A French corporation (*société anonyme*) with a share capital of €15,256,824
Registered office: 320, avenue Archimède
Les Pléiades III – Bâtiment B
13100 Aix-en-Provence
837 722 560 Aix-en-Provence Trade and Companies Registry

REGISTRATION DOCUMENT

The registration document was approved on 12 April 2021 by the AMF, in its capacity as competent authority under Regulation (EU) No. 2017/1129.

The AMF approves this document after verifying that the information it contains meet the standards of completeness, comprehensibility and consistency. The registration document was approved by the AMF under number: I.21-007

This approval should not be considered as an endorsement of the issuer subject of the registration document.

The registration document may be used for the purposes of a public offering of financial securities or the admission of financial securities to trading on a regulated market if it is supplemented by a securities note and, where applicable, a summary and its supplement(s). The prospectus as a whole is approved by the AMF in accordance with Regulation (EU) No. 2017/1129.

It is valid until 12 April 2022 and, during this period and at the latest at the same time as the securities note and under the conditions of Articles 10 and 23 of Regulation (EU) No. 2017/1129, shall be complemented by a supplement to the registration document in the event of significant new factors or material mistakes or inaccuracies.

Copies of this registration document are available free of charge from the Company at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence and in an electronic version on the Company's website (www.affluentmedical.com) and on the website of the Autorité des marchés financiers (www.amf-france.org)

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GENERAL COMMENTS

Definitions

In this Registration Document, and unless otherwise indicated:

- the terms "Company" or "Affluent Medical" mean Affluent Medical, a French corporation (*société anonyme*) whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, registered with the Aix-en-Provence Trade and Companies Registry under the number 837 722 560;

- the term "Group" means the Company and its subsidiaries and sub-subsidiaries controlled by Affluent Medical:

  - Kephalios, a French simplified joint stock company (*société par actions simplifiée*) whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, registered with the Aix-en-Provence Trade and Companies Registry under number 531 557 650;

  - Kardiozis, a French simplified joint stock company (*société par actions simplifiée*) whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, registered with the Aix-en-Provence Trade and Companies Registry under number 532 628 336;

  - Epygon, a French simplified joint stock company (*société par actions simplifiée*) whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, registered with the Aix-en-Provence Trade and Companies Registry under number 539 455 238;

  - Epygon Italie, an Italian limited liability company (*Società a Responsabilita Limitata*) whose registered office is located at via Ribes 5 – 10010 Colleretto Giacosa (TO), Italy, registered with the Turin Trade and Companies Registry under number 11311520016;

  - MyoPowers Medical Technologies France, a French simplified joint stock company (*société par actions simplifiée*) whose registered office is located at 18, rue Alain Savary, 25000 Besançon, France, registered with the Besançon Trade and Companies Registry under number 799 927 355;

  - Medev Europa, a Romanian limited liability company (*Societate cu Raspundere Limitata*) whose registered office is located at Bucureşti Sectorul 4, Bulevardul Regina Maria, Nr. 32, Parter Biroul NR. 3, Modul, Romania, registered with the Romanian National Office of the Trade Register under number J40/524/2020 and the unique identification code 42124756;

- the term "Registration Document" means this registration document as approved by the AMF.

The Registration Document has been prepared in accordance with Appendix I of Commission Delegated Regulation (EU) No. 2019/980 of 14 March 2019 supplementing Regulation (EU) No. 2017/1129 of the European Parliament and of the Council of 14 June 2017.

Disclaimer

The Registration Document contains, in particular in Chapter 5 "*Overview of business activities*" information on the Group's activities as well as the markets in which it operates and its competitive position. This information comes from studies conducted either by internal or external sources (*e.g.*, sector publications, specialised studies, information published by market analysis companies, analysts'

reports). To date, the Group believes that this information provides a true and fair view of its reference markets and its competitive position in these markets. However, this information has not been verified by an independent expert, and the Group cannot guarantee that a third party using different methods to collect, analyse or calculate market data would obtain the same results.

Forward-looking information

The Registration Document contains information on the Group's prospects and areas of development. These indications are sometimes identified by the use of the future, the conditional or forward-looking terms such as "estimate", "consider", "contemplate", "think", "have as an objective", "expect", "intend", "must", "aspire", "believe", "wish", "be able" or, where appropriate, the negative form of these same terms, or any other variation or similar terminology. This information is not historical data and should not be interpreted as a guarantee that the facts and data stated will occur. This information is based on data, assumptions and estimates considered reasonable by the Group. They are likely to change or be modified due to uncertainties related to the economic, financial, competitive and regulatory environment. This information is mentioned in various sections of the Registration Document and contains data relating to the Group's intentions, estimates and objectives concerning, in particular, the markets in which it operates, its strategy, its growth, its results, its financial position, its cash flow and forecasts. Forward-looking information mentioned in the Registration Document is given only as of the date of approval of the Registration Document. The Group operates in a competitive and constantly changing environment. It cannot therefore anticipate all the risks, uncertainties or other factors likely to affect its business, their potential impact on its business or the extent to which the materialisation of a risk or a combination of risks could have materially different results from those mentioned in any forward-looking information, it being noted that none of this forward-looking information is a guarantee of actual results. The Group makes no commitment to publish updates to this information or the assumptions on which it is based, with the exception of any legal or regulatory obligation applicable to it, in particular the AMF General Regulations and the Regulation (EU) No. 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse.

