financial assets and liabilities. It also modifies the recognition of the credit risk relating to financial assets by basing this on the expected losses approach rather than on losses incurred.

Assessing the impact
As the Group does not hold any financial derivative hedging instruments. The recognition of the IPF loan obtained in March 2017 was not be affected by IFRS 9 since no early repayment was expected in the short term. As of 31/12/2018, the renegotiation of the IPF debt led, under IFRS 9, to a €41k reduction in debt in exchange for financial income.
IFRS 9 also modifies the recognition of credit risk concerning financial assets based on the expected losses versus losses incurred approach.

Conclusion & Results
The Group has not identified any significant impact from the application of these new principles on opening equity at January 1, 2018. The Group did not record any significant impact in fiscal year 2018.

IFRS 15 - “Revenue from ordinary activities from contracts with customers”

This new standard deals with revenue recognition and is applicable as of January 1, 2018. It will replace the standards IAS 18 and IAS 11.
The basic principle of the IFRS 15 standard is income recognition based on the transfer of goods or services promised to a customer, in an amount that reflects the payment that the entity expects to receive in return for such goods or services. It specifies the manner in which an entity must recognize its sales based on the services it provides.

Works carried out by the Company:

Contracts relating to the sale of equipment include several components and whose main characteristics are as follows:
- delivery of the system;
- the installation and start-up of the system;
- training users;
- the warranty and maintenance of the systems;

In the 2018 financial year, the Company conducted an analysis of its key contracts.

Each contract tested was subjected to the methodology recommended by IFRS 15 in five key steps, to determine when to record income and for what amount:
1. Identify the contract(s) entered into with the customer
2. Identify the different performance obligations (PO) specified in the contract
3. Determine the transaction price (TP)
4. Distribute the TP between the different POs specified in the contract
5. Recognize sales when a PO has been fulfilled (or the extent to which it is)

The IFRS 15 analysis was conducted by involving the operational teams when necessary.

Conclusion & Results:

Following a complete analysis of normative changes in all its activities, the Group has not identified any significant impact in the application of these new principles on opening shareholders' equity as of January 1, 2018. The group did not observe any significant impact on the 2018 financial year.

IFRS 16 – Leases

This standard significantly changes the recognition and presentation in the financial statements for tenants of lease agreements. It is applicable as of January 1, 2019.

The principle of this new standard is that tenants will recognize most of their lease agreements as an asset (intangible or property, plant and equipment) against a corresponding financial debt. The lease agreement is thus presented as an asset purchased on credit, the principle of restatement of presentation of the finance lease of IAS 17 is, to a certain degree, extended to most leases.

Assessing the impact
The impact is currently being assessed. The main contracts concerned will be the two premises leases: in France for the Mauna Kea SA offices and in the United States for the Mauna Kea Inc. offices.

Transition method
The Group has not opted for the early application of this standard.

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.

As at December 31, 2018, the group owns a single US subsidiary Mauna Kea Technologies Inc.

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 project and use it;
(c) the Company is able to use the intangible asset;
(d) the Company is able to demonstrate the likelihood of future economic benefits from the asset;
(e) the Company has the technical, financial and other resources necessary to complete the project;
(f) the Company is able to reliably 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 as long as they met the criteria of IAS 38. Expenses related to research and the improvements of existing products remain as expenses for the financial year.

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 2018 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 made available under a consignment contract are recorded under capital assets.

Depreciation and amortization periods are as follows:

Fixtures and fittings ..... 7 years;
Research and development tools ..... 2 to 5 years;
Production tools ..... 3 to 7 years;
Cellvizio granted to reference centers, lent or consigned ..... 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 property, plant and equipment 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, 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.

The value in use is determined each year, in accordance with IAS 36: it corresponds to the discounted value of estimated future cash flows expected from the continued use of the assets and their disposal at the end of the intended use by the business. It does not take into account the impact of the financial structure, tax effects, or restructuring efforts not undertaken.

The recoverable amount must be estimated for each individual asset. If this is not possible, IAS 36 requires a company to determine the recoverable amount of the cash-generating unit (CGU) to which the asset belongs. Only one cash-generating unit has been defined at Group level. It is therefore at Group level that this impairment test was performed.

This value is based on the discounted cash flow method over a period of 5 years and using a terminal value calculated on the basis of an updated standard flow with a growth of 2%.

The future cash flows over the period 2019 to 2023 are based on the following assumptions:
- an average sales growth rate broken down by geographic area and by distribution model (pay-per-use, direct sales of systems, sales to distributors);
- a constant margin rate taking into account the cost of products sold depending on the type and generation of the products;
- a constant distribution of expenses by type (R & D, Sales & Marketing and General Expenses);
- investments (including systems made available through the pay-per-use program in the United States).

1.7 Financial assets

The Company's financial assets include loans and receivables, and the cash and cash equivalents.

The measurement and recognition of financial assets and liabilities are defined by IFRS 9 - Financial Instruments.

Loans and receivables

This category includes trade receivables, 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 for 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 customarily sold in the short term.

1.8 Inventories and work in progress

The inventories are valued at their cost or at their net realizable value (NRV), if the latter is lower. In the latter case, a corresponding impairment loss is recognized in profit or loss.

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 IFRS 9 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 preferred 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 or performance shares 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 the converted instruments 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 valuated 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.
The only liabilities identified relate to repayable advances and the IPF bond.

In accordance with the provisions of IFRS 9 and the clarifications made in autumn 2017 by the IFRS Interpretation Committee on the treatment of debt changes deemed not to be derecognizable, the Group immediately restates in the income statement the effect of changes in contractual borrowing conditions. The effective interest rate is thus maintained on the residual maturity of the debt.

1.14 Conditional advances

The Company receives a certain number of forms of assistance, in the form of subsidies or conditional advances. The details concerning this assistance are provided in Note 11: Borrowings and financial debts.

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 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 valuated 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 IAS 19 “Defined Benefit Plans: Employee Contributions”, service costs and net interest are recorded under operating profit (loss) and other remeasurements 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.

Provisions for risk related to the legal guarantee

The Group recorded a provision related to repair costs as part of the legal warranty granted when selling a system. This provision covered the costs incurred in connection with the return of a system for repair.

1.16 Revenue from ordinary activities

Sales primarily comprise the sale of innovative medical imaging devices for medical diagnostics, research and related services. Until December 31, 2017, the group has applied IAS 18 – Revenue from ordinary activities. As from 1 January 2018, IFRS 15 - Revenue from Contracts with Customers - replaces IAS 18.

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 transfer of goods or services promised to a customer is completed for the amount that reflects the payment that the entity expects to receive as consideration for those goods or services. 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. In the case of a consignment contract, Cellvizio remains an asset of the Company and the revenue is recognized under sales of consumables or services performed by healthcare 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 that prove that they have expenditures that meet the required criteria (research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause) receive a tax credit that can be used for the payment of the corporate tax due for the financial year in which the expenditures were made and the next three financial years, or, as applicable, be 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.
The IFRS 16 analysis related to leases is in progress as of December 31, 2018. The Group has not applied this standard early.

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 rate differences relating to the subsidiary Mauna Kea Technologies, Inc;
changes in pension plan provisions arising from changes in actuarial assumptions.

1.24 Significant 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, stock options and preferred stock

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

	12/31/2018		12/31/2017		Consolidation method
Entities	% 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)

	12/31/2016	Increase	Decrease	Reclassification	12/31/2017
Development costs	3 623				3 623
Patents, licenses and trademarks	1 559	29		86	1 674
Software packages	566	99			664
Patents, licenses and trademarks in progress	575	57		(86)	546
Total gross of intangible assets	**6 324**	**185**			**6 508**
Amort. / dép. of development costs	(2 688)	(448)			(3 135)
Amort. / dép. of patents, licenses and trademarks	(671)	(118)			(789)
Amort. / dép. of software packages	(400)	(84)			(483)
Total amort. / dép. of intangible assets	**(3 759)**	**(650)**			**(4 408)**
Total net of intangible assets	**2 565**	**(465)**			**2 100**

INTANGIBLE ASSETS
(Amounts in thousands of euros)

	12/31/2017	Increase	Decrease	Reclassification	12/31/2018
Development costs	3 623				3 623
Patents, licenses and trademarks	1 674	17		4	1 695
Software packages	664	38		210	913
Patents, licenses and trademarks in progress	546	46		(4)	588
Total gross of intangible assets	**6 508**	**101**		**210**	**6 819**
Amort. / dép. of development costs	(3 135)	(377)			(3 512)
Amort. / dép. of patents, licenses and trademarks	(789)	(122)			(912)
Amort. / dép. of software packages	(483)	(74)			(558)
Total amort. / dép. of intangible assets	**(4 408)**	**(573)**			**(4 981)**
Total net of intangible assets	**2 100**	**(472)**		**210**	**1 838**

No development costs were activated during the year.

The item reclassification of intangible assets represents mainly the capitalization of PLM (Product Life Management) for €207 thousand.

Amortization related to development costs concerns the second generation of Cellvizio and amounted to €377 thousand in 2018 compared to €448 thousand in 2017. These will be fully amortized as of December 31, 2019.

Patents in progress are subject to an annual impairment test as part of the impairment test at the CGU level.

The company tests the effects of a change in the cost of equity assumptions: the variation of +1 and -1 point respectively varies the valuation of the CGU by -8% and + 9%.

The company tests the effects of a change in the assumptions of the growth rate to infinity: the variation of +0.5 point and -0.5 point respectively varies the valuation of the CGU by +5% and -5%.

The company tests the effects of a change in the assumptions of the rate of achievement of the turnover: The sensitivity to -10 points and +10 points varies respectively the valuation of the CGU of -4% and + 4%.

In view of these results and summing up all the impacts of negative assumptions, the company did not recognize any impairment.

Note 4 : Property, plant, and equipment

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

PROPRETY, PLANT AND EQUIPMENT
(Amounts in thousands of euros)

	12/31/2016	Increase	Decrease / Scrappring	Exchange differences	Reclassements	12/31/2017
Industrial equipment	1 436	260	(69)	(29)	463	2 061
Fixture in buildings	51					51
Other tangible assets	1 348	282	(11)	(18)		1 601
Total gross of property, plant and equipment	**2 835**	**542**	**(80)**	**(46)**	**463**	**3 713**
Amort. / dép. of industrial equipment	(1 107)	(125)	49	21	(162)	(1 325)
Amort. / dép. of fixture in buildings	(44)	(5)				(49)
Dep other tang assets	(785)	(111)	2	14	7	(873)
Total amort. / dép. of property, plant and equipment	**(1 937)**	**(242)**	**51**	**35**	**(154)**	**(2 248)**
Total net of property, plant and equipment	**898**	**300**	**(29)**	**(12)**	**309**	**1 466**

PROPRETY, PLANT AND EQUIPMENT
(Amounts in thousands of euros)

	12/31/2017	Increase	Decrease / Scrappring	Exchange differences	Reclass.	12/31/2018
Industrial equipment	2 061	880		10	162	3 113
Fixture in buildings	51					51
Other tangible assets	1 601	273	(1)	8	(382)	1 500
Total gross of property, plant and equipment	**3 713**	**1 153**	**(1)**	**18**	**(220)**	**4 664**
Amort. / dép. of industrial equipment	(1 325)	(298)		(9)		(1 631)
Amort. / dép. of fixture in buildings	(49)	(1)				(50)
Dep other tang assets	(873)	(128)		(6)	9	(998)
Total amort. / dép. of property, plant and equipment	**(2 248)**	**(427)**		**(15)**	**9**	**(2 680)**
Total net of property, plant and equipment	**1 466**	**727**	**(1)**	**4**	**(210)**	**1 985**

Over the 2018 financial year, the Company reported an increase of €880 thousand representing mainly the systems made available in the United States with the "pay per use" business model.

All the systems produced by the company are first recorded in inventory and then reclassified as fixed assets if the latter are recorded as consignment (in the United States) or disposal (in France). This reclassification has been made following a management analysis based on the final destination of the systems. They are amortized over their remaining life.

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

The inventories and work in progress break down as follows:

INVENTORIES & WORK IN PROGRESS

(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Inventories of raw materials	1 041	610
Inventories & work in progress of finished goods	1 552	1 465
Total gross of inventories & work in progress	**2 592**	**2 075**
Dep. of inventories of raw materials	(53)	(54)
Dep. of inventories & work in progress of finished goods	(83)	(52)
Total dep. of inventories & work in progress	**(136)**	**(106)**
Total net of inventories & work in progress	**2 456**	**1 969**

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

The portion of the after-sales inventory in the gross value represented 6.5% at December 31, 2018 and 6.4% at December 31, 2017.

Note 7 : Trade receivables and other current assets

7.1 Trade receivables

TRADE RECEIVABLES

(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Trade receivables	3 168	3 215
Dep. of trade receivables	(1 525)	(1 181)
Total net of trade receivables	**1 643**	**2 034**

The decrease of the trade receivable in net value can be explained by an additional provision of €344 thousand.

Trade receivables past due and not impaired amounted to €856 thousand at December 31, 2018, as compared with €961 thousand at December 31, 2017.

The allowance for doubtful receivables represents 48% of receivables in gross value compared to 37% in 2017. The increase of such provision is attributable mainly to the depreciation of some receivables with an age of more than one year.

The analysis of receivables as of December 31, 2018 break down as follows:

DATE OF PAYMENT FOR TRADE RECEIVABLES

(Amounts in thousands of euros)

	Gross amount	Less than a year	Over a year
Trade receivables	3 168	1 697	1 471
Dep. of trade receivables	(1 525)	(345)	(1 181)
Total net of trade receivables	**1 643**	**1 353**	**290**

7.2 Other current assets

The other current assets break down as follows:

OTHER CURRENT ASSETS
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Personnel and related accounts	9	0
Research Tax Credit	2 186	1 917
Other tax receivables	309	257
Other receivables	193	176
Prepaid expenses	323	112
Total gross of other current assets	**3 019**	**2 462**
Dep. of other current asets		
Total net of other current assets	**3 019**	**2 462**

Other tax receivables are related to deductible VAT and a requested VAT reimbursement totalling €214 thousand compared to €219 thousand at December 31, 2017.

Other receivables mainly included advances to suppliers amounting to €122 thousand compared to €94 thousand at December 31, 2017.

Prepaid expenses in 2018 mostly corresponded to insurance, service subscriptions, computer maintenance, conference reservation costs and rent for the 1stquarter 2019.

The changes in the Research Tax Credit were as follows:

CHANGES IN THE RESEARCH TAX CREDIT RECEIVABLE
(Amounts in thousands of euros)

	12/31/2016	Operating revenue	Payment received	Capitalised portion	12/31/2017
Research Tax Credit	2 029	1 096	(1 208)		1 917

	12/31/2017	Operating revenue	Payment received	Capitalised portion	12/31/2018
Research Tax Credit	1 917	1 097	(828)		2 186

The Company had requested the reimbursement of the research tax credit for 2016 under the regime for EU SMEs in accordance with the legislation in force. This repayment was made in February 2018 in full.

The company also claimed the research tax credit for financial year 2017. The reimbursement request is still under consideration at the Ministry of Higher Education, Research, and Innovation.

Note 8 : Current financial assets

Current financial assets correspond to the cash balance of the securities account opened under the Company's liquidity contract held with Gilbert Dupont, which stood at €64 thousand at December 31, 2018 versus €125 thousand at December 31, 2017.

Note 9 : Cash and cash equivalents

Cash and cash equivalents break down as follows:

CASH AND CASH EQUIVALENTS
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Short-term bank deposits	8 623	17 454
Total of cash and cash equivalents	**8 623**	**17 453**

Note 10 : Share capital

10.1 Issued capital

The share capital is set at one million seven thousand nine hundred and ninety-three euros and fifty-two cents (€1,008,053.52). It is divided into 25,201,338 ordinary shares, fully subscribed and paid up, each with a par value of €0.04.

This figure does not include "Stock Warrants" (BSAs), founders' warrants (BSPCEs) or stock options granted to certain investors and natural persons, who may or may not be employees of the Company and free performance share units (PSUs).

The table below shows the history of the Company's share capital since December 31, 2017:

Type of transaction	Issued Capital (K Eur)	Share Premium (K Eur)	Number of shares comprising the issue capital (in thousand)
At December, 31 2017	974	87 973	24 347
Exercise BSA Plan of December,1st 2017	34	3 746	850
Exercise SO	0	10	4
Others	0	25	0
Total	1 008	91 753	25 201

The Company also opened, in December 2017, an equity financing facility with Kepler Cheuvreux covering a maximum number of 2,250,000 shares available for subscription over a maximum period of 24 months.

At December 31, 2018, 2,050,000 shares were purchased via the financing lines with Kepler, of which 850,000 shares in 2018. Out of the 2,250,000 BSAs subscribed as of December 1, 2017, 91% were used at the closing of the fiscal year.

10.2 Share purchase warrants, stock options and preferred stock

Since its formation, the Company issued "Stock Warrants" (BSA), stock warrants for its employees ("BSPCE" and others) as well as stock options (SO) and free performance shares (PS), the changes since December 31, 2017 are represented below.