Risk factors

Investors are invited to carefully read the risk factors described in Chapter 3 "*Risk factors*" in the Registration Document before making any investment decision. The occurrence of all or part of these risks is likely to have a material adverse effect on the Group's business, financial position, results or outlook. In addition, other risks not yet identified or considered immaterial by the Group as at the date of approval of the Registration Document could also have a material adverse effect.

Rounding

Certain figures (including data expressed in thousands or millions) and percentages presented in the Registration Document have been rounded. As applicable, the totals presented in this Registration Document may differ slightly from the totals that would have been obtained by adding the exact values (not rounded) of such figures.

Websites and hypertext links

References to any website and the content of hypertext links in the Registration Document are not part of the Registration Document.

Glossary

To aid the reader's understanding, a glossary containing the principle scientific and technical terms used (identified by an asterisk "*") is provided in Chapter 22 "*Glossary*" of the Registration Document.

1. RESPONSIBLE PERSONS, THIRD PARTY INFORMATION, EXPERT REPORTS AND APPROVAL OF THE COMPETENT AUTHORITY

1.1. Person responsible for the Registration Document

Mr Michel Finance, Chairman and Chief Executive Officer of the Company (*Président Directeur Général*).

1.2. Certification of the person in charge

"I hereby certify that the information contained in this Registration Document is, to the best of my knowledge, in accordance with the facts and contains no omission that might alter its import.

in Aix-en-Provence

on 12 April 2021

Michel Finance
Chairman and Chief Executive Officer

1.3. Expert reports

No report attributed to a person acting as an expert is included by reference in the Registration Document.

1.4. Third party information

No statements or information from third parties are included by reference in the Registration Document.

1.5. Declaration relating to the Registration Document

The Registration Document has been approved by the AMF as the competent authority under Regulation No. (EU) 2017/1129.

The AMF only approves this Registration Document as complying with the standards in terms of completeness, comprehensibility and consistency imposed by Regulation (EU) No. 2017/1129.

This approval should not be considered as an endorsement of the issuer that is the subject of the Registration Document.

1.6. Person responsible for the financial information

Affluent Medical
Mr Jérôme Geoffroy
Chief Financial Officer
Address: 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France
Telephone: +33 (0)4.42.95.12.20
Email address: investor@affluentmedical.com

2. STATUTORY AUDITORS

2.1. Statutory Auditors

- **PricewaterhouseCoopers Audit**
  represented by Mr Thierry Charron
  member of the Versailles Regional Association of Statutory Auditors
  63, rue de Villiers – 92200 Neuilly sur Seine, France
  appointed on 6 February 2018 for a period of six financial years ending at the close of the General Meeting held to approve the financial statements for the financial year ending on 31 December 2023.
- **Expertea**
  represented by Mr Jérôme Magnan
  member of the Aix-Bastia Regional Association of Statutory Auditors
  60, boulevard Jean Labro – 13016 Marseille, France
  appointed on 30 December 2020 for a period of six financial years ending at the close of the General Meeting held to approve the financial statements for the financial year ending on 31 December 2025.

2.2. Deputy Statutory Auditors

In accordance with the provisions of Article L. 823-1 of the French Commercial Code, the Company has not appointed deputy Statutory Auditors for PricewaterhouseCoopers Audit and Expertea.

2.3. Information on the Statutory Auditors having resigned, been dismissed or not been renewed

Not applicable.

3. RISK FACTORS

Investors are invited to consider all of the information contained in the Registration Document, including the risk factors described in this chapter, before deciding to acquire shares in the Group. The Group has carried out a review of the risks that could have a material adverse effect on the Group, its business, financial position, results, outlook or its ability to achieve its objectives. As at the date of approval of the Registration Document, the Group was not aware of any significant risks other than those presented in this chapter.

The attention of investors is drawn to the fact that the list of risks and uncertainties described below is not exhaustive. Other risks or uncertainties that are unknown or whose realisation is not considered by the Group, as at the date of approval of the Registration Document, as likely to have a material adverse effect on the Group, its business, financial position, results or its outlook, may exist or could become significant factors liable to have a material adverse effect on the Group, its business, financial position, its results, its development or its outlook.

In accordance with the provisions of Regulation (EU) No. 2017/1129 (the "Prospectus 3" Regulation) and Delegated Regulation (EU) No. 2019/980, this chapter presents the Group's main specific risks which could, as at the date of approval of the Registration Document, affect the Group's business, financial position, reputation, results or outlook. The risks presented are the risks identified by the Group after taking into account the action plans put in place. The main risk factors are grouped into four categories below, it being specified that within each of them, the risk factors are presented in decreasing order of importance resulting from the combination of their probability of occurrence and the magnitude of the negative impact of the risk according to the Group's assessment as at the date of approval of the Registration Document. The occurrence of new events, either internal to the Group or external, could therefore change this order of importance in the future.

The Group draws the attention of investors to the risks related to the health crisis linked to the Covid-19 pandemic, the scale of which in the medium and long term and the evolution of which are difficult to predict. This virus continues to circulate actively in a large number of countries, and restrictive measures relating to the movement of people and the interruption or restriction of certain human and industrial activities have been taken, particularly in countries where the Group is carrying out or is planning to conduct clinical studies (Austria, Italy, Spain, Czech Republic, Germany and Switzerland). The Group has inserted the potential impacts of the economic and public health crisis linked to the Covid-19 pandemic in the risks presented below.
Key for critical level of risk: *** High - ** Medium - * Low

Nature of the risk	***Probability of occurrence***	***Risk magnitude***	***Significance of the risk***
3.1 Risks related to the Group's business and markets			
• Risks related to delays or failures in the development of the Group's innovative implantable medical devices (section 3.1.1)	**	***	***
• Risks related to the unsuccessful marketing of the Group's products or technology (section 3.1.2)	**	***	***
• Risks related to current or future competition on the products developed by the Group (section 3.1.3)	*	**	**
3.2 Regulatory and legal risks			
• Risks related to obtaining marketing authorisations for the Group's medical devices or technology (section 3.2.1)	**	**	**
• Risks related to intellectual property rights (section 3.2.2)	**	**	**

• Risks related to pricing and changes in reimbursement policies for medical devices (section 3.2.3)	**	*	**
• Risks related to the Group's product liability (section 3.2.4)	*	*	*
3.3 Risks linked to the Group's organisation and operations			
• Risks related to the industrialisation of the Group's medical devices (section 3.3.1)			
- Risks related to the manufacturing processes of the Group's medical devices (section 3.3.1.1)	**	**	**
- Risks related to a potential failure of the industrial and product quality control processes of the Group (section 3.3.1.2)	*	**	**
• Risks related to third-parties (section 3.3.2)			
- Risks related to failures or defects of the Group's suppliers or subcontractors (section 3.3.2.1)	**	**	**
- Risks related to the Group's dependence on certain partners, suppliers and subcontractors (section 3.3.2.2)	*	**	**
• Risks related to the implementation of the Group's marketing strategy (section 3.3.3)	**	**	**
• Risks related to the maintenance and the performance of collaboration agreements signed with existing or future partners (section 3.3.4)	**	*	*
• Risks related to dependence on qualified personnel and key executives (section 3.3.5)	*	*	*
3.4 Financial risks			
• Liquidity risk (section 3.4.1)	**	**	**
• Risks related to the default or increase in insurance coverage costs (section 3.4.2)	*	**	**
• Dilution risk (section 3.4.3)	**	*	*
• Risks related to access to public subsidies and funding (section 3.4.4)	*	*	*
• Risks related to past and future losses (section 3.4.5)	*	*	*
• Risks linked to the depreciation of Group intangible assets (para. 3.4.6)	*	*	*

3.1. Risks related to the Group's business and markets

3.1.1. Risks related to delays and failures in the development of the Group's innovative implantable medical devices

The Group conducts research programmes and clinical programmes with the main objective of developing and marketing minimally invasive implantable medical devices for the efficient and innovative treatment of pathologies in the fields of urology for the treatment of severe urinary incontinence (Artus medical device), structural heart for the treatment of mitral insufficiency (Kalios and Epygon medical devices) and cardiovascular systems for the treatment of the abdominal aortic aneurysm* (Kardiozis technology) (see Chapter 5 "*Overview of business activities*" of the Registration Document).

To obtain the regulatory authorisations necessary for the marketing of class III medical devices such as Artus, Kalios and Epygon (see Chapter 9 "*Regulatory environment*" of the Registration Document), the Group must conduct preclinical and clinical studies in order to demonstrate their safety and efficacy in various regions, depending on local regulatory authorisations for their marketing. The development of a medical device takes place in several distinct phases (preclinical trials, feasibility studies and pivotal studies), each of which is costly and may lead to a failure or delay in the marketing of Artus, Kalios and Epygon products. The Group may not guarantee that the results of the preclinical trials and clinical trials (Dry, Optimise II or Minerva) in progress or to be carried out during these various phases (see Sections 5.2.2.2, 5.2.3.2 and 5.2.3.3 of the Registration Document), will demonstrate the tolerance, safety and efficacy of its medical devices. The Group could choose, or the regulatory authorities could force the Group, to suspend or terminate clinical trials if patients were or came to be exposed to unforeseen and serious risks or the risk of no clinical efficacy. Other adverse events could occur during a clinical trial due to medical problems that may or may not be related to one of the medical devices being tested, and require the Group to delay or interrupt the trial.

In addition, disappointing results during the initial phases of development of the Artus, Kalios or Epygon medical devices could result in the decision to not continue with the projects, or even lead to the abandonment of these projects, which the Group initially considered promising; this could also lead the Group to enter into co-development options with a partner conducting and financing these clinical programmes. The size of the samples, the duration of the Dry, Optimise II or Minerva studies and the parameters studied may not be sufficient to draw definitive conclusions about a programme, or to obtain the authorisation/certification/registration necessary to place the products on the market, which may require new investigations likely to extend the duration of the studies and their costs. Conversely, promising results during the initial phases, and even after the conduct of clinical trials at an advanced stage, do not guarantee the Group's ability to successfully complete the industrialisation and marketing of Artus, Kalios and Epygon.

The Group could also encounter difficulties in recruiting and retaining patients in the context of the Dry, Optimise II and Minerva clinical trials, particularly in the current context of the health and economic crisis linked to the Covid-19 pandemic. Such difficulties could have the effect of significantly extending the duration of the clinical trials planned.

To date, the Covid-19 pandemic has had an impact:

- on the process relating to the recruitment of patients in the context of the European pivotal study for the Kalios medical device (see section 5.2.3.2 of the Registration Document) causing a slow-down in patient recruitment as well as an extension in the anticipated duration of the study with a delay of approximately one year in the recruitment of approximately fifty patients, given that as of the date of approval of the Registration Document, 15 patients have benefitted from being implanted with the Kalios device. The monitoring of patients implanted with the Kalios medical device was carried out normally;
- on the identification of patients as part of the preparation of the clinical study for the Epygon medical device (see section 5.2.3.3 of the Registration Document).