In 2018, the Company issued a new free preference share plan, the terms of which have been approved by the shareholders at the General Meeting of October 5, 2018, and new stock options and stock warrants plans.

Type	Date of granting	Exercise price	Outstanding as of 12.31.17	Granted	Exercised	Cancelled	Outstanding as of 12.31.18	Potential number of shares
Options granted before january 1, 2018			3 491 426		854 000 *	1 487 442	1 149 984	2 275 813
SO	28/02/2018	3,12 €		300 000		70 000	230 000	230 000
SO	24/07/2018	2,54 €		80 000			80 000	80 000
SO	19/09/2018	2,86 €		40 000			40 000	40 000
SO	12/11/2018	2,59 €		600 000			600 000	600 000
SO	28/11/2018	2,52 €		35 000			35 000	35 000
BSA	28/02/2018	3,12 €		55 000			55 000	55 000
BSA	22/03/2018	2,92 €		50 000		50 000	0	0
BSA	12/11/2018	2,76 €		40 000			40 000	40 000
AP	10/10/2018			5 700			5 700	570 000
AP	12/11/2018			1 375			1 375	137 500
			3 491 426	1 207 075	854 000	1 607 442	2 237 059	4 063 313

* Of which 850,000 warrants exercised as part of PACEO financing set up in December 2017

Following the consolidation of shares (four old shares for a 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 terms and conditions for exercising preferred shares are described in the minutes of the Combined General Meeting of October 5, 2018 in resolutions 14 and 15 (https://www.maunakeatech.com/uploads/media/media_pdf/0001/03/PV%20AGM%205%20octobre%202018%20Rev.pdf).

10.3 Company's buyback of its own shares

The Combined General Meeting of October 5, 2018 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 terms and 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 recognized by the AMF;
- to meet the obligations related to stock options, free share awards, or employee savings plans, or other awards of shares to the employees and executives of the Company or the companies associated with it;
- to tender shares upon the exercise of rights attached to securities giving access to the share capital;
- to purchase shares to hold for subsequent exchange or use as consideration in potential acquisitions; or
- to cancel some or all of the shares of thereby bought back.

Maximum purchase price: €30 per share excluding fees and commissions, with a total limit of €5,000,000.

Maximum number of shares that may be purchased: 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

It is specified that the number of shares acquired by the Company to be retained and subsequently delivered in payment or in an exchange for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of its share capital.

Summary of the shares purchased and sold over the year:

	2018				
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total
Securities purchased	378 387	288 385	222 908	195 498	1 085 178
Price	3,69	2,90	0,79	2,55	
Total amount (in K€)	1 395	836	177	499	2 908
Securities sold	368 340	270 072	237 573	188 521	1 064 506
Price	3,69	2,91	0,71	2,57	
Total amount (in K€)	1 360	785	170	485	2 799

At December 31, 2018, the Company held 38,819 Mauna Kea Technologies shares acquired at an average price of €2.08 and valued at €2.01, i.e. an unrealized capital loss of €3 thousand.

Note 11 : Borrowings and financial debts

11.1 Loans from BPI (formerly OSEO)

On May 31, 2010, Mauna Kea Technologies obtained a repayable 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 Company is currently negotiating an extension of key Stage 4. The agreement with OSEO stipulates one final payment of €512 thousand which should be made in 2019 once Key Stage 4 is reached.

Based on the initial contract, the Company must repay OSEO a total of €3,996 thousand, including 2.45% interest, once cumulative sales of €2,500 thousand are 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 repayment in case of judicial liquidation, cessation of activities, dissolution or voluntary liquidation;
2/ A repayment by right and at the sole initiative of Oseo in case of:
- failure by the Company to comply with any of its contractual obligations,
- irregular situation regarding its tax and social obligations,
- inaccurate or untrue statements.

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 2017, the Company made repayments to COFACE amounting in all to €1,240 thousand. In June 2017, based on the most recent sales forecasts, the Company repaid €254 thousand of the €408 thousand outstanding from the loan granted for marketing and business development in the United States. The €154 thousand balance was repaid in full in 2018.

CHANGES IN REPAYABLE ADVANCES

(Amounts in thousands of euros)

	12/31/2016	Receipt	Repayment	Others	12/31/2017
OSEO Funding	2 635			65	2 699
COFACE	404		(254)	4	154
Total repayable advances	**3 038**		**(254)**	**68**	**2 853**

	12/31/2017	Receipt	Repayment	Others	12/31/2018
OSEO Funding	2 699			67	2 766
COFACE	154		(154)		(0)
Total repayable advances	**2 853**		**(154)**	**67**	**2 766**

11.3 Short-term loans and borrowings

Short-term loans and borrowings break down as follows::

SHORT-TERM LOANS AND BORROWINGS

(Amounts in thousands of euros)

	12/31/2016	Receipt	Repayment	Capitalized interests	Reclassification	Others	12/31/2017
COFACE	404		(254)			4	154
Bond					232		232
Total of short-term loans and borrowings	404		(254)		232	4	386

SHORT-TERM LOANS AND BORROWINGS

(Amounts in thousands of euros)

	12/31/2017	Receipt	Repayment	Capitalized interests	Reclassification	Others	12/31/2018
COFACE	154		(154)				
Bond	232				368		600
Total of short-term loans and borrowings	386		(154)		368		600

Short-term debt corresponds to the repayment of the IPF loan, the first maturity of which is scheduled for the end of the first half of 2019..

11.4 Long-term loans and borrowings

The Company has contracted non-dilutive funding of €7 million with IPF Partners, a fund specialized in alternative financing for European growth companies in the healthcare sector.

This financing was comprised of two tranches of loans: the first tranche of €4 million was issued in February 2017; the second for the remaining €3 million was available in the next 12 months, subject to previously established closing conditions. Second tranche has not been issued.

This debt consists of 4,000,000 secured bonds with a total value of €4.0 million. The interest on the bonds will bear interest at an annual rate equal to the three-month EURIBOR +8.5%. The first tranche of bonds has a 5.5 years maturity, with interest only payments for the first 24 months.

In November 2018, the Company signed the amendment to the existing contract, which includes two additional tranches of debt, including a first tranche of €5.0 million available until the end of April 2019, and another tranche of €5.0 million available until September 2019, both tranches being subject to conditions for achieving predefined revenue levels. As at December 31, 2018, the company met the conditions necessary to raise the first tranche.

At 31/12/2018, the renegotiation of the IPF bond issue led, under IFRS 9, to a €41k reduction in debt in exchange for financial income.

The loans would bear interest at an annual rate equal to 3 month Euribor + 8.0%. The first loan tranche has a term of 5 years, with deferred principal repayment for the first 15 months. The second loan tranche has a term of 4 years, with deferred principal repayment for the first 12 months. The issuance of bonds is subject to certain restrictive financial performance conditions, included in the terms and conditions of the contract.

Long-term loans and borrowings break down as follows:

LONG-TERM LOANS AND BORROWINGS
(Amounts in thousands of euros)

	12/31/2016	Receipt	Repayment	Capitalized interests	Reclassification	Others	12/31/2017
Deposits and guarantees received		16					16
Shareholders' accounts	5						5
Repayable advances OSEO Funding	2 635					64	2 699
Bonds issues		3 900		110	(232)	70	3 848
Total of long-term loans and borrowings	**2 645**	**3 916**		**110**	**(232)**	**134**	**6 567**

	12/31/2017	Receipt	Repayment	Capitalized interests	Reclassification	Others	12/31/2018
Deposits and guarantees received	16		(4)				11
Shareholders' accounts	5						5
Repayable advances OSEO Funding	2 699					67	2 766
Bonds issues	3 848			124	(368)	71	3 675
Total of long-term loans and borrowings	**6 567**		**(4)**	**124**	**(368)**	**138**	**6 457**

"Other" changes involve the discounting of long-term conditional advances as well as borrowing arrangement costs.

11.5 Cash flow hedges

The Group has no financial derivative instruments.

11.6 Maturities of financial liabilities

The maturities of financial liabilities as of December 31, 2018 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 borrwings	6 457		16	6 440
Short-term loans and borrowings	600	600		
Trade payables	2 087	2 087		
Other current liabilities	2 195	2 195		
Total of financial liabilities	**11 339**	**4 883**	**16**	**6 440**

The maturities of long-term loans and borrowings relating to repayable advances are determined on the basis of estimates of expected repayments at December 31, 2018.

Note 12 : Non-current provisions

Non-current provisions break down as follows:

NON-CURRENT PROVISIONS

(Amounts in thousands of euros)

	12/31/2016	Allowance	Unused reversals	Used reversals	Others	12/31/2017
Pension plan provision	155	37	(9)		(0)	183
Provisions for personnel disputes	91		(63)			28
Provision for software update	15					15
Others provisions for expenses		58				58
Total of non-current provisions	**261**	**95**	**(72)**		**(0)**	**283**

NON-CURRENT PROVISIONS

(Amounts in thousands of euros)

	12/31/2017	Allowance	Unused reversals	Used reversals	Others	12/31/2018
Pension plan provision	183	16	(26)		7	180
Provisions for personnel disputes	28	57				85
Provision for software update	15					15
Others provisions for expenses	58	84				142
Total of non-current provisions	**283**	**158**	**(26)**		**7**	**422**

12.1 Retirement commitments

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

	12/31/2018	12/31/2017
% social security expenses	48%	48%
Salary increases	2%	2%
Discount rate	1,97%	1,70%

- retirement age: 65;
- terms of retirement: voluntary retirement;
- mortality table: INSEE 2015;
- collective agreement: metal industries;
- turnover: high and digressive based on age.

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 Provisions for labor disputes

At December 31, 2018, the Company recognized an additional €57 thousand provision concerning a labor-related dispute dating back to 2014. No new labor-related dispute has been identified.

12.3 Other provision for risks and expenses

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 directly subcontracts a service provider for the recycling of this waste.

"Other provisions for expenses" corresponds to the provision for the risk of repair of systems sold under the legal one-year guarantee granted on the sale of a Cellvizio.

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)

	12/31/2018	12/31/2017
Trade payables	2 087	1 663

The €424 thousand increase in trade payables is due mainly to the lag in the posting of 2019 expenses over 2018.

13.2 Other current liabilities

Other current liabilities break down as follows:

OTHER CURRENT LIABILITIES
(Amounts in thousands of euros)

	12/31/2018	12/31/2015
Taxes payable	107	106
Staff and social security payable	1 554	1 438
Deferred revenue	555	560
Total of other current liabilities	**2 216**	**2 104**

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

Deferred revenues mainly comprise the deferred portion of training and equipment installation under IFRS 15.

Note 14 : Financial instruments on the balance sheet

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

(Amounts in thousands of euros)

As of 31 December 2018	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	1 643			1 643	
Other current assets (2)	3 019			3 019	
Current financial assets (1)	64			64	
Cash	8 623	8 623			
Total of assets	**13 483**	**8 622**		**4 859**	
Liabilities					
Long-term loans and borrowings	6 457				6 457
Short-term loans and borrowings	600				600
Trade payables	2 087				2 087
Other current liabilities (2)	2 216				2 216
Total of liabilities	**11 361**				**11 361**

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

(Amounts in thousands of euros)

As of 31 December 2017	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	138			138	
Trade receivables	2 034			2 034	
Other current assets (2)	2 256			2 256	
Current financial assets (1)	125			125	
Cash	17 453	17 453			
Total of assets	**22 007**	**17 453**		**4 553**	
Liabilities					
Long-term loans and borrowings	6 799				6 799
Short-term loans and borrowings	154				154
Trade payables	1 663				1 663
Other current liabilities (2)	1 544				1 544
Total of liabilities	**10 160**				**10 160**

(1) L'évaluation de ces actifs financiers à la juste valeur par résultat se réfère à un marché actif (catégorie de niveau 1 selon IFRS 7).

(2) Les avances et acomptes versés et reçus ne donnant pas lieu à remboursement en trésorerie et les produits et charges constatés d'avances qui ne répondent pas à la définition d'un passif financier n'ont pas été repris.

Note 15 : Sales and operating revenue

Sales and operating revenue consists of the following:

SALES AND OPERATING REVENUE
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Sales	6 760	6 687
Research Tax Credit and other tax credits	1 141	1 144
Total of revenue	**7 901**	**7 831**

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

The competitiveness and employment tax credit is recognized under Research Tax Credit and other tax credits.

Sales by type as of December 31, 2018 are broken down as follows:

SALES BY TYPE OF PRODUCT
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Total sales of "equipements"	2 683	3 101
Total sales of "consumables" (probes)	2 812	2 397
Total sales of "services"	1 265	1 188
Total sales by type	**6 760**	**6 687**

Sales by geographic region as of December 31, 2018 are broken down as follows:

SALES BY GEOGRAPHICAL AREA
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
EMEA (Europe, Middle-east, Africa)	1 544	1 282
including France	*335*	*499*
America	3 618	3 453
including USA	*3 263*	*3 092*
Asia	1 599	1 952
including China	*1 290*	*877*
including Japan	*62*	*331*
Total sales by geographical area	**6 760**	**6 687**

For the purposes of geographical analysis, the management of the Group allocates 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, 2018, one distributor from the APAC region accounted for more than 17.73% of sales.

Note 16 : Charges de personnel

The Group employed 100 persons as of December 31, 2018 compared with 90 persons as of December 31, 2017.
The employee benefits expense breaks down as follows:

EMPLOYEE BENEFITS EXPENSE
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Wages and salaries, social security costs	10 345	8 874
Net pension costs	(10)	28
Share-based payment transaction expenses	138	210
Total of employee benefits expense	**10 474**	**9 113**

Staff costs increased by €1,471 thousand, mainly due to the recruitment of a sales team in the United States and the internalization of certain previously sub-contracted services.

Note 17 : Share-based payments

Share-based payments concern all stock warrants (BSA/BSPCE), stock options (SO) and preferred shares (PS) awarded to employees, service providers and members of the Board of Directors.

They have been recorded as expenses since the award knowing that the terms for exercising BSPCEs and SOs are as follows for the plans awarded before 2017:
- 25% of the founders' warrants/stock options may be exercised starting on the first anniversary of their award;
- 25% of the founders' warrants/stock options may be exercised starting on the second anniversary of their award;
- 25% of the founders' warrants/stock options may be exercised starting on the third anniversary of their award;
- the remaining balance, i.e., 25% of the founders' warrants/stock options, may be exercised starting on the fourth anniversary of their award;
- no later than ten years from their issue, or seven years for stock options granted before 2011, it being specified that founders' warrants/stock options not yet exercised by the end of this ten-year period automatically become null and void.

The terms for exercising stock options are the following for plans allocated in 2017:

- 20% of the options at the end of the first year from the first anniversary date of their award; and
- 40% of the options at the end of the second year from the second anniversary date of their award;
- and 20% of the options at the end of the third and fourth years from the date of their award; and
- no later than ten (10) years from their award, it being specified that the options that have not yet been exercised at 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 ten years of their issue automatically become null and void.

Concerning the preferred shares, the terms and conditions for exercising preferred shares are described in the minutes of the combined general shareholders meeting on October 5, 2018 in resolutions 14 and 15 (https://www.maunakeatech.com/uploads/media/media_pdf/0001/03/PV%20AGM%205%20octobre%202018%20Rev.pdf)

The main characteristics and terms are as follows:

2018 Preference Shares definitively acquired by their beneficiaries at the Acquisition Date will be convertible into new or existing ordinary shares at the Company's choice ('Ordinary Shares'), at the request of each beneficiary affected, at any time with effect from the second anniversary of the Acquisition Date and no later than the fifth anniversary of the Acquisition Date ('Conversion Period'), unless otherwise specified in the 2018 Preference Shares allocation plan or contrary decision by the Board of Directors notified to each bearer of 2018 Preference Shares according to the following procedures:

a. in the event of Departure between the Acquisition Date (included) and the first anniversary of the Acquisition Date (excluded), each Preference Share will be convertible into twenty (20) Ordinary Shares.

b. in the event of Departure between the first anniversary of the Acquisition Date (included) and the second anniversary of the Acquisition Date (excluded), each 2018 Preference Share will be convertible into thirty-three (33) Ordinary Shares.

c. In the event of Departure between the second anniversary (included) and the third anniversary (excluded) of the Acquisition Date, the conversion ratio will be determined as follows:

(i) if Reference Price 1 is strictly less than the Bottom Price, each 2018 Preference Share will be convertible into thirty-three (33) Ordinary Shares;

(ii) if Reference Price 1 is strictly greater than the Intermediate Price, each 2018 Preference Share will be convertible into sixty-six (66) Ordinary Shares;

(iii) if Reference Price 1 is between the Bottom Price (included) and the Intermediate Price (included), the number of Ordinary Shares to which each 2018 Preference Share will be entitled is:

$$33 + 33 \times \frac{\text{Reference Price 1} - \text{Bottom Price}}{\text{Intermediate Price} - \text{Bottom Price}}$$

where:

- the term 'Bottom Price' means 1.75 times the Allocation Price;

- the term 'Allocation Price' means the average of closure prices recorded on Euronext or any other main listing location for the Mauna Kea Technologies share over the 60 trading sessions prior to the allocation date of the relevant 2018 Preference Shares ('Allocation Date');

- the term 'Intermediate Price' means 2.5 times the Allocation Price; and

- the term 'Reference Price 1' means the highest average of closure prices for the share on Euronext or any other main listing location for the Mauna Kea Technologies share over a period of 60 consecutive trading sessions, calculated at any time from the Acquisition Date and until the second anniversary of the Acquisition Date;

d. in the event of Departure following the third anniversary of the Acquisition Date, the number of Ordinary Shares to which each Preference Share will be entitled is equal to the sum:

(x) of the number of Ordinary Shares determined according to the provisions of paragraph 3.c) above as if the beneficiary's Departure occurred between the second and third anniversary of the Acquisition Date, and

(y) of the following number of Ordinary Shares:

(i) if Reference Price 2 is strictly less than the Bottom Price: zero;

(ii) if Reference Price 2 is strictly greater than the Top Price: the difference between one hundred Ordinary Shares and the number of Ordinary Shares determined in (x) (such that the sum of (x) and (y) equals 100);

(iii) if Reference Price 2 is between the Bottom Price (included) and the Top Price (included): the difference, if positive, between:

- $33 + 67 \times \frac{\text{Reference Price 2} - \text{Bottom Price}}{\text{Top Price} - \text{Bottom Price}}$; and

- the number of Ordinary Shares determined in (x).

where:

- the term 'Bottom Price' means 2.45 times the Allocation Price;

- the term 'Top Price' means 3.5 times the Allocation Price; and

- the term 'Reference Price 2' means the highest average of closure prices for the share on Euronext or any other main listing location for the Mauna Kea Technologies share over a period of 60 consecutive trading sessions, calculated at any time from the date of the first anniversary of the Acquisition Date and until the third anniversary of the Acquisition Date.