In addition to the above, the following consequences of the health crisis linked to the Covid-19 pandemic can be considered and contribute to postponing deadlines and increasing the cost of the programme of preclinical and clinical studies on the Artus, Kalios and Epygon medical devices:

- delays in obtaining authorisations from the administrative authorities and regulatory bodies (local authorities, ethics committees, etc.) or in interactions with other bodies and third parties required to launch the preclinical and clinical trials planned by the Group;
- delays in receiving supplies and equipment for the production of medical devices;
- delays or difficulties in launching clinical trials, including difficulties in recruiting and training investigators and clinical site staff;

- diversion of healthcare resources from the conduct of clinical trials, of hospital staff supporting the conduct of these clinical trials;
- interruption of key clinical trial activities, such as monitoring of clinical trial sites, due to restrictions on travel or movement imposed or recommended by federal or state authorities, employers or others;
- the interruption of the follow-up of certain patients participating in the clinical studies, due to the lack of access to the study centres for medical visits, resulting in the inability to generate new clinical data or affecting the reliability of the data generated;
- changes in local regulations due to the measures taken with regard to the Covid-19 pandemic, which could require the Group to modify the terms of its clinical trials, which could lead to unforeseen costs or even the interruption of said trials.

The delays potentially caused by the Covid-19 pandemic to the Artus, Kalios and Epygon clinical programmes would de facto impact the publication dates of the data and results of these studies and all subsequent stages leading to the marketing of the Group's medical devices.

In particular, once recruited, the patients participating in these trials could suspend or end their participation at any time without having to justify it. Thus, if too many patients were to end their participation in a clinical trial, the analysis of the results of the study in question could no longer be of sufficient statistical significance or would require the inclusion of more patients which could result in a delay in the conclusions of the study concerned and an additional cost compared to the planned budget.

Finally, the regulatory authorities of the various countries in which the Group intends to market its medical devices could interpret the results differently from the Group. In any event, they would demand additional tests, at their discretion, or require additional or unexpected requirements during new trials. The outcome of these studies is therefore highly uncertain from all standpoints and the Group cannot therefore guarantee that clinical trials on the Artus, Kalios or Epygon medical devices will lead to marketable results, or that these clinical trials will be carried out within time frames that allow profitable marketing.

These risks, if they materialise, could occur in the short or medium term, as the Group is currently in the clinical phase for its three products, Kalios, Artus and Epygon:

- the Kalios European pivotal study, Optimise II, is ongoing and is due to be completed in the 2nd half of 2022 (see section 5.2.3.2 of the Registration Document) - it has been delayed by approximately 18 months compared with the Company's initial plan, firstly due to the additional time required of approximately six months for the regulatory authorisations for the clinical study to be processed in view of the regulatory changes for medical devices with the move from Directive 93/42/EEC of 14 June 1993 to Regulation (EU) 2017/745 of 5 April 2017 (see section 9.1.1 of the Registration Document) and secondly due to the reduced number of patients because of the Covid-19 pandemic, causing a delay of 12 months in the recruitment schedule;
- the European Dry Artus pilot study was launched between the 2nd and the 3rd quarters of 2021 and is to be followed immediately by a pivotal study ending in the 2nd quarter of 2022, at the same time the pivotal clinical study in the United States should start in 2022 and end in the 2nd half of 2024 (see section 5.2.2.2 of the Registration Document);
- Epygon's "First in Human" study for which the Company has obtained regulatory approvals in three countries is due to be launched during the 1st half of 2021 and end in the 3rd quarter. On the basis of the results of this feasibility study, the Company intends to launch studies in Europe and the United States between the 2nd half of 2022 and the 1st half of 2022 (see section 5.2.3.3 of the Registration Document).

The development programs for the Epygon and Artus devices have also been delayed compared to the

initial programme which involved clinical studies in Europe during 2019 and which will be launched in the 2ndhalf of 2021 for Epygon and between the 2nd and 3rd quarters of 2021 for Artus, it being specified that the Artus "First in Human" study has been duly completed. These differences can be explained by the Group's more extensive pre-clinical tests on technical reliability and the lower level of financial resources, which did not allow the rapid development anticipated.

If any of the risks described above were to materialise, or in the event of a failure or delay in completing clinical trials of a product, the marketing of the product might not be authorised or may be delayed, which would have a material adverse impact on the Group's business, outlook, development and financial position.

3.1.2. Risks related to the unsuccessful marketing of the Group's products or technology

As at the date of approval of the Registration Document, Artus, Kalios, Epygon and the Kardiozis technology have not received any authorisation, certification or, as the case may be, have not been subject to any registration with regards to their marketing or, as the case may be, their licensing to a third party. If the Group, or a third party to which the Group has granted a license for the Kardiozis technology, succeeds in obtaining a marketing authorisation, certification or registration, the Artus, Kalios, Epygon medical devices or those based on the Kardiozis technology could, however, fail to obtain the support of the medical community, healthcare prescribers and third-party payers.

This risk, if it were to materialise, could occur in the longer term, given that the marketing launch of the Group's most advanced product, Kalios, is scheduled to begin in Europe from 2023 and that, concerning the Group's two other products, Artus and Epygon, the first sales should begin in Europe in 2024 and 2025 and in the United States in 2025 and 2026 respectively (see sections 5.1.1, 5.2.2.2, 5.2.3.2 and 5.2.3.3 of the Registration Document).

The Group's development and its ability to generate revenues will depend on the degree of acceptance of the Artus, Kalios or Epygon medical devices by the market and its ability to license the Kardiozis technology, which are themselves based on several factors, including:

- the effectiveness and perceived therapeutic benefit of these medical devices and this technology by prescribers, patients or business partners;
- the absence of any occurrence of side effects or undesirable interactions;
- the ease of use of the implants;
- the cost of treatments;
- the reimbursement policies of governments and other third-party payers;
- the effective implementation of a scientific publication strategy;
- the support of opinion leaders in the various targeted indications;
- the effectiveness of the training programme for practitioners in the various targeted indications;
- the reputation of partners, if any; and
- the development of products competing with Artus, Kalios or Epygon or of a technology competing with Kardiozis thrombogenic fibres* (see section 3.1.3 of the Registration Document).

The absence of market acceptance for Artus, Kalios, Epygon and those based on the Kardiozis technology, particularly in Europe and the United States, or the absence of a license agreement for the Kardiozis technology with any of the industrial players in the cardiovascular sector could adversely affect the commercial potential and profitability of each implant and, more generally, the outlook and results of the Group.

3.1.3. Risks related to current or future competition on the products developed by the Group

The Group operates in a competitive field in which several technologies or alternative therapeutic methods are being marketed, researched and are at various stages of development. The Group competes with larger companies such as Boston Scientific ($9.9 billion in revenue in 2020, including $1.2 billion in urology and $3.9 billion in cardiology and cardiovascular), Medtronic ($28.9 billion in revenue in 2020, including 10.4 billion in cardiology and cardiovascular), Edwards Lifesciences (revenue of $4.4 billion in cardiology in 2020) and Abbott (revenue of $34.6 billion in 2020, including $11.8 billion for its medical devices division)[1], which have greater clinical experience (clinical data, experience in obtaining regulatory approvals), industrial experience (manufacturing) and commercial experience (commercial infrastructure, distribution networks, experience in product launches) and which have significantly greater material and financial resources as well as a stronger reputation. The Group cannot rule out the possibility that new players or manufacturers of implants for minimally invasive surgery* in the fields of urology, structural heart or cardiovascular may decide to make significant investments in these sectors and develop competing technologies or new therapeutic methods that could eventually gain significant market shares and restrict the marketing of the Group's medical devices (Artus, Kalios, Epygon or those based on the Kardiozis technology).

To the Group's knowledge, the market for the treatment of abdominal aortic aneurysm is the most competitive market in terms of products already marketed. It is dominated by three players (Medtronic, Gore and Cook Medical – see section 5.2.4.1 of the Registration Document), explaining the Group's strategy of seeking an industrial partner to which to license its Kardiozis technology for stent grafting. Concerning mitral insufficiency, two products implanted via the transcatheter route* are currently marketed for mitral valve repair (MitraClip from Abbott Vascular (CE Marking and FDA approval obtained in 2008 and 2013 respectively) and Pascal from Edwards Lifesciences (CE Marking obtained in 2019) - see section 5.2.3.2 of the Registration Document), there is still no product available on the market for mitral valve replacement by the transcatheter route. However a first device, the Tendyne developed by Abbott, obtained the CE marking* in 2020. Lastly, for the treatment of severe urinary incontinence, Boston Scientific's AMS 800 device, mainly authorised for men, has dominated the market for artificial urinary sphincters* since it was released on the market (see section 5.2 of the Registration Document). The version of this product currently marketed dates from 1987.

It may not be possible to market the Artus, Kalios, Epygon products or those based on Kardiozis technology before competing products arrive on the market and they may not be able to compete with products offering qualitative advantages in terms of efficacy and ease of use or/and prices likely to make them obsolete. The Group's development, ability to achieve its objectives, and its results could be significantly affected.

3.2. Regulatory and legal risks

3.2.1. Risks related to obtaining and maintaining marketing authorisations

As at the date of approval of the Registration Document, the Group's medical devices are in clinical study phase and none of them has received authorisation, certification or registration for its marketing.

In Europe and the United States as well as in many other countries, access to the medical devices market is controlled and product marketing must be authorised by a regulatory authority (see chapter 9 of the Registration Document). All requests for authorisation, certification or registration may not be granted by regulatory health authorities in a given country or geographical area, including CE marking in Europe for Artus, Kalios or Epygon and PMA procedures or 510(k) in the United States for Artus or Epygon. In such cases, the Group may not be able to market its medical devices in the country or geographical area concerned. In addition, obtaining an authorisation, certification or registration in a

[1] Financial data from the companies' annual reports for 2020

given country or a given geographic region does not systematically or immediately lead to obtaining an authorisation, certification or registration in other countries.

With the coming into force of Regulation (EU) 2017/745 of 5 April 2017, the European regulation on medical devices is moving closer to the FDA regulation in the US (see chapter 9 of the Registration Document). The European certificate continues to be issued by a notified body while in the United States registrations are issued directly by the FDA. Regulatory processes take approximately the same length of time and costs are generally higher in the United States for clinical studies due to a generally higher cost per patient.

The Group and, with regard to the Kardiozis technology, its partners, will have to demonstrate, through adequate and controlled clinical trials, that their Artus, Kalios, and Epygon implants, and Kardiozis technology are safe, effective and have a positive benefit/risk ratio (see section 3.1.1 of the Registration Document), before a marketing authorisation can be obtained.

The Group hopes to obtain CE marking for its Kalios, Artus and Epygon medical devices in the 4th quarter of 2022, the 4th quarter of 2023 and 2nd half of 2025 respectively and obtain FDA regulatory approvals for Artus and Epygon in the 2nd half of 2024 and 4th quarter of 2025 respectively (see sections 5.1.1, 5.2.2.2, 5.2.3.2 and 5.2.3.3 of the Registration Document).