It is stipulated that this ratio will be adjusted to take account of shares to be issued to maintain the rights of bearers of securities giving access to the Company's capital and beneficiaries of 2018 Preference Shares, in accordance with the applicable legal and regulatory provisions.

The Preference Shares may be converted only during a period of five years and six months following the expiration of the Holding Period (the "Holding Period").

The detail of the share-based payments is presented in the table below:

Type	Date of granting		Exercise price	Maturity	Number of shares	Cancelled	Exercised	Outstanding at 12/31/2018	Vestible sahres equivalent as of 21/31/2018	Execicable bonds as of 12/31/2018
SO 2008	02/06/2008		1	02/06/2018	670 000	481 408	188 592	0	0	0
BCE-A	04/08/2008		1	05/08/2018	500 000	500 000	0	0	0	0
BSPCE 6	04/08/2008		1	04/08/2018	1 225 000	892 508	332 492	0	0	0
BSPCE 6	08/12/2008		1	08/12/2018	35 000	35 000	0	0	0	0
BSPCE 6	24/11/2009		1	24/11/2019	637 500	396 256	154 992	86 252	21 563	21 563
SO 2008	01/03/2010		1	01/03/2020	250 000	100 000	10 000	140 000	35 000	35 000
SO 2010	31/01/2011		1	31/01/2021	245 000	128 752	56 248	60 000	15 000	15 000
BSPCE 2010	15/02/2011		1	15/02/2021	915 000	506 752	318 248	90 000	22 500	22 500
BSPCE 2010	01/03/2011		1	01/03/2021	200 000	0	150 000	50 000	12 500	12 500
BSPCE 2011	05/12/2011		13	01/03/2021	129 500	117 000	0	12 500	12 500	12 500
BSPCE 2012	04/12/2012		10,79	04/12/2022	239 500	204 625	625	34 250	34 250	34 250
SO 2012	04/12/2012		10,79	04/12/2022	161 000	161 000	0	0	0	0
BSPCE 2013	07/05/2013		10,28	07/05/2023	63 000	36 000	0	27 000	27 000	27 000
SO 2014	12/02/2014		10,56	12/02/2024	10 000	10 000	0	0	0	0
BSPCE 2014	12/02/2014		10,56	12/02/2024	281 000	125 000	0	156 000	156 000	156 000
BSA 2014	01/09/2014		6,12	01/09/2024	160 000	60 000	0	100 000	100 000	100 000
SO 02 2016	02/02/2016		2,54	02/02/2026	96 000	72 000	10 500	13 500	13 500	6 000
SO 07 2016	26/07/2016		1,6	26/07/2026	80 000	0	10 000	70 000	70 000	40 000
BSA 07 2016	26/07/2016		1,68	26/07/2026	115 000	25 000	0	90 000	90 000	60 000
AP 07 2016	26/07/2016	*		NA	7 765	1 850	0	5 915	591 500	0
AP 11 2016	15/11/2016	*		NA	570	350	0	220	22 000	0
SO 03 2017	21/03/2017		2,92	21/03/2027	60 000	0	0	60 000	60 000	15 000
SO 07 2017	19/07/2017		2,34	19/07/2027	154 000	104 000	0	50 000	50 000	10 000
SO 02 2018	28/02/2018		3,12	28/02/2028	300 000	70 000	0	230 000	230 000	0
SO 07 2018	24/07/2018		2,54	24/07/2028	80 000	0	0	80 000	80 000	0
SO 09 2018	19/09/2018		2,86	19/09/2028	40 000	0	0	40 000	40 000	0
SO 11 2018	12/11/2018		2,59	12/11/2028	600 000	0	0	600 000	600 000	0
SO 11 2018	28/11/2018		2,52	28/11/2028	35 000	0	0	35 000	35 000	0
BSA 02 2018	28/02/2018		3,12	28/02/2028	55 000	0	0	55 000	55 000	0
BSA 03 2018	22/03/2018		2,92	22/03/2028	50 000	50 000	0	0	0	0
BSA 11 2018	12/11/2018		2,76	12/11/2028	40 000	0	0	40 000	40 000	0
AP 10 2017	17/10/2017	*		NA	2 340	1 990	0	350	35 000	0
AP 10 2018	10/10/2018	*		NA	5 700	0	0	5 700	570 000	0
AP 11 2018	12/11/2018	*		NA	1 375	0	0	1 375	137 500	0
					7 444 250	**4 079 491**	**1 231 697**	**2 133 062**	**3 155 813**	**567 313**

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

- risk-free interest rate: Government borrowing rate (GFRN index);
- dividend: none;
- turnover: 15%;
- volatility: 60% for warrants, founders' warrants and stock options granted before December 31, 2011, 35% for founders' warrants and stock options granted in 2012, 34% for founders' warrants and stock options granted in 2013, 32% and 33% for plans granted in 2014, 33% for plans granted in 2015, 29.99% for plans granted in 2016, 55% for plans granted in 2017, and 59% for plans granted in 2018.

As of 2012, the volatility applied corresponds to the average historic volatility of a panel 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 life 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)

	12/31/2018	12/31/2017
Share-based payments (expense of the period)	138	210
	138	**210**

Note 18 : External expenses

18.1 Research & Development Department

RESEARCH & DEVELOPMENT
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Purchases consumed	59	70
Employee benefits expenses	2 525	2 453
External expenses	1 417	1 134
Impôts et taxes	36	34
Net change in amortisation and depreciation	612	553
Other	3	21
Total of Research & Development	**4 653**	**4 265**

18.2 Sales & Marketing Department

SALES & MARKETING
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Purchases consumed	(24)	78
Employee benefits expenses	5 416	4 474
External expenses	2 839	2 515
Net change in amortisation and depreciation	814	502
Other	52	17
Total of Sales & Marketing	**9 097**	**7 586**

This increase is related to the increase in the salesforce in the United States.

18.3 Administrative Expenses

ADMINISTRATIVE EXPENSES

(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Purchases consumed	52	46
Employee benefits expenses	1 828	1 411
External expenses	1 819	1 533
Taxes	108	81
Net change in amortisation and depreciation	136	156
Other	7	122
Total of Administrative expenses	**3 953**	**3 350**

At December 31, 2018, the increase in general and administrative expenses related to staff expenses is mainly due to the internalization of certain services previously outsourced externally, as well as the change in management team.

Note 19 : Financial income and expenses

Financial income and expenses break down as follows:

FINANCIAL REVENUE AND EXPENSES

(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Foreign exchange gains	112	172
Gains on cash equivalents	3	33
Other financial incomes	2	0
Total of financial revenue	**116**	**205**
Foreign exchange losses	(281)	(183)
Interest expenses	(481)	(418)
Losses on cash equivalents	(3)	0
Discounting expenses	(138)	(138)
Total of financial expenses	**(902)**	**(739)**
Total of financial revenue and expenses	**(786)**	**(534)**

Interest expenses of €481 thousand correspond to interest on the IPF loan contracted in February 2017.

Note 20 : Income tax

Under current tax laws, the Group has total tax losses of €78,356 thousand that may be carried forward indefinitely in France and total tax losses of €38,369 thousand that may be carried forward for 20 years in the United States, i.e. a total of €116,725 thousand at December 31, 2018. The deferred tax asset base net of temporary passive differences was not capitalized as a precautionary measure, 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 PROOF
(Amounts in thousand of euros)

	12/31/2018	12/31/2017
Profit/(loss)	(12 785)	(10 245)
Income tax expense		
Profit before tax	**(12 785)**	**(10 245)**
Theoretical tax expense - 34,43%	**(4 402)**	**(3 527)**
Other non-deductible expenses and tax-exempt income	24	4
Effect of tax rate differences	(18)	(14)
Deferred tax assets not recognised	4 396	3 538
Actual income tax expense		

Note 21 : Commitments

Obligations pursuant to ordinary rental agreements

The Group uses the following premises:

- head 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 including two that are sub-leased;

- the premises in the United States: The commercial lease between the company Capkey Gates, Sugarloaf partners LLC and Mauna Kea Technologies Inc signed on January 15, 2013 and renewed through February 28, 2017 for the lease of offices located at 1325 Satellite Boulevard, Unit 108, Suwanee, GA, 30024, United States. This lease was terminated at the end of 2016.

A new lease was signed on December 16, 2016 with Geros LLC for the rental of offices at 24 Denby Road, 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, 2018:

OBLIGATIONS PURSUANT TO ORDINARY RENTAL AGREEMENTS
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Portion with terms of less than 1 year	204	205
Portion with terms of between 1 and 5 years	591	674
Portion with terms of more than 5 years	16	115
Total of commitments pursuant to ordinary rental agreements	**811**	**994**

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 its operations, it has made commitments to purchase a certain quantity of sub-assemblies from certain suppliers as described in the table below:

OBLIGATIONS PURSUANT TO OTHER AGREEMENTS
(Amounts in thousands of euros)

	12/31/2018	12/31/2017
Portion with terms of less than 1 year	1 133	2 518
Portion with terms of between 1 and 5 years	172	85
Total of supplier commitments	**1 305**	**2 603**

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)

	12/31/2018	12/31/2017
Wages and salaries - General direction	281	266
Share-based payments - General direction	97	0
Pension plan - General direction	2	4
Attendance Fees - Executive Officers	233	227
Share-based payments - Executive Officers	29	0

Note 23 : 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 preferred shares outstanding during the financial year.

EARNINGS PER SHARE

Profit / (loss) (in K€) *	12/31/2018	12/31/2017
Weighted average number of shares outstanding (in thousands)	**(12 785)**	**(10 245)**
Earnings per share (in €)	25 201	21 123
	(0,51)	**(0,49)**
Weighted average number of potential shares (in thousands)	27 222	24 224

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.

The primary risks to which the Group is exposed are interest rate risk, credit risk and exchange rate risk.

Exchange rate risk

The main currency for which the Group is exposed to significant exchange rate risk is the US dollar.
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 services 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 €342 thousand at December 31, 2018;

- a -10% change in the EUR/USD exchange rate would result in a drop in earnings of €(418) thousand at December 31, 2018.

Liquidity risk

See Note 1.9: Cash and cash equivalents

Interest Rate Risk

The Company's exposure to interest rate risk mainly concerns the 4,000,000 bonds contracted with IPF Partners. This debt is subject to the annual interest rate of three-month EURIBOR + 8.5%. The first tranche of bonds has a 5.5 year maturity, with interest only payments for the first 24 months.

At December 31, 2018, the Company did not hold any investment securities, whose interest rate changes have a direct impact on the rate of return for these investments and the cash flows generated.

The repayable BPI/OSEO advances at a 2.45% interest rate for an overall, non-discounted amount of €2,904 thousand are detailed in Note 11: Borrowings and financial debts. They are not subject to interest rate risk.

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 21, 2019, the Company announced a mutual decision to terminate the development and distribution agreements with Cook Medical due to the lack of sales performance in the urology market and the lack of sales activity.

Despite the lack of sales performance in the urology market, the Company made significant progress over the past few years in product development, certification and clinical validation of our Cellvizio technology in urology.

Consolidated financial statements prepared under IFRS for the year ended December 31, 2017

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the company financial statements and the statutory auditors' report on the company financial statements for the year ended December 31, 2017 as presented in the 2018 annual financial report are included for reference in this document.

Consolidated financial statements prepared under IFRS for the year ended December 31, 2016

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the company financial statements and the statutory auditors' report on the company financial statements for the year ended December 31, 2016 as presented in the 2017 annual financial report are included for reference in this document.

Table of the past five consolidated financial years

Table of results for the past five consolidated financial years (in €k)

Type of indication / Period	12/31/2018	12/31/2017	12/31/2016	12/31/2015	12/31/2014
Durée de l'exercice	12 months	12 months	12 months	12 months	12 months
I - Financial position at year-end					
a) Share capital	1,008	974	800	647	560
b) Number of share issued					
c) Number of bonds convertible into shares					
II - Comprehensive income from operations					
a) Sales excluding taxes	6,760	6,687	8,787	8,547	11,016
b) Profit (loss) before tax, depreciation, amortization and provisions	-11,411	-9,171	-8,815	-11,870	-13,089
c) Income tax	0	0	0	0	0
d) Profit (loss) after tax, but before depreciation, amortization and provisions	-11,411	-9,171	-8,815	-11,870	-13,089
e) Profit (loss) after tax, depreciation, amortization and provisions	-12,785	-10,245	-9,744	-12,643	-13,973
f) Amount of profits distributed					
g) Employee chareholding					
III – Earning per share					
a) Profit (loss) after tax, but before depreciation and amortization					
b) Profit (loss) after tax, depreciation, amortization and provisions					
c) Dividends paid per share					
IV - Employee:					
a) Number of employees	100	90	76	91	120
b) Total payroll	10,324	8,874	8,744	11,515	12,364
c) Amounts paid under pension plan provisions and share-based payment	128	238	319	420	1,284

20.2 Annual statements

Financial statement for the financial year ended 12/31/2018

I. BALANCE SHEET AS OF DECEMBER 31, 2018

A. Balance sheet – Assets

Rubric	Gross amount	Dep. and Amort. Prov.	Net 12/31/18	Net 12/31/17
Uncalled issued capital				
INTANGIBLE ASSETS				
Start-up costs				
Development costs				
Concessions, patents and similar rights	893,097	541,887	351,210	185,247
Goodwill				
Other intangible assets	18,850	11,207	7,643	
Advances, prepayments on intangible assets				
PROPERTY, PLANT AND EQUIPMENT				
Land				
Buildings	51,090	50,381	709	1,648
Technical facilities, machinery and equipment	1,248,523	1,004,717	243,806	133,111
Other tangible assets	1,162,416	865,586	296,830	357,196
Assets under construction	148,444		148,444	318,362
Advances and prepayments				
LONG-TERM INVESTMENTS				
Companies accounted for by the equity method				
Other participating interests	23,077	23,077		
Loans related to participating interests	46,334,105	42,225,521	4,108,584	875,988
Other fixed securities				
Loans				
Other long-term investments	267,193		267,193	329,330
FIXED ASSETS	50,146,795	44,722,376	5,424,420	2,200,884
INVENTORIES & WORK IN PROGRESS				
Raw materials and supplies	1,040,576	53,449	987,128	555,375
Work in progress - goods				
Work in progress - services				
Semi-finished and finished goods	1,415,113	82,833	1,332,279	1,644,346
Goods				
Advances and prepayments on orders	114,695		114,695	38,053
RECEIVABLES				
Trade receivables	3,447,603	1,445,622	2,001,982	2,247,994
Other receivables	2,671,335		2,671,335	2,428,834
Capital subscribed and called but not paid				
MISCELLANEOUS				
Investment securities				
Cash and cash equivalents	8,165,994		8,165,994	17,337,768
ACCRUALS				
Prepaid expenses	319,924		319,924	92,450
CURRENT ASSETS	17,175,240	1,581,903	15,593,336	24,344,820
Deferred issuance expenses				
Bond redemption premium				
Unrealized foreign exchange losses	6,341		6,341	6,997
TOTAL	67,328,376	46,304,279	21,024,097	26,552,701

B. Balance sheet – Liabilities

Rubrics	2018 Financial year	2017 Financial year
Share capital (of which paid up: 1,008, 054)	1,008,054	973,894
Issue, merger and contribution premiums	91,753,281	87,972,844
Revaluation reserve		
Legal reserve		
Statutory or contractual reserves		
Regulated reserves		
Other reserves	(19,560)	(19,560)
Retained earnings	(74,786,685)	(70,804,485)
PROFIT/(LOSS) FOR THE YEAR	(11,871,126)	(3,982,200)
Investment subsidies		
Regulated provisions		
SHAREHOLDERS' EQUITY	6,083,964	14,140,493
Proceeds from the issue of participating securities		
Conditional advances	2,903,563	3,057,307
OTHER EQUITY	2,903,563	3,057,307
Provisions for risks	91,341	34,997
Provisions for expenses	14,782	14,782
PROVISIONS	106,123	49,779
FINANCIAL DEBTS		
Convertible bonds		
Other bonds		
Loans and borrowings from credit institutions		
Other loans and borrowings	4,245,292	4,125,170
Advances and prepayments received on current orders		
OPERATING LIABILITIES		
Trade payables	2,023,248	1,474,177
Tax and employee-related liabilities	1,412,273	1,437,436
OTHER LIABILITIES		
Amount due on fixed assets and related accounts		
Other payable	62,804	62,753
ACCRUALS		
Deferred revenues	209,060	213,388
LIABILITIES	7,952,675	7,312,924
Unrealized foreign exchange gains	3,977,772	1,992,199
TOTAL	21,024,097	26,552,701

II. INCOME STATEMENT AS OF DECEMBER 31, 2018

Rubrics	2018 Financial year			2017
	France	Exports	Total	Financial year
Sales of goods		89,549	89,549	1,606
Sale of manufactured goods	218,567	6,885,533	7,104,100	5,395,817
Sale of services rendered	103,200	1,041,598	1,144,798	889,821
NET SALES	321,767	8,016,680	8,338,448	6,287,244
Production in stock			(162,807)	185,464
Fixed asset production				
Operating subsidies			2,861	18,283
Write-backs of impairments, provisions (and amortization), cost transfers			88,754	115,831
Other income			107,481	84,922
OPERATING REVENUE			8,374,736	6,691,744
Purchases of goods (including customs duties)			302	4,692
Change in stocks (goods)				769
Purchases of raw materials and other supplies			1,633,394	1,092,441
Change in stocks (raw materials and supplies)			(312,683)	158,996
Other purchases and external expenses			6,018,692	4,957,941
Taxes and similar payments			161,661	153,739
Wages and salaries			4,888,217	4,572,162
Social security expenses			2,143,104	2,005,466
Operating allowances:				
Amortization on fixed assets			238,046	247,822
Impairment on fixed assets				
Impairment on current assets			346,103	181,390
Provisions			57,000	
Other expenses			257,335	239,169
OPERATING EXPENSES			15,431,172	13,614,586
OPERATING REVENUE			(7,056,436)	(6,922,842)
JOINT VENTURES				
Profits transferred in and losses transferred out				
Profits transferred out and losses transferred in				
FINANCIAL REVENUE			432,553	2,409,778
Financial revenue from participating interests				
Revenue from other investments and long-term receivables				
Other interest and similar revenue			384,729	457,647
Write-backs of provisions, cost transfers			1,728	1,883,527
Foreign exchange gains			46,095	68,604
Net proceeds from disposals of investment securities				
FINANCIAL EXPENSES			6,391,047	609,014
Depreciation, amortization and provisions - financial items			5,637,758	3,783
Interest and similar expenses			677,979	464,959
Foreign exchange losses			75,310	140,273
Net expenses on disposals of investment securities				
FINANCIAL NET INCOME			(5,958,494)	1,800,764
PROFIT BEFORE TAX			(13,014,930)	(5,122,078)
NON-RECURRING REVENUE			3,844	10,869
Non-recurring revenue from non-capital transactions				
Non-recurring revenue from capital transactions			3,844	10,869
Write-backs of provisions, cost transfers				
NON-RECURRING EXPENSES			1,104	15,478
Non-recurring expenses on non-capital transactions			35	
Non-recurring expenses on capital transactions			1,069	15,478
Depreciation, amortization and provisions exceptional items				
NON-RECURRING INCOME (EXPENSE)			2,740	(4,609)
Employee profit-sharing				
Income tax			(1,141,064)	(1,144,487)
TOTAL INCOME			8,811,133	9,112,392
TOTAL EXPENSES			20,682,259	13,094,592
PROFIT OR LOSS			(11,871,126)	(3,982,200)

III. APPENDIX

1 THE COMPANY'S ACTIVITY AND HIGHLIGHT OF THE FINANCIAL YEAR

1.1. The Company's activity

Established in 2000, Mauna Kea Technologies is a global medical device company focused on leading innovation in endomicroscopy and optical biopsy. The Company designs, develops and markets innovative tools to visualize and detect cell abnormalities in real time during standard gastrointestinal and pulmonary endoscopy procedures. Its flagship product, Cellvizio, is a confocal miniprobe endomicroscopy system which provides physicians and researchers high-resolution images of tissues at the cellular level. Large-scale, international, multi-center clinical trials have demonstrated Cellvizio's ability to help physicians to more accurately detect early forms of diseases and make immediate treatment decisions. Designed to help physicians in their diagnoses, provide patients with better treatment and reduce hospital costs, the Cellvizio system can be used with practically all endoscopes.

1.2. Highlight of the financial year

The financial statements cover the financial year from 1/1/2018 to 12/31/2018, i.e. for a period of 12 months.

On November 13, 2018, the Company signed an amendment to its subscription agreement dated February 3, 2017 with IPF Partners, a provider of alternative financing solutions. The amendment provides the option for the Company to subscribe two new tranches of €5 million each.

The first tranche for €5.0 million is available until April 2019, and another tranche of €5.0 million is available until September 2019. Both tranches would be subject to conditions for achieving pre-defined revenue levels. As at December 31, 2018, the Company met the necessary conditions to raise the first tranche.

The loans would bear interest at an annual rate equal to three month Euribor + 8.0%. The first loan tranche has a term of five years, with deferred principal repayment for the first 15 months. The second loan tranche has a term of four years, with deferred principal repayment for the first 12 months. The issuance of warrants is subject to certain restrictive financial performance conditions, included in the terms and conditions of the contract.

2 MAJOR EVENTS SINCE THE REPORTING PERIOD

On February 21, 2019, the Company announced a mutual decision to terminate the development and distribution agreements with Cook Medical due to the lack of sales performance in the urology market and the lack of sales activity.

Despite the lack of sales performance in the urology market, the Company made significant progress over the past few years in product development, certification and clinical validation of our Cellvizio technology in urology.

3 ACCOUNTING RULES AND METHODS

The Company's annual financial statements were prepared according to the standards, principles and methods of the general accounting plan attached to regulation 2016(07) of the French Accounting Standards Authority (Autorité des Normes Comptables) of November 4, 2016, approved by order of December 2016, in accordance with the provisions of French legislation, in line with the principle of prudence and in accordance with the general rules for preparing and presenting the annual financial statements:

i. continuity of accounting methods from one financial year to another;
ii. independence of financial years;
iii. going concern.

The going concern assumption was adopted by the Board of Directors taking into account the following elements:

- the cash position at 31 December 2018 of €8.2m;
- sales prospects (including those resulting from signed partnerships);
- the receipt of the 2017 research tax credit of €1.1 million in 2019;
- the granting of a repayable advance and a PERSEE grant of €0.6 million in 2019;
- the drawdown of Tranche C of IPF's €5 million debt in 2019.

In this context, the Company considers that it is in a position to meet its commitments until December 31, 2019.

The accounting elements are valued according to the historical cost method.

The most significant accounting principles and methods, used in the preparation of the company financial statements are as follows:

3.1. Fixed assets

3.1.1. Property, Plant and equipment

Property, plant and equipment and intangible assets are recorded at the cost of acquisition and their depreciation and amortization is calculated on the basis of their estimated useful lives. The depreciation method and period by category of fixed assets is as follows:

egory	Term	Method
Software packagesPatents, licenses and trademarks	1 to 3 years ars	Straight line method ght line method
Other property, plant and equipment:		
- fixtures	7 years	Straight line method
- tools	2 to 7 years	Straight line method
- computer equipment	3 years	Straight line method
- furniture	5 years	Straight line method

Development costs are recorded under expenses.

3.1.2. Long-term investments and investment securities

The elements constituting the fixed assets were valued according to the historical cost method, which is marked by the use of nominal costs expressed in current euros. The gross value comprises the purchase price, excluding transaction costs. Where the inventory value is less than the gross value, a provision for impairment is recorded for the difference.

3.2. Evaluation of inventories

Inventories are valued at their cost of acquisition according to the following methods:

Description	Methods
Raw materials	First-in first-out
Work in progress	Cost of work in progress
Finished products	Cost price, except for marketing costs

The acquisition cost is comprised of:
- the purchase price, including customs duties and other non-recoverable taxes;
- post-deduction of trade rebates, deductions, cash discounts and other similar elements;
- transport, handling and storage costs (if justified by specific operating conditions);
- and other costs directly attributable to the acquisition.

The cost of production includes consumption of raw materials, direct costs, depreciation of assets used in production.

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

Where applicable, stocks were impaired through provisions to take into account their realizable value on the reporting date.

3.3. Receivables

Receivables are recorded at their nominal value. A provision for impairment is made where the inventory value is less than the book value.

3.4. Provisions

Pursuant to the principle of prudence, provisions for risks and expenses are made to face probable outflows of resources in favor of third parties with no counterparty for the Company. These provisions are estimated by taking into consideration the most probable assumptions on the reporting date.

3.5. Foreign currency transactions

The expenses and revenue in foreign currency are recorded for their corresponding value on the transaction date.
Foreign currency receivables and payables existing at year-end are converted at the exchange rate on this date. The conversion difference is recorded in the balance sheet under “Translation differences”.
Unrealized foreign exchange gains that have not been offset are recorded under provision for risks.
Foreign currency cash accounts existing at year-end are converted at the exchange rate on this date. The unrealized foreign exchange gains or losses resulting from this conversion are recorded in profit/loss.

3.6. Subsidies and conditional advances

The Company receives a certain number of forms of assistance, in the form of subsidies or conditional advances. Details of these aids are provided in the balance sheet notes 5.3.
Subsidies are recorded:

- where there is reasonable assurance that the Company will comply with the conditions attached to the subsidies;
- and when they are received.

In practice, subsidies are thus recognized when the documentation justifying the R&D expenses incurred has been accepted by the funding agency.

Conditional advances from public authorities were made subject to a contract with BPI (formerly "OSEO Innovation") and "Coface".

The Company has this type of contract for advances as of December 31, 2018. These advances are 100% repayable (at their nominal value) in the event of technical and/or commercial success. The advances received from Coface were completely repaid as of December 31, 2018.

3.7. Research Tax Credit

Research tax credits are granted to companies by the French government in order to encourage them to conduct technical and scientific research. Companies that prove that they have expenditures that meet the required criteria (research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause) receive a tax credit that can be used for the payment of the corporate tax due for the financial year in which the expenditures were made and the next three financial years, or, as applicable, be reimbursed for the excess portion.

The Company has been receiving the Research Tax Credit since its establishment.

The Company requested the repayment of the 2017 Research Tax Credit under the regime for EU SMEs, in accordance with the regulations in force. As of the date of this document, the repayment had not yet been received.

3.8. Deviation from general principles

3.8.1 Change in the valuation methods

There was no notable change in the valuation method during the financial year.

3.8.2 Change in the presentation methods

There was no notable change in the presentation method during the financial year.

3.9. Revenue recognition

The revenue consists of 3 types of products:
- System sales
- Consumable sales (probes)
- Maintenance and repair services

The company recognizes the sales of systems and consumables in revenue when the transfer of ownership is realized. This transfer of ownership is documented by a contract, a purchase order and a delivery note.

Whereas sales of maintenance services covering a period exceeding the financial year are recognized as deferred income. These deferred revenues are therefore spread over time according to the duration of the services contracted with the customer.

4 INFORMATIONS ON BALANCE SHEET ASSETSRELATIVES AU BILAN ACTIF

4.1. Property, plant and equipment and intangible assets

4.1.1 Table of acquisitions and disposals during the financial year

Figures expressed in euros	At 12/31/2017	Acquisitions	Transfers between and corrections +/-	Disposals	At 12/31/2018
Start-up and development costs					
Other intangible fixed asset items	663,591	46,582	201,774		911,947
Total Intangible assets	663,591	46,582	201,774	0	911,947
Land					
Building and freehold land					
Building on non-freehold land					
Building, installations,fixtures.....	51,090				
General installations and fixtures (1)	501,723	7,778	(2,635)		506,866
Technical facilities, machinery and equipment (1)	1,085,450	200,501	(37,297)	(131)	1,248,523
Vehicles					
Office adn computer equipment, furniture (1)	620,420	36,261	8,076	(9,207)	655,550
Recoverable packaging and other items					
Total Property, plant, and equipment	2,258,683	244,540	(31,856)	(9,338)	2,462,029
Property, plant and equipment in progress (1)	318,363		(169,918)		148,444
Total Property, plant, and equipment outstanding	318,363	0	(169,918)	0	148,444
Prepayments					
TOTAL	3,240,637	291,122	0	(9,338)	3,522,420

(1) These changes in the property, plant and equipment and intangible asset items from one financial year of another are due to asset acquisition and sale transactions by the Company for its business.

4.1.2 Depreciation and amortization table

The depreciation and amortization of property, plant and equipment and intangible assets are calculated on a straight line or digressive basis, according to the nature of the goods and based on the estimated useful life.

Technical depreciation and amortization table:

Figures expressed in euros	At 12/31/2017	Allowance	Decreases or write-backs	At 12/31/2018
Start-up and development costs				
Other intangible assets	478,343	74,750		553,094
Total Amort. of Intangible assets	478,343	74,750	0	553,094
Land				
Buildings	49,441	939		50,381
General installations and fixtures	282,295	48,629		330,924
Technical facilities, machinery and equipment	952,339	52,509	131	1,004,717
Vehicles				
Office and computer equipment, furniture	482,652	61,217	9,207	534,661
Recoverable packaging and other items				
Total Amort. of Property, plant, and equipment	1,766,727	163,295	9,339	1,920,683
TOTAL	2,245,070	238,045	9,339	2,473,777

4.1.3 Provisions for fixed asset impairment

See section 5.2. Statement of provisions.

4.2. Long-term investments

Table of transactions for the financial year :

Figures expressed in euros	Gross value at 12/31/17	Acquisitions and transfers between items	Disposals and Transfers between items	Gross value At 12/31/2018	provision	Net value At 12/31/2018
Other participating interests	37,486,171	8,871,011		46,357,182	42,248,598	4,108,584
Loans and other long-term investments	331,058	1,174	65,039	267,193		267,193
TOTAL	37,817,229	8,872,185	65,039	46,624,375	42,248,598	4,375,777

4.3. Stocks of goods and work in progress

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 held by the Company for use by After-Sales Customer Service. They are impaired by 80%.

The inventory amount is broken down as follows:

Figures expressed in euros	Gross Amount	Impairment	Balance at 12/31/18
Raw materials	1,040,576	53,449	987,128
Finished products	1,415,113	82,833	1,332,279
TOTAL	2,455,689	136,282	2,319,407

4.4. Provisions for impairment of inventories and receivables

See section 5.2. Statement of provision.

4.5. Maturity of receivables

The gross value of receivables held by the Company amounts to €53,040,160 as of 12/31/2018 and can be broken down as follows:

Figures expressed in euros	Gross Amount	At no more than one year	At more than one year
FIXED ASSETS:	46,601,298	267,193	46,334,105
Loans related to participating interests	46,334,105		46,334,105
Loans			
Other long-term investments	267,193	267,193	
CURRENT ASSETS:	6,438,862	6,438,862	0
Receivables	3,447,603	3,447,603	
Doubtful receivables			
Personnel and related accounts	18,136	18,136	
Social security bodies	5,211	5,211	
Statement: various taxes	2,522,001	2,522,001	
Group companies and associates			
Sundry debtors	125,987	125,987	
Prepaid expenses	319,924	319,924	
TOTAL	53,040,160	6,706,055	46,334,105
Amounts of loans granted during the year			
Amounts of repayments received during the year			
Loans and advances granted to partners (natural persons)			

4.6. Trade receivables

RECEIVABLES	Gross amount	Dep. And Amort. Prov.	Net 12/31/2018	Net 12/31/2017
Trade receivables	3,447,603	1,445,622	2,001,982	2,247,994
Other receivables	2,671,335		2,671,335	2,428,834
Capital subscribed and called but not paid				
TOTAL	6,118,938	1,445,622	4,673,317	4,676,828

Including Group receivables:

Figures expressed in euros	2018	2017
Mauna Kea Technologies Inc	1,302,005	1,021,666
TOTAL	1,302,005	1,021,666

Provisions are determined per the terms and conditions outlined in section 5.2.5.