A delay, which may in particular be due to the consequences of the Covid-19 pandemic failure in obtaining an authorisation, certification or registration in all or some of the Group's markets for a given product or technology could lead to losses in terms of the development costs incurred, the market value of the medical device and the related intellectual property, additional redevelopment costs and an inability to market the product on a larger or smaller scale.

In addition, although regularly obtained, an authorisation, certification or registration on all or some of the Group's markets can be suspended, particularly in case of a failure to comply with applicable regulations relating to their manufacture or marketing. The Group's failure to comply with the applicable regulations in a given territory may expose the Group to administrative or legal sanctions, the withdrawal of its marketing authorisations, the distribution of information or warning notices to the general public, the recall or withdrawal of the products concerned, a total or partial suspension of production or distribution, fines, or more generally damage to its reputation, or civil or criminal penalties.

Finally, if after an authorisation, certification or registration is obtained by the Group or its partners, the Group's products cause unacceptable side effects or side effects not detected during the clinical trial period, the authorisation, certification or the registration concerned could be withdrawn. Such an event could make it impossible to continue marketing the product in question, limit the targeted indications and thus reduce the market outlook.

The occurrence of one or more of these risks could have a significant adverse effect on the Group's business, outlook, development, and results, potentially beyond the sole territory concerned.

3.2.2. Risks related to intellectual property rights

The commercial success of the Artus, Kalios or Epygon medical devices and the Kardiozis technology, as well as the Group's viability in the medium and long term, will depend on its ability to obtain, maintain and enforce the protection of its innovations through patents, and to protect against third parties, its rights to patents (including those relating to implants and instruments), trademarks and the related applications, as well as its other intellectual property or similar rights (including its commercial secrets, business secrets and know-how) in Europe, the United States and other major markets in which the Group intends to sell its products.

The Group's innovations are currently, in whole or in part, protected by patents and patent applications owned or licensed by the Group (see section 5.3.3 of the Registration Document). The Group has 31 patent families (of which 29 are fully owned and two under exclusive license from the *Centre Hospitalier Universitaire Vaudois* (CHUV) signed with Kephalios (see section 5.3.3 of the Registration Document)). The protection of medical devices is ensured for Artus and Kalios until 2037, for Epygon until 2038 and for Kardiozis until 2041.

In addition, the Company intends to pursue its policy to protect its intellectual property by filing new patents at the time it believes the most appropriate. In particular, the Group intends to file new patent applications and applications where appropriate. Possibilities also exist to file for supplementary extension of the protection in order to obtain an extension to the period of protection of its patents beyond their initial expiration date in the United States and in other countries.

In any event, the Group is exposed to the following risks for its intellectual property rights, and the following possibilities cannot be excluded:

- the Group may not succeed in developing patentable inventions, which could substantially reduce the value and sales of its products and processes;
- the Group fails to protect its patents or other intellectual property rights;
- the Group's patent applications currently under review may not be issued by the concerned authorities or may be issued in a modified form;
- the Group may be unable to obtain a supplementary protection certificate, which could limit the period of protection of any patent granted to a Group company;
- the Group's patents may be challenged and considered invalid;
- the Group's patents may not prevent the issue of patents to third parties covering similar products or processes;
- the Group may not be able to ensure respect for the rights to its patents or other intellectual property rights;
- the Group may be exposed to demands from third parties relating to the award of licensing rights or remuneration or an injunction restricting the use of its intellectual property rights, whether or not such claims are legitimate;
- the scope of the protection granted by the Group's intellectual property rights may not be sufficient to protect it against infringement or competition or any other violation or prior control of the patented technologies held by third parties;
- the Group may face significant expenditures in trying to protect its intellectual property rights, and it cannot be guaranteed that such expenditures will ensure that the Group wins its case or satisfactory reparations for its injury;
- the Group's intellectual property rights are interpreted or granted differently depending on the country, which could reduce the protection granted;
- changes in the legal systems for the protection of intellectual property rights in a certain number of countries, which can be applicable without advance notice;
- the Group's know-how and its confidential information is unduly disclosed or exploited by third parties, in particular researchers from universities, public or private entities, subcontractors or other third-party contractors linked to the Group under collaboration, partnership or research agreements, despite the measures implemented by the Group to avoid such a risk (signature of confidentiality agreements or confidentiality clauses inserted in agreements);
- the Group's employees, co-contracting parties, subcontractors or other parties may claim property rights or demand compensation in consideration for the intellectual property in the creation of which they contributed, despite the Group's efforts to take the measures necessary

to prevent such a risk. It is specified that in the context of its contractual relations with its employees, co-contractors, its subcontractors or other parties, the Group includes clauses stating that the intellectual property created belongs to the Group.

The Group's current and future patent applications may not result in the issuance of patents, or once the patents are granted, these may be challenged, invalidated or bypassed, or may not provide effective protection against competition and third-party patents covering similar composites, products, processes, technologies, results or activities. The lack of sufficiently extended protection, the invalidation or bypass of patents could have negative effects on the Group.