4.7. Accrued revenue

The amount of accrued revenue included in the following balance sheet items is:

Figures expressed in euros	At 12/31/2018	At 12/31/2017
Receivables - Invoices to be raised	940,223	757,809
Accrued revenue	118,000	118,000
TOTAL	1,058,222	875,809

The invoices to be raised represent the re-invoicing of management fees and current account interest to the subsidiary Mauna Kea Technologies Inc.

Accrued revenue corresponds to the subsidies from the OSEO/BPI.

4.8. Investment securities

As of December 31, 2018, the Company held no money market funds.

4.9. Accruals

4.9.1. Prepaid expenses

Prepaid expenses amount to €319,924.

Figures expressed in euros	At 12/31/2018	At 12/31/2017
Operating expenses	319,924	92,450
Financial expenses		
Non-recurring expenses		
TOTAL	319,924	92,450

4.9.2. Translation differences

DIFFERENCE ON THE ASSET SIDE		DIFFERENCE ON THE LIABILITY SIDE	
	Euros		Euros
Decrease in receivables	5,461	Decrease in liabilities	385
Increase in liabilities	879	Increase in receivables	3,977,387
TOTAL	6,341	TOTAL	3,977,772

5 INFORMATION ON BALANCE SHEET LIABILITIES

5.1. Equity

Issued capital
The share capital is set at one million eight thousand fifty three euros and fifty-two cents (€1,008,053.52). It is divided into 25,201,338 ordinary shares, fully subscribed and paid up, each with a par value of €0.04.

This figure does not include Stock Warrants (BSAs), "Founders' 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, 2017:

Type of transaction	Issued Capital (K Eur)	Share Premium (K Eur)	Number of shared comprising the issued capital (in thousand)
As of December 31, 2017	974	87 973	24 347
Exercise BSA Plan of 12/01/2017	34	3 746	850
Exercise SO	0	10	4
Others	0	25	0
Total as of December 31, 2018	**1 008**	**91 753**	**25 201**

The Company also opened, in December 2017, an equity financing facility with Kepler Cheuvreux covering a maximum number of 2,250,000 shares available for subscription over a maximum period of 24 months.

At December 31, 2018, 2,050,000 shares were purchased via the financing lines with Kepler, of which 850,000 shares in 2018. Out of the 2,250,000 BSAs subscribed as of December 1, 2017, 91% were used at the closing of the fiscal year.

Stock warrants and stock options and preferred stock awarded to employees or service providers

Since its formation, the Company issued "Stock Warrants" (BSA), stock warrants for its employees ("BSPCE" and others) as well as stock options (SO) and free performance shares (PS), the changes since December 31, 2017 are represented below.

In 2018, the Company issued a new free preference share plan, the terms of which have been approved by the shareholders at the General Meeting of October 5, 2018, and new stock options and stock warrants plans.

Type	Date of granting	Exercise price	Outstanding as of 12.31.17	Granted	Exercised	Cancelled	Outstanding as of 12.31.18	Potential number of shares
Options granted before january 1, 2018			3 491 426		854 000 *	1 487 442	1 149 984	2 275 813
SO	28/02/2018	3,12 €		300 000		70 000	230 000	230 000
SO	24/07/2018	2,54 €		80 000			80 000	80 000
SO	19/09/2018	2,86 €		40 000			40 000	40 000
SO	12/11/2018	2,59 €		600 000			600 000	600 000
SO	28/11/2018	2,52 €		35 000			35 000	35 000
BSA	28/02/2018	3,12 €		55 000			55 000	55 000
BSA	22/03/2018	2,92 €		50 000		50 000	0	0
BSA	12/11/2018	2,76 €		40 000			40 000	40 000
AP	10/10/2018			5 700			5 700	570 000
AP	12/11/2018			1 375			1 375	137 500
			3 491 426	1 207 075	854 000	1 607 442	2 237 059	4 063 313

* Of which 850,000 warrants exercised as part of PACEP financing set up in December 2017.

Following the consolidation of shares (four old shares for a 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 terms and conditions for exercising preferred shares are described in the minutes of the Combined General Meeting of October 5, 2018 in resolutions 14 and 15 (https://www.maunakeatech.com/uploads/media/media_pdf/0001/03/PV%20AGM%205%20octobre%202018%20Rev.pdf).

Company's buyback of its own shares

The Extraordinary General Meeting of October 5, 2018, 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 terms and 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 the obligations related to stock option, free share award, or employee savings plans, or other awards of shares to the employees and executives of the Company or the companies associated with it;
- to tender shares upon exercise of the rights attached to securities giving access to the share capital;
- to purchase shares to hold for their subsequent exchange or use as consideration in potential acquisitions; or
- to cancel some or all of the shares of stock thereby bought back.

Maximum purchase price: €30 per share excluding fees and commissions, with a total limit of €5,000,000.

Maximum number of shares that may be purchased: 10% of the total number of shares as of the share buyback date. When shares are purchased for market-making purposes and to ensure the liquidity of the Company's share, the number of shares included in the calculation of the 10% ceiling above is equal to the number of shares purchased, less the number resold during the term of the authorization.

It is specified that the number of shares acquired by the Company to be retained and subsequently delivered in payment or in an exchange for the purpose of any merger, de-merger, or capital contribution may not exceed 5% of its share capital.

Summary of the shares purchased and sold over the year:

	2018				
	Q1	Q2	Q3	Q4	Total
Shares purchased	378 387	288 385	222 908	195 498	1 085 178
Price	3,69	2,90	0,79	2,55	
Total amount (in k€)	1 395	836	177	499	2 908
Shares sold	368 340	270 072	237 573	188 521	1 064 506
Price	3,69	2,91	0,71	2,57	
Total amount (in k€)	1 360	785	170	485	2 799

At December 31, 2018, the Company held 38,819 Mauna Kea Technologies shares acquired at an average price of €2.08 and valued at €2.01, i.e. an unrealized capital loss of €2,556.42.

Appropriation of earnings for financial year 2017:

The financial statements for the financial year 2017 showed a net loss of €(3,982,200). Following the decision of the Ordinary Shareholders' Meeting approving the financial statements, this loss was allocated to retained earnings.

5.2. Statement of provisions

Details of the provisions by type are as follows:

5.2.1. Provision pour litiges

Figures expressed in euros	At 12/31/2017	Allowance	Write-backs	At 12/31/2018
Provisions for disputes	28,000	57,000		85,000
TOTAL	28,000	57,000		85,000

At December 31, 2018, the Company recognized a €57,000 provision concerning a labor-related dispute.

5.2.2. Provisions pour risks

Figures expressed in euros	At 12/31/2017	Allowance	Write-backs	At 12/31/2018
Provisions for foreign exchange losses	6,997	6,341	6,997	6,341
TOTAL	6,997	6,341	6,997	6,341

5.2.3. Provisions for expenses

Figures expressed in euros	At 12/31/2017	Allowance	Write-backs	At 12/31/2018
Other provision for risks and expenses	14,782			14,782
TOTAL	14,782	0	0	14,782

5.2.4. Provisions for fixed asset impairment

Figures expressed in euros	At 12/31/2017	Allowance	Write-backs	At 12/31/2018
Provisions for other long-term investments	36,611,911	5,638,415	(1,728)	42,248,598
TOTAL	36,611,911	5,638,415	(1,728)	42,248,598

During the 2018 financial year, an advance of €8,871,011 was granted to the subsidiary Mauna Kea Technologies Inc. The total amount of advances stood at €46,334,105. This sum has been provisioned for the negative net asset value of the subsidiary, i.e., €42,225,521.

5.2.5. Provisions pour dépréciation des stocks

Figures expressed in euros	At 12/31/2017	Allowance	Write-backs	At 12/31/2018
Raw materials	54,346		(897)	53,449
Finished products	51,746	40,703	(9,616)	82,833
TOTAL	106,092	40,703	(10,513)	136,282

5.2.6. Provisions for impairment of receivables

Figures expressed in euros	At 12/31/2017	Allowance	Write-backs	At 12/31/2018
Item: Doubtful receivables	1,180,776	305,400	(40,555)	1,445,621
Item: Other receivables				
TOTAL	1,180,776	305,400	(40,555)	1,445,621

5.3. Liabilities repayment schedule

LIABILITIES	Gross amount End of FY.	Less than 1 year	1 to 5 years	At more than 5 years
Convertible bonds				
Other bonds				
Loans and borrowings from credit institutions:				
repayable within a maximum of one year at inception				
repayable after more than one year at inception				
Other loans and borrowings	4,245,292	845,292	3,400,000	
Trade payables	2,023,248	2,023,248		
Personnel and related accounts	663,956	663,956		
Social security and other welfare agencies	618,284	618,284		
State and other public authorities:				
Income tax				
Value added tax	8,724	8,724		
Guaranteed bonds				
Other taxes and related accounts	121,309	121,309		
Amount due on fixed assets and related accounts				
Group companies and associates	5,000			5,000
Other payable	57,804	57,804		
Liabilities representing borrowed securities or securities provided as collateral				
Deferred revenues	209,060	209,060		
TOTAL	7,952,677	4,547,677	3,400,000	5,000
Loans repaid during the year				
Loans repaid during the year				

5.4. Trade payables

Figures expressed in euros	At 12/31/2018	Aut 31/12/2017
Group suppliers		
Suppliers in France	805,814	360,880
International suppliers	90,215	159,057
Suppliers whose invoices are not yet received	1,127,218	954,240
Valeurs nettes comptables	2,023,248	1,474,177

5.5. Accrued expenses

The amount of accrued expenses included in the following balance sheet items is:

Rubrics	2018 Financial year	2018 Financial yea
OPERATING LIABILITIES		
Trade payables	1,127,218	954,240
Tax and employee-related liabilities	1,108,303	1,078,842
FINANCIAL DEBTS		
Convertible bonds		
Other bonds		
Loans and borrowings from credit institutions		
Other loans and borrowings (of which loans to individuals:)		
Advances and prepayments received on current orders		
OTHER LIABILITIES		
Amount due on fixed assets and related accounts		
Other payable		
ACCRUALS		
Deferred revenues		
LIABILITIES	2,235,521	2,033,082

5.6. Accruals

5.6.1. Deffered revenues

Deferred revenue breaks down as follows:

Figures expressed in euros	At 12/31/2018	At 12/31/2017
Operating revenue	209,060	213,387
Financial revenue		
Non-recurring revenue		
TOTAL	209,060	213,387

5.6.2. Translation differences

See section 4.9.2.

5.7. Amount due to related companies

The Company has no liability towards its subsidiary.

6 INFORMATION ON THE INCOME STATEMENT

6.1. Breakdown of the net sales amount

Sales for financial year 2018 break down as follows:

Figures expressed in euros	2018 Financial year			2017 Financial year
	France	EEC + Export	Total	Total
Sales of goods		89,549	89,549	1,606
Sales of finished products	218,567	6,885,533	7,104,100	5,395,817
Sales of finished products	103,200	1,041,598	1,144,798	889,821
Sales	321,767	8,016,680	8 338 448	6,287,244
%	3.86 %	96.14 %	100.00 %	

6.2. Other operating revenue

Figures expressed in euros	At 12/31/2018	Au 12/31/2017
Production in stock	(162,807))	185,464
Fixed asset production		
Other management revenue and operating subsidies	2,861	18,283
Write-backs of depreciation and amortization, provisions, cost transfers and other revenue	88,754	115,831
Other income	107,481	84,921
TOTAL	(36,289)	404,499

The cost transfers include re-invoicing of training costs to the OPCAIM, employee benefits in kind, as well as refunds related to health insurance and other insurance companies.

6.3. Compensation of the statutory auditors

Depending on their mission statements, the summary of fees of the Statutory Auditors for the current and previous financial years is as follows:

Amount in euros	2018 Financial year		2017 Financial year	
	EY	EXCO	EY	COFIDEC
Audit				
Statutory auditors, certification and review of the annual financial statements and the consolidated financial statements				
- Mauna Kea Techonologies SA	49,250	49,000	49,250	40,125
- Fully consolidated subsidiaries	34,075		34,075	
Sub-Total	83,325	49,000	83,325	40,125
Others services rendered by the network to the fully consolidated subsidiaries				
Services other than account certification (SACC)	46,600	0	38,410	
Sub-Total	46,600		38,410	
TOTAL	129,925	49,000	121,735	40,125

6.4. Net financial income

The financial net income for the year was (5,958,494) € and breaks down as follows :

Rubrics	2018 Financial year	2017 Financial year
FINANCIAL REVENUE	432,553	2,409,778
Financial revenue from participating interests		
Revenue from other investments and long-term receivables		
Other interest and similar revenue	384,729	457,647
Write-backs of provisions, cost transfers	1,728	1,883,527
Foreign exchange gains	46,095	68,604
Net proceeds from disposals of investment securities		
FINANCIAL EXPENSES	6,391,047	609,014
Depreciation, amortization and provisions - financial items	5,637,758	3,783
Interest and similar expenses	677,979	464,959
Foreign exchange losses	75,310	140,273
Net expenses on disposals of investment securities		
FINANCIAL NET INCOME	(5,958,494)	1,800,764

The Company has not paid any dividends.

The financial allowances are mainly related to the impairment of current account advances to the subsidiary Mauna Kea Technologies Inc. for €5,638,415.

6.5. Non-recurring income

The non-recurring income of €2,740 for the financial year breaks down as follows:

Rubrics	2018 Financial year	2017 Financial year
NON-RECURRING REVENUE	3,844	10,869
Non-recurring revenue from non-capital transactions		
Non-recurring revenue from capital transactions	3,844	10,869
Write-backs of provisions, cost transfers		
NON-RECURRING EXPENSES	1,104	15,478
Non-recurring expenses on non-capital transactions	35	
Non-recurring expenses on capital transactions	1,069	15,478
Depreciation, amortization and provisions exceptional items		
RECURRING INCOME (EXPENSE)	2,740	(4,609)

6.6. Income tax

6.6.1. Tax situation

As of December 31, 2018, the Company has a tax loss carry forward of €78,377,269.

6.6.2. Deferred taxes

BASES	Opening balance (€'000)	Change in net income for the financial year (€'000)	Closing balance (€'000)
Differences between the tax regime and the accounting treatment of some revenues and expenses:			
Social security contribution			
Other provisions for risks	6,997	(656)	6,341
TOTAL	6,997	(656)	6,341

6.6.3. Tax credits

The Company benefits from the provisions of Articles 244 quarter B and 49 septies F of the French General Tax Code relating to research tax credits. The Research Tax Credit amount for financial year 2018 was €1,097,033. The amount of other tax credits stood at €44,031 and corresponds mainly to the competitiveness and employment tax credit.

In accordance with the information note from the ANC dated February 28, 2013, the competitiveness and employment tax credit (CICE) is recognized as a decrease in corporate income tax.

During the year ended December 31, 2018, the CICE made it possible to incur certain expenses allowing the Company to be more competitive. The actions taken by the Company during the year were largely for research and innovation.

7 MISCELLANEOUS INFORMATIONS

7.1 Average number of salaried and temporary employees

Over the 2018 financial year, the average number of employees broke down as follows:

2018 Financial Year	Workforce
Executives	64
Supervisors, technicians and employees	9
Operators	2
TOTAL	75

7.2 List of subsidiaries and investments

Companies concerned	Issued capital	capital held	Capitaux propres y compris résultat	Résultat Net
Mauna Kea Technologies Inc (*)	30,000	100%	- 48,562,536	- 4,687,614

(*)The amounts are shown in US dollars

7.3 Information on related parties

There is no information on transactions between related parties as current transactions are excluded from the list of transactions with related parties.

7.4 Compensation of administrative bodies

The compensation of the management bodies is not provided as this would reveal individual compensation.

7.5 Financial commitments

7.5.1 Commitments given

Commitments given	Total	-1 year	from 1 to 5 years	+5 years
Related to leases	763,317	155,889	590,983	16,444
Related to supply contracts	1,304,997	1,132,655	172,342	
	2,068,314	1,288,544	763,325	16,444

7.5.2 Commitments received

No commitment was received as of 12/31/2018.

7.6 Commitments towards employees

7.6.1. Retirement commitments

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

	12/31/2018	12/31/2017
% social security expenses	48%	48%
Salary increases	2%	2%
Discount rate	1,97%	1,70%

- retirement age: 65;
- terms of retirement: voluntary retirement;
- Mortality table: INSEE 2015,
- collective agreement: metal industries;
- digressive employee turnover based on age.

The amount of pension plan provision was 179,431 euros at the end of 2018 financial year.

The Company does not finance its pension plan provision. No retirements took place over the last two financial years.

No provision has been recorded in the income statement.

The discount rate comes from iBoxx Corporate AA10+ references adjusted for the term of the Company's plan estimated at 23 years.

7.6.2. Individual right to training (DIF)

In accordance with the provisions of law No. 2004(391) of May 4, 2004, on vocational training, the Group's French companies grant their employees an individual right to training of a minimum of twenty hours per calendar year, which can accrue for a maximum period of six years. At the end of this period, and if the employee fails to make use thereof, all the rights will be limited to a maximum of one hundred and twenty hours.

From January 1, 2015, the Individual Training Account (CPF) will replace the DIF. Hours acquired as of December 31, 2018 under CPF should be used before December 31, 2023.

This account is no longer managed by the Company but directly by the Caisse des Dépôts et Consignation. To benefit from the hours acquired under CPF, employees must register on the CPF's website: http://www.moncompteformation.gouv.fr.

Company financial statements for the year ended December 31, 2017

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the company financial statements and the statutory auditors' report on the company financial statements for the year ended December 31, 2017 as presented in the 2017 annual financial report are included for reference in this document.

Company financial statements for the year ended December 31, 2016

In accordance with Article 28 of Regulation (EC) No 809/2004 on prospectuses, the company financial statements and the statutory auditors' report on the company financial statements for the year ended December 31, 2016 as presented in the 2016 annual financial report are included for reference in this document.

Examination of the financial statement and results

The financial statements for the year ended December 31, 2018, which we submit for your approval, have been drawn up in accordance with the rules of presentation and valuation methods pursuant to current legislation.

Income statement

Net revenues amounted to €8,338,447 compared with €6,287,244 for the previous year, representing an increase of 33%.

The net effect of the change in finished products of €162,807 and the change in ancillary products €199,096 was €36,289.

Consequently, operating revenues totaled €8,374,736 versus €6,691,744 for the previous year, representing an increase of 25%.
Operating expenses amounted to €15,431,172 versus €13,614,586 for the previous year, representing an increase of 13%, and consisted of the following items:

- Purchases of merchandise:	€302
- Change in inventories:	€0
- Purchases of raw materials and other supplies:	€1,633,394
- Change in inventories:	€(312,683)
- Other purchases and external charges:	€6,018,691
- Taxes:	€161,661
- Wages and salaries:	€4,888,217
- Social security expenses:	€2,143,104
- Depreciation, amortization and provisions:	€238,046
- Impairment allowances:	€403,103
- Other expenses:	€257,335

The operating result was €(7,056,436) compared with €(6,922,841) for the previous year.

Our financial revenue and expenses amounted to €432,553 and €6,391,047 respectively, representing a net financial loss of €(5,958,494), compared with €1,800,763 for the previous year. This decrease is mainly due to the provision established for the current account of the US subsidiary in the amount of €5,638,415.

Consequently the profit before tax stood at €(13,014,930) compared with €(5,122,077) for the previous year.

Non-recurring income stood at €2,740 compared with €(4,609) for the previous year.

After taking into account the Research Tax Credit of €1,097,033 and other tax credits amounting to €44,031, the result for the year is €(11,871, 126) compared with €(3,982,199) for 2017.

Balance sheet

Assets

Intangible assets amounted to a net €358,853.

Property, plant and equipment amounted to a net €689,789.

Financial assets as of December 31, 2018 stood at the net amount of €4,375,777.

Current assets stood at a net €15,593,336 and prepaid expenses came to €319,923.

Liabilities

Share capital stood at €1,008,053 as of December 31, 2018, versus €973,893 at the end of the previous year, and share issuance and merger premiums totaled €91,753,281 as of December 31, 2018.

Other reserves amounted to €(19,560) at December 31, 2018.

Accumulated losses amounted to €(74,786,684) as of December 31, 2018.

Company's indebtedness position with regard to the volume and complexity of its business

Liabilities amounted to €7,952,677 (compared with €7,312,923 at the end of the previous year), consisting mainly of:

- the bond issue:	€4,233,980
- miscellaneous financial debts:	€11,312
- trade payables:	€2,023,248
- taxes payable and social security liabilities:	€1,412,274
- other payables for:	€62,804
- deferred revenue:	€209,059

In accordance with article L. 441-6-1 of the French Commercial Code, we point out that trade receivables totaling €2,001,982 (versus €2,247,994 the previous year) and trade and customer payables totaling €21,266 (versus €739,963 the previous year) break down by due date as follows:

Invoices received and unpaid on the reporting date which are due

	Article D. 441 I-1°: invoices received and unpaid on the reporting date which are due						Article D. 441 I-2°: invoices issued and unpaid at the reporting date which are due					
	0 days	1 to 30 days	31 to 60 days	61 to 90 days	91 days and over	Total (1 day and over)	0 days	1 to 30 days	31 to 60 days	61 to 90 days	91 days and over	Total (1 day and over)
(A) Payment default tranches												
Number of invoices concerned	118					182	22					45
Total amount of invoices concerned incl. tax (payables) and excl. tax (receivables) (in €K)	321	413	22	15	125	575	833	101	0	0	1 542	1 643
Percentage of total amount of purchases (incl. tax) in the year	4,2%	5,4%	0,3%	0,2%	1,6%	7,5%						
Percentage of sales (incl. tax) in the year							10,0%	1,2%	0,0%	0,0%	18,5%	19,7%
(B) Invoices omitted from (A) relating to doubtful or unrecognized receivables and payables												
No. of invoices omitted	0						0					
Total amount of invoices omitted	0						0					
(C) Reference payment terms used (contractual or legal – Article L. 441-6 or Article L. 443-1 of the French Commercial Code)												
Payment terms used to calculate payment default	■ Contractual terms: payment on the 15th or 30th day of the month after the due date indicated by the suppliers ☐ Legal terms						■ Contractual terms ☐ Legal terms					

Non-Tax-deductible expenses

In application of Article 223 quater of the French General Tax Code, we ask you to approve the sumptuary expenses and non-deductible expenses referred to in Article 39-4 of this Code, which amount to €7,059.

Table of results for the past five financial years

Type of indication / period	12/31/18	12/31/17	12/31/16	12/31/15	12/31/14
Duration of the financial year	12 months	12 months	12 months	12 months	12 months
I - Financial position at year-end					
a) Share capital	1,008,053	973,893	800,074	647,068	559,701
b) Number of shares issued					
c) Number of bonds convertible into shares					
II - Comprehensive income from operations					
a) Sales excluding taxes	8 338 447	6 287 244	7 331 438	7 368 575	11 655 908
b) Profit/(loss) before tax, depreciation, amortization and provisions	-6 786 079	-6 652 102	-6 335 344	-8 169 270	-7 368 551
c) Income tax	-1 141 064	- 1 144 487	- 863 631	- 1 264 596	-1 311 400
d) Profit/(loss) after tax, but before depreciation, amortization and provisions	-5 645 015	- 5 507 615	- 5 491 713	- 6 904 674	-6 057 151
e) Profit/(loss) after tax, depreciation, amortization and provisions	-11 871 126	-3 982 199	-10 610 123	-15 424 674	-14 741 711
f) Amount of profits distributed					
g) Employee shareholding					
III - Earnings per share					
a) Profit/(loss) after tax, but before depreciation and amortization					
b) Profit/(loss) after tax, depreciation, amortization and provisions					
c) Dividends paid per share					
IV - Employees:					
a) Number of employees	74	71	62	72	88
b) Total payroll	4 888 217	4 572 162	4 664 788	5 959 220	6 280 833
c) Total amounts paid in relation to employee benefits	2 143 104	2 005 466	2 069 015	2 546 525	2 746 803

20.3 Pro forma financial information

Not applicable.

20.4 Historical financial statements of Mauna Kea Technologies SA

See section 20.2.

20.5 Vérification of historical annual financial informations

Statutory auditors' report on the consolidated financial statements

EXCO Socodec
51, avenue Françoise Giroud – Parc Valmy – BP 16601
21066 Dijon Cedex
S.A.R.L. au capital de € 3 200 000

Commissaire aux Comptes
Membre de la compagnie régionale de Dijon

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

Commissaire aux Comptes
Membre de la compagnie régionale de Versailles

Mauna Kea Technologies
Year ended December 31, 2018

Statutory auditors' report on the consolidated financial statements

To the Annual General Meeting of Mauna Kea Technologies,

Opinion

In compliance with the engagement entrusted to us by your Annual General Meetings, we have audited the accompanying consolidated financial statements of Mauna Kea Technologies for the year ended December 31, 2018.

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, 2018 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.

The audit opinion expressed above is consistent with our report to the Audit Committee.

Basis for Opinion

- **Audit Framework**

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements section of our report.

- **Indépendence**

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from January 1, 2018 to the date of our report and specifically we did not provide any prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No 537/2014 or in the French Code of Ethics (Code de déontologie) for statutory auditors.

Justification of Assessments - Key Audit Matters

In accordance with the requirements of Articles L. 823-9 and R. 823-7 of the French Commercial Code (Code de commerce) relating to the justification of our assessments, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the financial statements of the current period, as well as how we addressed those risks.

These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the financial statements.

- **Revenue Recognition**

Key Audit Matter	Our response
The products and service sales of the Group are booked in accordance with the procedures described in Note 1.16 to the consolidated financial statements. The Group's sales revenue results mainly from the sale of innovative medical imaging devices for medical diagnosis, research and related services. Regarding the sale of products, revenue is recognized either at the products availability or delivery according to the order's conditions. Regarding pay-per-use, the Cellvizio is recorded in asset and the revenue is recognized when the probes are sold or when the health care practitioner performs the medical treatment, since the system remains the Group's property. We have considered revenue recognition to be a key audit matter given the importance of revenues as a financial indicator of the Group but also the	We have analyzed the revenue recognition methods and controls implemented by the Group. Our work consisted in: ► analyzing the contractual clauses, by sampling, mainly of the most significant contracts of the financial year, in order to assess the consistency of the accounting method applied; ► analyzing the consignment contracts signed in the current year and examining the actual amounts invoiced from medical treatments performed; ► analyzing the most significant transactions of the year by obtaining the purchase orders, invoices, delivery vouchers as well as the significant transactions with new customers or in countries where the Group has a reduced activity; ► assessing the correct application of the separation principle of the fiscal years, by

importance of revenue flows close to the year-end.

sampling of a selected significant transactions recorded before and after the year-end in order to determine whether these products were related to the right period.

- Going Concern

Key Audit Matter	Our response
The financing of the Group's operations is performed mainly by capital contributions (by capital increase), debt or loan issuance. As indicated in Note 1.1 to the consolidated financial statements, going concern assumption was adopted by the Board of Directors taking into account the cash position at December 31, 2018, sales prospects (including those resulting from signed partnerships), the receipt of the 2017 research tax credit, the granting of a repayable advance and the drawdown of Tranche C of IPF. The valuation of the estimated financing needs for the next twelve months and the Group's capacity to find proper financing are considered as a key audit matter in order to determine if the going concern assumption can apply to the consolidated financial statements.	We examined the available or forthcoming financing. Our work notably consisting in: ► analyzing the projected expenses for the next twelve months and assessing their consistency with the Group's activity and strategy; ► comparing the amount of the financing needed to the expected expenses; ► reconciling the available funding lines with the financing contracts. In addition, we: ► analyzed the projected cash flows for the next twelve months prepared by the Finance Department taking into account the financing sources and sales prospects; ► reconciled these projections in relation with the actual figures as at 31 December 2018 and to the budget approved by the Board of Directors; ► analyzed the sensitivity of each of the key assumptions implemented by management to changes in the business plan; ► reconciled the historical estimates made by management with the actual figures as of December, 31 2018; ► Interviewed management regarding its knowledge of subsequent events to December, 31 2018, which may affect the projected cash flows. We also considered whether Note 1.1 to the consolidated financial statements contains the appropriate disclosure.

Specific verifications

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by laws and regulations of the information given in the Group's management report of the Board of Directors.

We have no matters to report as to their fair presentation and their consistency with the consolidated financial statements.

Report on Other Legal and Regulatory Requirements

- Appointment of the Statutory Auditors

We were appointed as statutory auditors of Mauna Kea Technologies by the annual general meeting held on June 13, 2018 for EXCO SOCODEC and on May 25, 2011 for ERNST & YOUNG et Autres.

As at December 31, 2018, EXCO SOCODEC and ERNST & YOUNG et Autres were in the first year and eighth year of total uninterrupted engagement respectively.

Responsibilities of Management and Those Charged with Governance for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards as adopted by the European Union and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The Audit Committee is responsible for monitoring the financial reporting process and the effectiveness of internal control and risks management systems and where applicable, its internal audit, regarding the accounting and financial reporting procedures.

The consolidated financial statements were approved by the Board of Directors.

Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements

- **Objectives and audit approach**

Our role is to issue a report on the consolidated financial statements. Our objective is to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As specified in Article L. 823-10-1 of the French Commercial Code (Code de commerce), our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.

- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the consolidated financial statements.

- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the consolidated financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.

- Evaluates the overall presentation of the consolidated financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

- Obtains sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. The statutory auditor is responsible for the direction, supervision and performance of the audit of the consolidated financial statements and for the opinion expressed on these consolidated financial statements.

Report to the Audit Committee

We submit to the Audit Committee a report which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the consolidated financial statements of the current period and which are therefore the key audit matters that we are required to describe in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) N° 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L. 822-10 to L. 822-14 of the French Commercial Code (Code de commerce) and in the French Code of Ethics (code de déontologie) for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Dijon and Paris-La Défense, april 16, 2019

The Statutory Auditors

EXCO SOCODEC	ERNST & YOUNG et Autres
Olivier Gallezot	Cédric Garcia

Statutory auditors' report on the financial statement

EXCO Socodec
51, avenue Françoise Giroud – Parc Valmy – BP 16601
21066 Dijon Cedex
S.A.R.L. au capital de € 3 200 000

Commissaire aux Comptes
Membre de la compagnie régionale de Dijon

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

Commissaire aux Comptes
Membre de la compagnie régionale de Versailles

Mauna Kea Technologies

Year ended December 31, 2018

Statutory auditors' report on the financial statements

To the Annual General Meeting of Mauna Kea Technologies,

Opinion

In compliance with the engagement entrusted to us by your Annual General Meetings, we have audited the accompanying financial statements of Mauna Kea Technologies for the year ended December 31, 2018.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and of the financial position of the Company as at December 31, 2018 and of the results of its operations for the year then ended in accordance with French accounting principles.

The audit opinion expressed above is consistent with our report to the Audit Committee.

Basis for Opinion

- **Audit Framework**

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the Statutory Auditors' Responsibilities for the Audit of the Financial Statements section of our report.

- **Indépendence**

Nous avons réalisé notre mission d'audit dans le respect des règles d'indépendance qui nous sont applicables, sur la période du 1er janvier 2018 à la date d'émission de notre rapport, et notamment nous n'avons pas fourni de services interdits par l'article 5, paragraphe 1, du règlement (UE) n° 537/2014 ou par le Code de déontologie de la profession de commissaire aux comptes.

Justification of Assessments - Key Audit Matters

In accordance with the requirements of Articles L. 823-9 and R. 823-7 of the French Commercial Code (Code de commerce) relating to the justification of our assessments, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the financial statements of the current period, as well as how we addressed those risks.

These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the financial statements.

- **Revenue Recognition**

Key Audit Matter	Our response
The products and service sales of the Company are booked in accordance with the procedures described in Note 3 to the annual financial statements. The Company's revenue results mainly from the sale of systems, consumables (probes) and maintenance and repair services. Regarding the sale of products, revenue is recognized upon transfer of ownership. We have considered revenue recognition to be a key audit matter given the importance of revenues as a financial indicator of the group but also the importance of revenue flows close to the year-end.	We have analyzed the revenue recognition methods and controls implemented by the Company. Our work consisted in: ► analyzing the contractual clauses, by sampling, mainly of the most significant contracts of the financial year, in order to assess the consistency of the accounting method applied; ► analyzing the most significant transactions of the year ended December 31, 2018 by obtaining the purchase orders, invoices, delivery vouchers as well as the significant transactions with new customers or in countries where the Company has a reduced activity; ► assessing the correct application of the separation principle of the fiscal years, by sampling of a selected significant transactions recorded before and after the year-end in order to determine whether these products were related to the right period.

- **Going Concern**

Risk identified	Our response
The financing of the Company's operations is performed mainly by capital contributions (by capital increase), debt or loan issuance. As indicated in Note 3 to the annual financial statements, going concern assumption was adopted by the Board of Directors taking into account the cash position as at December 31, 2018, sales prospects (including those resulting from signed partnerships), the receipt of the 2017 research tax credit, the granting of a repayable advance and the drawdown of Tranche C of IPF.	We examined the available or forthcoming financing. Our work notably consisting in: ► analyzing the projected expenses for the next twelve months and assessing their consistency with the Company's activity and strategy; ► comparing the amount of the financing needed to the expected expenses; ► analyzing the available financing sources.

The assessment of estimated financing needs for the next twelve months and the Company's capacity to find proper financing are considered as a key audit matter in order to determine if the going concern assumption can apply to annual financial statements.

In addition, we:

- analyzed the projected cash flows for the next twelve months prepared by the Finance Department taking into account the financing sources and sales prospects;
- reconciled these projections with the actual figures as at 31 December 2018 and to the budget approved by the Board of Directors;
- analyzed the sensitivity of each of the key assumptions implemented by management to changes in the business plan;
- verified the accuracy of the historical estimates made by management;
- interviewed the management regarding its knowledge of subsequent events to December, 31 2018, which may affect the projected cash flows .

We also considered whether Note 3 to the annual financial statements contains the appropriate disclosure.