The growth of the minimally invasive surgical medical device industry and the correlated increase in the number of patents issued increase the risk that Artus, Kalios, Epygon or Kardiozis's technology may constitute infringement, or that third parties may consider them an infringement, to their intellectual property rights in certain jurisdictions:

- the Group's products, processes, technologies, results or activities could infringe or violate patents or other intellectual property rights belonging to third parties;
- third parties may have been the first inventors of the products, or the first to file patent applications for inventions also covered by the Group's own patent applications (in effect, the Group cannot be certain it is the first to design an invention and file a patent application, given the fact that the publication of patent applications is differed, in most countries, by 18 months after an application is filed);
- third-party holders of intellectual property rights may not grant a license to a Group company if it appears that one of the products, processes, technologies, results or activities of the Group violates the rights of such third parties;
- third parties could bring legal action against the Group on the basis of an intellectual property right, even when such actions are malicious or without foundation;
- trademark rights or other prior intellectual property rights may belong to a third party and could form the basis of an infringement action against the Group or an action to restrict or prevent the Group's use of its trademarks, domain names or other similar rights; and
- that the Group's domain names will be the target by a third party with prior rights (for example, trademark rights), of a Uniform Dispute Resolution Policy (UDRP) or similar proceeding or an action for infringement.

In this respect, by summons of 12 June 2019, the company Implantica Marketing Limited brought an action for patent infringement before the Paris Court of Justice against the Company and MyoPowers. The Company claims that the development of the Artus medical device would reproduce certain claims made by the French part of a European patent belonging to it, and seeks compensation for the damage it claims to have suffered. It therefore seeks that the Company and MyoPowers be ordered to pay the sum of €2,000,000 in provisional damages and €500,000 in respect of its alleged moral damage. The Company and MyoPowers have made several claims, notably to demonstrate the invalidity of the patent invoked by Implantica Marketing Limited and, consequently, the absence of infringement. In this regard, in the decision of 4 June 2020 ruling on an application for a provisional ban by Implantica Marketing Limited, the court admitted that there were serious doubts about the validity of the patent invoked, which also expired on 8 February 2021. Consequently, in its decision dated 4 June 2020, the court rejected Implantica Marketing Limited's application seeking an interim ban on the development of the Artus medical device pending a decision on the merits in the patent infringement case. Implantica was ordered to pay €50,000which has been paid. Since the decision of 4 June 2020, the proceedings on the merits have resumed: Implantica Marketing Limited reiterated its claims for damages mentioned above in submissions dated 11 January 2021; the Company and MyoPowers responded via submissions dated 10 March 2021. The closing arguments are expected to be scheduled for June 2021. In light of these events, the Group did not make provisions for risks and contingencies respect of this dispute.

Any action against the Group related to its intellectual property rights or the rights of third parties, whatever the outcome, could generate substantial costs, require significant mobilisation by the Group's

executive team to the detriment of the operational development, compromise the Group's reputation and, therefore, impact its financial position. Some competitors, with more resources than the Group, may be better equipped to bear the costs of such proceedings and take one or more actions as described above with the aim of obtaining substantial advantages over the Group on the market in which these companies compete with the Group.

Given the importance of intellectual property rights for the business and viability of the Group, the materialisation of one or more of the risks listed above could have a significant negative impact on the outlook for marketing one or more of the Group's medical devices in question as well as the Group's financial position.

3.2.3. Risks related to pricing and changes in reimbursement policies for medical devices

Once the necessary approvals have been obtained, the Group's commercial performance will depend, in part, on its ability to set the selling price of Artus, Kalios and Epygon, whether the price is paid by patients or by third-party payers such as insurance companies, competent public entities and social organisations.

The conditions for setting the selling price and the reimbursement level of the medical devices are decided by the competent public commissions and entities, as well as by social security organisations or private insurers.

Affluent Medical envisages average selling prices to end customers which could be between €8,000 and €10,000 for Artus (see section 5.2.2.2 of the Registration Document), around €4,000 for Kalios (see section 5.2.3.2 of the Registration Document) and between €35,000 and €50,000 for Epygon (see section 5.2.3.3 of the Registration Document).

The reimbursable nature of a medical device affects the choice of healthcare institutions regarding the products they buy and the prices they are willing to pay. The Group's ability to reach acceptable price and reimbursement levels, a decrease in reimbursement by third-party payers for a medical device or a decision not to cover a device could reduce demand for this product by healthcare institutions and could have a significant impact on its ability to market its products successfully and, as a result, its ability to generate revenue and be profitable.

In addition, reimbursement policies vary from one country to another. The Company cannot be certain it will benefit from optimal reimbursement in Europe, the United States or in the other markets in which the Company could sell its products, which could have a major impact on the marketing of new products in the countries concerned. There is no guarantee that a country that has implemented price controls or reimbursement caps for the Group's medical devices will authorise favourable pricing and reimbursement arrangements for any one of its products in development, notably in the context of legislative or administrative reforms of the reimbursement systems of the countries where the Group intends to market its products.

Thus, if a delay in the price negotiation procedure results in a significant marketing delay, if a Group product does not obtain reimbursement or the level of reimbursement is not appropriate, or if the price and reimbursement level accepted for Artus, Kalios or Epygon are subsequently decreased, this could have a material adverse effect on the Group's ability to achieve its objectives, its development, and results.

3.2.4. Risks to the Group's product liability

The Group could be exposed to liability risks, in particular liability for defective products, during clinical development and, in the future, during the manufacture and marketing of its various implantable medical devices in class III, Artus in urology and Kalios or Epygon in structural heart.

Criminal complaints or legal action could be filed or initiated against the Group by users (patients, practitioners, researchers and other health or research professionals), the regulatory authorities, distributors and any other third party using or marketing the Group's products in the markets in question. For example, it could be held liable by patients participating in the clinical trials because of unexpected side effects. In addition, the Group could incur liability because of undetected side effects caused by the interaction of one of the Group's products with other products after said product is placed on the market.

These actions may also include liability for the Group resulting from actions by its partners, licensees, co-contractors or subcontractors, over which the Group exerts little or no control.