Specific verifications

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by laws and regulations.

Information given in the management report and in the other documents with respect to the financial position and the financial statements provided to the Shareholders

We have no matters to report as to the fair presentation and the consistency with the financial statements of the information given in the Board of Directors' management report and in the other documents with respect to the financial position and the financial statements provided to the Shareholders.

We attest that the information relating to payment terms referred to in article D. 441-4 of the French Commercial Code (Code de commerce) is fairly presented and consistent with the financial statements.

Information relating to Corporate Governance

We attest that the Corporate Governance section of the Management Report sets out the information required by Articles L. 225-37-3 and L. 225-37-4 of the French Commercial Code (Code de commerce).

Concerning the information given in accordance with the requirements of Article L. 225-37-3 of the French Commercial Code (Code de commerce) relating to remunerations and benefits received by the directors and any other commitments made in their favour, we have verified its consistency with the financial statements, or with the underlying information used to prepare these financial statements and, where applicable, with the information obtained by your Company from controlling and controlled companies. Based on these procedures, we attest the accuracy and fair presentation of this information.

With respect to the information relating to items that your Company considered likely to have an impact in the event of a takeover bid or exchange offer, provided pursuant to Article L. 225-37-5 of the French Commercial Code (Code de commerce), we have agreed this information to the source documents communicated to us. Based on these procedures, we have no observations to make on this information.

- **Other information**

In accordance with French law, we have verified that the required information concerning the identity of the shareholders or holders of the voting rights has been properly disclosed in the management report.

Report on Other Legal and Regulatory Requirements

- **Appointment of the Statutory Auditors**

We were appointed as statutory auditors of Mauna Kea Technologies by the annual general meeting held on June 13, 2018 for EXCO SOCODEC and on May 25, 2011 for ERNST & YOUNG et Autres.

As at December 31, 2018, EXCO SOCODEC and ERNST & YOUNG et Autres were in the first year and eighth year of total uninterrupted engagement respectively.

Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with French accounting principles and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The Audit Committee is responsible for monitoring the financial reporting process and the effectiveness of internal control and risks management systems and where applicable, its internal audit, regarding the accounting and financial reporting procedures.

The financial statements were approved by the Board of Directors.

Statutory Auditors' Responsibilities for the Audit of the Financial Statements

Objectives and audit approach

Our role is to issue a report on the financial statements. Our objective is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As specified in Article L. 823-10-1 of the French Commercial Code (Code de commerce), our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.

- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the financial statements.

- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.

- Evaluates the overall presentation of the financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

Report to the Audit Committee

We submit to the Audit Committee a report which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the financial statements of the current period and which are therefore the key audit matters that we are required to describe in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) N° 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L. 822-10 to L. 822-14 of the French Commercial Code (Code de commerce) and in the French Code of Ethics (Code de déontologie) for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Dijon and Paris-La Défense, April 16, 2019

The Statutory Auditors

EXCO SOCODEC	ERNST & YOUNG et Autres
Olivier Gallezot	Cédric Garcia

20.6 Date of most recent financial information

December 31, 2018.

20.7 Consolidated interim financial information

Not applicable.

20.8 Dividend distribution policy

20.8.1. Dividends paid during the last three financial years

N/A.

20.8.2. 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.

20.9 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, 2018, no new labor dispute was reported.

20.10 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, 2018.

SECTION 21
21. ADDITIONAL INFORMATION

21.1 Issued capital

21.1.1 Securities not representing capital

Amount of share capital

At December 31, 2018, the Company's share capital totaled €1,008,053.52 divided into 25,201,338 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

In accordance with the provisions of Article L. 233-13 of the French Commercial Code, and taking into account the information received in accordance with Articles L. 233-7 and L. 233-12 of said code, we indicate that no shareholders have direct or indirect holdings of more than 5%, 10%, 15%, 20%, 25%, 33.33%, 50%, 66.67%, 90% and 95% of the share capital or of the voting rights at the Company's annual general meetings as at December 31, 2018:

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.

By virtue of this contract, at December 31, 2018, the Company held 38,819 shares representing 0.02% of its share capital. At this date, the portfolio value was €64,143.68, based on the closing price at December 31, 2018, i.e. €2.01.
These shares, valued based on the FIFO method, were acquired based on a carrying amount of €80,582.16.

During the financial year 2018 under this contract, 1,085,178 shares were bought at an average price of €2.68 and 1,064,506 shares were sold at an average price of €2.63.

The Company did not redeem its Treasury shares for other reasons.

The Company has not informed any other limited liability company that it holds more than 10% of its capital. The Company has no cross-holdings and has not therefore disposed of any shares.

Summary of transactions performed by the Company on its own securities between January 1, 2018 and December 31, 2018:

	2018				
	Q1	Q2	Q3	Q4	Total
Shares purchased	378 387	288 385	222 908	195 498	1 085 178
Price	3,69	2,90	0,79	2,55	
Total amount (in k€)	1 395	836	177	499	2 908
Shares sold	368 340	270 072	237 573	188 521	1 064 506
Price	3,69	2,91	0,71	2,57	
Total amount (in k€)	1 360	785	170	485	2 799

Features of the Company's share buyback program:

The Ordinary General Meeting of June 13, 2018, 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.

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

Plan no.	BSPCE 08			BSPCE 08 A	BSPCE 10		BSPCE 11	BSPCE 12 & 13		BSPCE 14
Date of General Meeting	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)	1 225 000	35 000	637 500	500 000	915 000	200 000	129 500	239 500	63 000	281 000
of which the number that may be subscribed by corporate officers:										
Alexandre LOISEAU	0	0	0	500 000	0	0	0	0	0	100 000
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	08/05/09	02/15/12	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	08/05/18	02/15/21	03/01/21	12/05/21	12/04/22	05/07/23	02/12/24
BPSCE 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)	(4)	(4)	(4)	(4)
Number of shares subscribed at December 31, 2018 (3)	83 123	0	38 748	0	79 562	37 500	0	625	0	0
Cumulative number of BCE canceled or invalid as at December 31, 2018 (1)	892 508	35 000	396 256	500 000	506 752	0	117 000	204 625	36 000	125 000
BSPCE remaining at December 31, 2018 (1)	0	0	86 252	0	90 000	50 000	12 500	34 250	27 000	156 000
Total number of shares that may be subscribed for at December 31, 2018 (3)	0	0	21 563	0	22 500	12 500	12 500	34 250	27 000	156 000

(1) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 had no impact on the number of BSA authorized, issued, void, canceled 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 account for the 4-for-1 reverse stock split approved by the General Meeting of 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 BPSCE.
(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 may 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 BSPCE, may be exercised starting on the fourth anniversary of their award.
(6) The terms for exercising these BSPCE are identical to those under (5) except for 100,000 BSPCE that vest immediately

At December 31, 2018, the exercise of all BSPCE, potentially exercisable or not at the date of this report under the conditions set forth in (5), could lead to the creation of 286 313 new ordinary shares after taking the 4-for-1 reverse stock split into account.

Stock Option Plans

Information on the Stock Option Plans									
Date of General Meeting	05/27/08	06/30/10	05/27/15	05/27/15	05/27/15	05/03/17	05/03/17	05/03/17	05/03/17
Date of Chairman's decisions	03/01/10	01/31/11	02/02/16	07/26/16	03/21/17	07/19/17	02/28/18	07/24/18	09/19/18
Total number of options authorized	960 000	750 000	400 000	400 000	400 000	400 000	400 000	400 000	400 000
Total number of options granted (1)	250 000	245 000	96 000	80 000	60 000	154 000	300 000	80 000	40 000
Total number of shares that may initially be subscribed for (2)	250 000	245 000	96 000	80 000	60 000	154 000	300 000	80 000	40 000
of which the number that may be subscribed by corporate officers	0	0	0	0	0	0	0	0	0
Number of beneficiaries who are not corporate officers	3	5	10	2	1	12	14	2	4
Start date for exercise of the options	03/01/10	01/31/12	02/02/17	07/26/17	03/21/18	07/19/18	02/28/19	07/24/19	09/19/19
Option expiration date	03/01/20	01/31/21	02/02/26	07/26/26	03/21/27	07/19/27	02/28/28	07/24/28	09/19/28
Subscription price (3)	4,00 €	4,00 €	2,54 €	1,60 €	2,92 €	2,34 €	3,12 €	2,54 €	2,86 €
Exercise procedures	(4)	(4)	(5)	(5)	(5)	(6)	(6)	(6)	(6)
Number of shares subscribed at December 31, 2017 (3)	2 500	14 062	10 500	10 000	0	0	0	0	0
Cumulative number of stock options canceled or invalid (1)	100 000	128 752	72 000	0	0	104 000	70 000	0	0
Stock options remaining at December 31, 2017 (1)	140 000	60 000	13 500	70 000	60 000	50 000	230 000	80 000	40 000
Number of shares that may be subscribed for as of December 31, 2017 (3)	35 000	15 000	6 000	40 000	15 000	10 000	0	0	0

(1) The 4-for-1 reverse stock split approved by the General Meeting of May 25, 2011 had 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 account for the 4-for-1 reverse stock split approved by the General Meeting of 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.

-

(6) The procedures for exercising stock options (S.O.) are as follows:

- 20% of the S.O. may be exercised starting on the first anniversary of their allocation;
- 40% of additional S.O. may be exercised starting on the second anniversary of their allocation;
- 250% of additional S.O. may be exercised starting on the third anniversary of their allocation;
- the remaining balance, i.e. 20% of the S.O., may be exercised from the fourth anniversary of their allocation.

As of December 31, 2018, the exercise of all stock options granted could lead to the creation of 243,500 new ordinary shares, that could potentially be exercised or not as of the date of this report under the conditions set forth in paragraph (5) and (6).

Share Warrant (BSA) Plan

	BSA 2014	BSA 2016	BSA 2017-2	BSA 2018	BSA 2018
Date of General Meeting	07/11/14	05/04/16	05/03/17	05/03/17	10/05/18
Date of Chairman's decisions	09/01/14	07/26/16	12/01/17	02/28/18	11/12/18
Number of authorized share warrants (BSA)	400 000	400 000	-	400 000	400 000
Total number of BSA issued (1)	160 000	115 000	2 250 000	55 000	40 000
Total number of shares that may initially be subscribed for (2)	160 000	115 000	2 250 000	55 000	40 000
of which the number that may be subscribed by corporate officers:	120 000	115 000	0	55 000	0
André Michel Ballester	30 000				
Christopher Mc Fadden	30 000	40 000			40 000
Jean-Luc Boulnois	30 000	25 000			
Joseph Devivo		25 000			
Marie Meynadier	30 000	25 000			
Jennifer Tseng				30 000	
Molly O'Neill				25 000	
Number of beneficiaries who are not corporate officers	1	0	1	0	0
Start date for exercise of the BSA	09/01/15	07/26/17	12/01/17	02/28/19	11/12/19
BSA expiration date	09/01/24	07/26/26	12/01/19	02/28/28	11/12/28
BSA issue price	0,61 €	0,1600 €		0,3000 €	0,2800 €
BSA exercise price (3)	6,120 €	1,6800 €	(5)	3,1200 €	2,7600 €
Exercise procedures	(4)	(4)	(5)	(4)	(4)
Number of shares subscribed at December 31, 2017 (3)	0	0	2 050 000	0	0
Cumulative number of BSA canceled or invalid as of December 31, 2017 (1)	60 000	25 000	0	0	0
BSA remaining at December 31, 2017 (1)	100 000	90 000	200 000	55 000	40 000
Number of shares that may be subscribed for as of December 31, 2017 (3)	100 000	60 000	200 000	0	0

Only their exercise conditions are adjusted (price and parity).

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 BSA 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 BSA may 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: please refer to Section 10.1 of this Registration Document

At December 31, 2018, the exercise of all BSA granted, potentially exercisable or not at the date of this report under the conditions set forth in paragraph (4), could lead to the creation of 390,000 new ordinary shares.

Preference shares (AP)

Information relating to the preference shares					
Date of General Meeting	05/04/16	05/04/16	05/04/16	10/05/18	10/05/18
Date of Chairman's decisions	07/26/16	11/15/16	10/17/17	10/10/18	11/12/18
Total number of options authorized	8 500	8 500	8 500	9 000	9 000
Total number of options granted (1)	7 765	570	2 340	5 700	1 375
Total number of shares that may initially be subscribed for (2)	7 765	570	2 340	5 700	1 375
of which the number that may be subscribed by corporate officers	2 875	0	0	4500	0
Number of beneficiaries who are not corporate officers	62	4	4	1	21
Start date for exercise of the options	07/26/17	11/15/17	10/17/18	10/10/19	11/12/19
Option expiration date	*	*	*	*	*
Subscription price	*	*	*	*	*
Exercise procedures	*	*	*	*	*
Number of shares subscribed at December 31, 2018	0	0	0	0	0
Number of shares subscribed at December 31, 2018	5 915	220	350	0	0
Cumulative number of canceled preference shares returned to the pool	1 850	350	1 990	0	0
Preference shares remaining at December 31, 2018	5 915	220	350	5 700	1 375
Number of shares that may be subscribed for as of December 31, 2018	0	0	0	0	0
Total number of potential shares maximum if procedures are fullfilled (5)	5 915	220	350	5 700	1 375

*** 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 Preferred share will be convertible into twenty Ordinary Shares.

b. in the event of the Beneficiary's 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 the Beneficiary's Departure between the second anniversary (inclusive) and the third anniversary (exclusive) of the Acquisition Date, the conversion ratio 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 Preferred Share shall carry entitlement to the following number of Ordinary Shares:

33 + 33 × [(Reference Price 1 / Floor 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 "Floor Price" means the Acquisition Price plus two 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) 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 lower then the Ceiling Price: the difference between one hundred Ordinary Shares and the number of Ordinary Shares determined in (x) (such that the sum of (x) and (y) equals 100);
(iii) if the Reference Price 2 is between the Floor Price (inclusive) and the Ceiling Price (inclusive): the positive difference, if any, between:
where:

- 33 + 67 × [(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 issuance resolutions approved by the General Meetings of October 5, 2018, and May 3, 2017, voting on an extraordinary basis, 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 2017 financial year

Date of the Annual General Meeting	Purpose of the authorization	Expiration date	Use made by the Board of Directors
Combined General Meeting of May 3, 2017			
May 3, 2017 (18th resolution)	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, maintaining preferential subscription rights for shareholders – Maximum nominal amount: €240,022, included in the overall maximum amount of €240,022 set by the Annual General Meeting (articles L. 228-129 to L. 225-129-6, L. 225-91, L. 228-92 and L. 228-93 of the French Commercial Code).	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.
May 3, 2017 (19th resolution)	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: €240,022, included in the overall maximum amount of €240,022 set by the Annual General Meeting (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)	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.
May 3, 2017 (20th resolution)	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 to 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: €240,022, included in the overall maximum amount of €240,022 set by the Annual General Meeting (articles L. 225-129 to L. 225-129-6, L.225-135,	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.

	L. 225-135-1, L. 225-136, L. 228-91, L.228-92 and L. 228-93 of the French Commercial Code)		
May 3, 2017 (21st resolution)	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: €120,011, included in the overall maximum amount of €240,022 set by the Annual General Meeting (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 et seq. of the French Commercial Code)	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.
May 3, 2017 (22nd resolution)	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: €240.022, included in the overall maximum amount of €240.022 set by the Annual General Meeting. (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 et seq. of the French Commercial Code)	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.
May 3, 2017 (24th resolution)	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 (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)	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.
May 3, 2017 (25th resolution)	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: €240,022, included in the overall maximum amount of €240,022 set by the Annual General Meeting (articles L. 225-129 to L. 225-129-6, L. 225-148, L. 228-91 and L. 228-92 of the French Commercial Code).	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.
May 3, 2017	Delegation of authority granted to the Board	October 5, 2018	The Board made no

(26th resolution)	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 €240.022 set by the Annual General Meeting. (Article L. 225-147 of the French Commercial Code)	A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	use of this delegation during 2018.
May 3, 2017 (28th resolution)	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: €24,000 maximum stand-alone amount (articles L. 225-129, L. 225-129-2 and L. 225-130 of the French Commercial Code)	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board made no use of this delegation during 2018.
May 3, 2017 (30th resolution)	Delegation of authority to be 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 (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 et seq. of the French Commercial Code)	October 5, 2018 A delegation with the same purpose was granted by the General Meeting of October 5, 2018.	The Board meeting of February 28, 2018, making use of said delegation, decided to issue, at a unit price of €0.30, 55,000 warrants (BSAs) to directors of the Company each with the right to subscribe to an ordinary share with a nominal value of €0.04 at a price of €3.12 (including share premium). The Board meeting of March 22, 2018, making use of said delegation, decided to issue, at a unit price of €0.16, 50,000 warrants (BSAs) to a service provider of the Company each with the right to subscribe to an ordinary share with a nominal value of €0.04 at a price of €2.92 (including share premium).
Extraordinary General Meeting of October 5, 2018			
October 5, 2018 (2nd resolution)	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, maintaining preferential subscription rights for shareholders – Maximum nominal amount: €302,416,	December 5, 2020 (26 months)	The Board made no use of this delegation during 2018.

	included in the overall maximum amount of €302,416 set by the Annual General Meeting (articles L. 228-129 to L. 225-129-6, L. 225-91, L. 228-92 and L. 228-93 of the French Commercial Code).		
October 5, 2018 (3rd resolution)	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: €302,416, included in the overall maximum amount of €302,416 set by the Annual General Meeting (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)	December 5, 2020 (26 months)	The Board made no use of this delegation during 2018.
October 5, 2018 (4th resolution)	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 to 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: €302,416, included in the overall maximum amount of €302,416 set by the Annual General Meeting (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)	December 5, 2020 (26 months)	The Board made no use of this delegation during 2018.
October 5, 2018 (6th resolution)	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 or debt financing facility - Maximum nominal amount: €151,208, included in the overall maximum amount of €302,416 set by the Annual General Meeting (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 et seq. of the French Commercial Code)	April 5, 2020 (18 months)	The Board made no use of this delegation during 2018.
October 5, 2018 (7th resolution	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	April 5, 2020 (18 months)	The Board made no use of this delegation during 2018.

	rights for shareholders, for the benefit of a first category of persons meeting pre-determined criteria. Maximum nominal amount: €302,416, included in the overall maximum amount of €302,416 set by the Annual General Meeting. (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 et seq. of the French Commercial Code)		
October 5, 2018 (8th resolution)	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 second category of persons meeting pre-determined criteria. Maximum nominal amount: €302,416, included in the overall maximum amount of €302,416 set by the Annual General Meeting. (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 et seq. of the French Commercial Code)	April 5, 2020 (18 months)	The Board made no use of this delegation during 2018.
October 5, 2018 (9th resolution)	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 (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)	April 5, 2020 (26 months)	The Board made no use of this delegation during 2018.
October 5, 2018 (10th resolution)	Delegation of authority granted to the Board of Directors to issue ordinary shares and securities giving access to the Company's capital, in the event of a public offer with an exchange component initiated by the Company Maximum nominal amount: €302,416, included in the overall maximum amount of €302,416 set by the Annual General Meeting. (articles L. 225-129 to L. 225-129-6, L. 225-148, L. 228-91 and L. 228-92 of the French Commercial Code).	December 5, 2020 (26 months)	The Board made no use of this delegation during 2018.
October 5, 2018 (11th resolution)	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,	December 5, 2020 (26 months)	The Board made no use of this delegation during 2018.

	included in the overall maximum amount of €302,416 set by the Annual General Meeting. (Article L. 225-147 of the French Commercial Code)		
October 5, 2018 (13th resolution)	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: €24,000 maximum stand-alone amount (articles L. 225-129, L. 225-129-2 and L. 225-130 of the French Commercial Code)	December 5, 2020 (26 months)	The Board made no use of this delegation during 2018.
October 5, 2018 (17th resolution)	Delegation of authority to be 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 (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 et seq. of the French Commercial Code)	April 5, 2020 (18 months)	The Board of Directors on February 12, 2018, making use of said delegation, decided to issue 40,000 Warrants (BSAs) to a director of the Company at a price of €0.82, each with the right to subscribe to an ordinary share with a nominal value of €0.04 at a price of €2.76.

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 (€)
21/04/00	Constitution	62 000	62 000	1,00	62 000,00		4,00
04/07/00	100-for-1-share split	6 138 000	6 200 000	0,01	62 000,00		0,04
21/09/00	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		
02/05/11	Exercise of BSPCE	1	35 727 780	0,01	357 277,80	0,99	
25/05/11	4-for-1 reverse stock split	-26 795 835	8 931 945	0,04	357 277,80		NA
11/07/11	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
12/05/15	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
12/07/16	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
2017	Exercise of BSA - Kepler - Plan of the 11/18/2016	1 005 000	21 006 838	0,04	840 273,52	2 700 267,00	
2017	Exercise of BSA - Kepler - Plan of the 10/06/2017	2 100 000	23 106 838	0,04	924 273,52	7 627 047,50	Average of 3,74
2017	Exercise of BSA - Kepler - Plan of the 12/01/2017	1 200 000	24 306 838	0,04	972 273,52	4 868 244,00	Average of 4,18
2017	Exercise of BSPCE	24 000	24 330 838	0,04	973 233,52	95 080,00	5,06
2017	Exercise of SO	16 500	24 347 338	0,04	973 893,52	31 850,00	4,4
2018	Exercise of BSA - Kepler - Plan of the 12/01/2017	850 000	25 197 338	0,04	1 007 893,52	3 745 937,50	Average of 4,51
2018	Exercise of SO	4 000	25 201 338	0,04	1 008 053,52	10 000,00	2,54

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 his or her 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 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. He or she 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 and the Board of Directors. He or she 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 him 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

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-I of the French Commercial Code (in particular the total number of shares and voting rights said person holds), by registered letter with return receipt requested, or by any equivalent means for persons residing outside France, sent to the 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
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 in early 2015 and again in early 2019 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 13485:13485 and ISO 9001:9001 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.

Since August 2018, the Company has chosen to work with a preferred partner in China, the company Shanghai YouHe Medical Technology Co., Ltd based in Shanghaï. It will sell Cellvizio for gastroenterological and pulmonary applications in China and will integrate the Cellvizio platform into its commercial offers for advanced endoscopy systems for the aforementioned segments. The commercial territory allocated to Shanghai YouHe Medical Technology Co., Ltd includes southern and eastern China. The company is continuing its research to identify a commercial partner for northern China.

SECTION 23
23. THIRD-PARTY INFORMATION, STATEMENTS BY EXPERTS AND DECLARATIONS OF INTEREST

N/A.

SECTION 24
24. DOCUMENT 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
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.

SECTION 26
26. CORRESPONDENCE TABLE

Correspondence table of the annual financial report and the management report pursuant to the French Commercial Code

To make it easier to read the annual financial report and the management report required under the French Commercial Code, the following thematic table shows where to find the main information provided in this Registration Document.

Rubrics	Information for	Sections	Page
1. COMPANY FINANCIAL STATEMENTS	Annual Financial Report	20.2	P 208
2. CONSOLIDATED FINANCIAL STATEMENTS	Annual Financial Report	20.1	P 170
3. MANAGEMENT REPORT			
3.1. Information on the Company's activity	-		-
• Overview of the activities (progress made and difficulties encountered) and earnings of the Company, each subsidiary and the Group Art. L. 232-1, L. 233-6, R. 225-102 and/or L. 233-6 and L. 233-26 of the French Commercial Code		6.1	P 43
• Presentation of the ongoing business, earnings, financial situation and indebtedness of the Company and the Group Art. L. 233-26, L. 225-100 par. 3, L. 225-100-1 and/or L. 225-100-2 of the French Commercial Code	Annual Financial Report	9.2 9.3.4 9.3.5	P 108 P 113 P 114
• Foreseeable development of the Company and/or the Group Art. L. 232-1, R. 225-102 and/or L. 233-26 and R. 225-102 of the French Commercial Code	-	12.1 12.2	P 128
• Key financial and non-financial indicators of the Company and the Group Art. L. 225-100 par. 3 & 5, L. 225-100-1, L. 223-26 and/or L.	Annual Financial Report	3	P 9

225-100-2 of the French Commercial Code			
• Subsequent events affecting the Company and the Group Art. L. 232-1 and/or L. 233-26 of the French Commercial Code		20.2 (appendix III.2) 20.1 (Note 25)	P 208 P 170
• Information on the use of financial instruments including the financial risks and risks in terms of pricing, credit, liquidity and cash facing the Company and the Group Art. L. 225-100 par. 6, L. 225-100-1 and/or L. 225-100-2 and L. 223-26 of the French Commercial Code	Annual Financial Report	20.1 (Note 24)	P 204
• Main risks and uncertainties of the Company and of the Group Art. L. 225-100, par. 4 and 6, L. 225-100-1 and/or L. 225-100-2, par. 2 and 4, of the French Commercial Code	Annual Financial Report	4	P 12
• Information on R&D by the Company and the Group Art. L. 232-1 and/or L. 233-26 of the French Commercial Code		6.2 11	P 52 P 121
3.2. Information on the Company's legal, financial and tax affairs			
• Choice of one of the two modes of general management of the Company in the event of a change Art. R. 225-102 of the French Commercial Code.		14.1	P 130
• Breakdown and changes in shareholding • Names of controlled entities holding treasury shares and share of the capital they own Art. L. 233-13 of the French Commercial Code		18.1 21.1.3	P 165 P 252
Significant stakes acquired in companies headquartered in France during the period Art. L. 233-6 par. 1 of the French Commercial Code		NA	
• Notice of holdings of more than 10% of the capital of another limited liability company; disposal of cross shareholdings Art. L 233-29, L. 233-30 and R. 233-19 of the French Commercial Code		NA	
• Company share buybacks and disposals Article L. 225-211 of the French Commercial Code	Annual Financial Report	21.1.3	P 249

Statement showing the share capital held by employees		21.1.4	P 253
Overview of information likely to have an impact in the event of a public offering: Art L. 225-100-3 of the French Commercial Code - structure of the Company's issued capital; - statutory restrictions on the exercise of voting rights and the transfer of shares or contractual clauses brought to the Company's attention in application of Article L. 233-11 of the French Commercial Code; - direct or indirect stakes in the Company's share capital of which it is aware by virtue of Articles L. 233-7 and L. 233-12 of the French Commercial Code; - list of holders of any securities conferring special rights of control and description of these rights; - control mechanisms provided in any employee shareholding scheme where rights of control are not exercised by the employees, - Shareholder agreements the Company is aware of and which may impose restrictions on the transfer of shares and the exercise of voting rights; - rules applicable to the appointment and replacement of members of the Board of Directors or management board and to amendments to the bylaws; - powers of the Board of Directors or management board, in particular the issuance and buyback of shares; - agreements entered into by the Company which are amended or terminated in the event of a change of control of the Company unless this disclosure (if not legally mandated) would seriously harm its interests; - agreements providing for indemnities for members of the Board of Directors or management board or employees if they resign or are dismissed without due cause or if their employment is terminated as a result of a public takeover offer.	Annual Financial Report	21.1 18.3 18.3 18.1 18.3 18.4 14.1.1 20.1 (Note 10.3) 18.5 18.6 15.1.1	P 252 P 165 P 165 P 165 P 165 P 166 P 130 P 190 P 167 P 167 P 138
• Summary table of the currently valid delegations to increase the share capital granted by the General Meeting Art. L. 225-100 par. 7 of the French Commercial Code	Annual Financial Report.	21.1.5	P 261.
Mention of any adjustments: - for securities giving access to the capital and stock options in the event of share buybacks - for securities giving access to the capital in case of		21.1.4	P 253

financial transactions. Art. R. 228-90, R. 225-138 and R. 228-91 of the French Commercial Code			
• Amount of dividends distributed for the past three financial years Art. 243a of the French General Tax Code		20.8	P 251
Amount of dividends distributed for the past three financial years Art. 243a of the French General Tax Code.		20.2	P 208
Terms of payment and breakdown of the balance on trade and customer payables by due date Art. L. 441-6-1, D. 441-4 of the French Commercial Code		20.2	P 208
• Injunctions or fines for anti-competitive practices Art. L. 464-2 I par. 5 of the French Commercial Code		4.2.1	P 15
• Agreements between a corporate officer or shareholder holding more than 10% of voting rights and a subsidiary (excluding day-to-day agreements) Art. L. 225-102-1 par. 13 of the French Commercial Code		15.1	P 138
3.3 Information on corporate			
• List of all offices and positions held in any company by each corporate officer during the period Art. L. 225-102-1 par. 4 of the French Commercial Code		14.1.1 14.1.2	P 130 P 134
• Compensation and benefits in kind paid during the period to each corporate officer by the Company, entities it controls and the entity controlling it Art. L. 225-102-1 par. 1-3 of the French Commercial Code		15	P 138
• Agreements on taking up, terminating or changing positions Art. L. 225-102-1 par. 3 of the French Commercial Code		15.1.1	P 138
• If stock options are granted, mention of the information whereby the Board of Directors decided to: - either prevent executives from exercising their options for the duration of their term of office;- or require executives to hold all or part of the shares resulting from options already exercised in registered form for the duration of their term of office (specifying the percentage set).		15.1.1	P 138

Art. L. 225-185-185 par. 4 of the French Commercial Code			
• Summary of trading in the Company's shares by executives and related parties Art. L. 621-18-2, R. 621-43-1 of the French Monetary and Financial Code; Art. 223-22 and 223-26 of the General Regulations of the AMF [*Autorité des Marchés Financiers*/French Financial Markets Authority])		15.3	P 149.
• If bonus shares are granted, mention of the information whereby the Board of Directors decided to: - either prevent executives from selling their bonus shares for the duration of their term of office;- or set the number of these shares they must keep in registered form for the duration of their term of office (specifying the percentage set) Art. L. 225-197-1-II par. 4 of the French Commercial Code		15.1.1	P 138
3.4 The Company's CSR information			
• Account of the consequences of the Company's activity on its employees and the environment and of its social commitments to sustainable development, combating discrimination and promoting diversity Art. L. 225-102-1 par. 5-8, R. 225-104, R. 225-105 and R. 225-105-2-II of the French Commercial Code		8.3 8.4	P 97 P 106
• Information on dangerous activities Art. L. 225-102-2 of the French Commercial Code.			
4. Statement of the natural persons responsible for the annual financial report	**Annual Financial Report**	**1.1** **1.2**	**P 6**
5. Statutory auditors' report on the company financial statements	**Annual Financial Report**	**20.5**	**P 239**
6. Statutory auditors' report on the consolidated financial statements	**Annual Financial Report**	**20.5**	**P 239**

GLOSSARY

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;

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;

Biopsy: mechanism that consists of taking a sample from the organism in order to carry out a microscopic examination;

Optical biopsy: see endomicroscopy;

Bronchoscopy: endoscopic examination enabling the visual exploration of the trachea and the bronchi and taking samples for analysis;

Catheter: medical device consisting of a tube designed to be inserted into the lumen of a body cavity or blood vessel, enabling drainage or infusion of liquids, or access for other medical devices;

Cholangiocarcinoma: biliary tract tumor;

Colonoscopy: specific case of endoscopy consisting of an exploratory examination of the colon (from the rectum to the small intestine);

Cystoscopy (or endourology): 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;

Dysplasia: cellular/architectural modifications, the intensity of which defines the grade of dysplasia (Low grade = benign tumor, High grade = malignant tumor, in situ = not crossing the basal membrane).

Echoendoscopy: exploration of the tracheobronchial tree combining endoscopy and ultrasonography. It is used to identify and take biopsies of structures situated behind walls and not visible with conventional endoscopy (essentially nodes, tumors and cysts).
At the end of the bronchoscope, an ultrasound probe is used to capture images in mode B and Doppler;

Distal tip: The farthest tip of a mini-probe, for instance. The distal tip of the confocal mini-probes contains optical micro lenses;

Endo-brachy esophagus (EBO or Barrett's Esophagus): complication of 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;

White light endoscopy: traditional endoscopy;

EGD (Esophagogastroduodenoscopy): upper endoscopy used to examine the esophagus, stomach and duodenum;

Multicenter clinical trials: clinical trials that take place in several different places simultaneously;

Randomized clinical trial: Clinical trial of a new treatment during which participants are assigned at random to the control group or the experimental group;

Histology: a branch of biology and medicine that studies biological tissues;

Narrow Band Imaging (NBI): NBI is a technology developed by Olympus based on an optical filter which can be used to improve visibility and contrast between capillaries, veins and other microstructures;

Distal lesion: lesions situated at the farthest tip of a given organ esophagus, biliary tract, etc.);

Dysplastic lesion: precancerous lesion;

Barrett's Esophagus: see Endo-brachy-esophagus (EBO);

Metaplasia: transformation of a cellular tissue. Reversible phenomenon not disturbing the tissue's functions;

Advanced mosaic: optimized treatment of a succession of adjacent images used to reconstruct wide field maps of a mucosa;

Mucosectomy: endoscopic treatment of a precancerous lesion consisting of a resection of the mucosa and possibly of the sub-mucosa in a hollow organ, such as the colon, esophagus or stomach;

Confocal miniprobes: invention of Mauna Kea Technologies. They are made up of a bundle of several tens of thousands of optical fibers sequentially scanned by a laser beam emitted by the scanning unit. They 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;

Nodules: abnormal, rounded, and palpable formations on or under the skin, which can be benign or malignant. Some nodules can be cancerous tumors;

Optoelectronics: combination of optical and 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;

Resection: surgical ablation of part of an organ or a pathological tissue such as a tumor;

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;

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;

Biliary and/or pancreatic duct strictures: shrinkage of the natural ducts, whether pancreatic or biliary;

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.);

Ureter: the ureters are muscular channels which carry urine from the kidneys to the bladder. In adults, the ureters are generally 25 to 30 cm long;

Transpleural route: route of access across the pleura, i.e. the space between the lungs and the thoracic wall.

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