For the American market, understanding of the medical risk is complex and specific risk coverage is required. The issue of "product liability" in the United States is a crucial one in a market that is conducive to costly litigation, which, in particular, may take the form of collective action (Class actions), under the terms of which a group of patients could decide to bring legal action against the Group because of the damages (bodily, moral, financial, etc.) that have been caused by the use of one of the devices marketed by the Group, all the more so for a medical device that is less critical for the lives of patients, such as Artus for the treatment of severe urinary incontinence.

The Group believes that its current insurance coverage, at its stage of development, is sufficient to defend against liability actions that may be brought against it (see section 3.4.5 of the Registration Document) or to handle an exceptional situation.

If the Group is held liable because of the products, its reputation and the marketing of its products could be seriously affected, which could have a material negative effect on the Group and its outlook, and, where applicable, its financial position.

3.3. Risks related to the Group's organisation and operations

3.3.1. Risks related to the industrialisation of the Group's medical devices

3.3.1.1. Risks related to the manufacturing processes of the Group's medical devices

The Group internalises part of the process to manufacture its products for two of its innovative medical devices, Epygon and Artus, for the purposes of clinical studies and intends to continue this internalisation when they enter the marketing phase. The manufacturing process for the Kalios ring is almost totally outsourced to third parties.

All the Group's products must comply with the requirements related to the applicable manufacturing standards, particularly in terms of quality management. The Group might not, however, be able to meet the requirements attached to these manufacturing standards. If this were the case, it could affect the Group's quality system and its ability to market its medical devices.

The manufacturing process for the products depends on the Group's capacity to maintain an adequate supply level of raw materials. The Group's supply of any of the raw materials and equipment required for its activities could be reduced or interrupted, particularly in the event of a default by one of its suppliers or an increase in supply costs. In such case, the Group may not be able to find other suppliers of specific raw materials and quality materials, in appropriate volumes and at an acceptable cost (see sections 3.3.2.1 and 3.3.2.2 of the Registration Document). The Group may not be able to continue to develop, produce and market its products within the time frames it has set and in a competitive manner. In addition, such materials are subject to stringent manufacturing requirements and rigorous testing. Delays in the completion and validation of the facilities and manufacturing processes of these materials at the Group's suppliers, possibly due to the consequences of the Covid-19 pandemic, which could disrupt the planned operational organisation (delays in receiving supplies and equipment, travel restrictions, etc.), could also affect its ability to produce and market its products profitably and within

a reasonable time frame. In the context of the Covid-19 pandemic, the Group holds regular discussions with its partners, service providers and suppliers to limit these risks.

The Group's procurement policy will have to be reviewed during the industrialisation stage, notably with the signature of agreements aimed at securing supplies in the long-term from several suppliers, and the Group's inability to secure its long-term supplies during the industrialisation which may, moreover, constitute a risk.

If a disruption in the Group's supply of raw materials and materials necessary for the manufacture of its products were to occur, the production of the Group's products could be slowed to a greater or less extent, or even be completely stopped.

In addition, the manufacture of the Group's products, whether partly carried out internally or subcontracted, is particularly complex and demanding. The entire manufacturing process of the Group's products, in accordance with designs patented by the Group or the know-how developed by the Group's employees for products partly manufactured within the Group's structures, Artus in the premises of MyoPowers in Besançon and Epygon at the premises of Epygon Italie in Colleretto, thus falls within the scope of application of the certificates/authorisations obtained by the Group to obtain the CE marking and/or FDA approval*.

In this respect, the Group uses clean rooms for its manufacturing activities, one located in Besançon for the production of Artus medical devices, the other in Colleretto for the production of Epygon medical devices. These are rooms in which the concentration of particles suspended in the air is controlled and which are constructed and used in order to minimise the introduction, production and retention of the particles inside these rooms and in which other parameters, such as temperature, humidity and pressure are controlled. As a result, if there is a change in the parameters of these clean rooms, and if there is a risk of contamination, the quality of the production could be placed at risk, which could generate additional costs and affect the Group's ability to develop and profitably market its products. The necessary increase in the production capacity of its two clean rooms, once marketing authorisations have been obtained for Artus and Epygon, could also lead to a risk of delay in marketing the two products.

The occurrence of one or more of these risks could have a material adverse impact on the Group, its business, and, where applicable, its financial position and results.

3.3.1.2. Risks related to a potential failure of the industrial and product quality control processes of the Group

Post-market monitoring of medical devices (the "**Materiovigilance**") provided for by the national regulations of the markets in which the Group intends to market its products, aims to prevent the (re) occurrence of incidents and risks of serious incidents which would put the medical devices into question, by taking the appropriate preventive and/or corrective measures. At the time of a declaration of Materiovigilance on a product, an investigation is then systematically conducted in order to determine the origin of the incident. All such incidents and actions are reported to the competent national authority and, as applicable, may be communicated to the public, which could result in a reputational risk for the Group.

Identified non-conformities may also be observed and communicated thanks to the controls performed by independent laboratories through the design and manufacturing process, as well as in the context of the controls before release of a medical device, as well as during audits (internal or external), or regulatory inspections, or even by the customer.

In accordance with regulatory requirements, the Group's quality systems, and those of MyoPowers, Kephalios and Epygon, which are certified to ISO 13485:2016, provide internal or external procedures

to detect any case of non-conformity of the products with regulations and other applicable standards (see section 5.3.4 of the Registration Document).

The Group's subcontractors may not comply with the applicable regulations. The competent authority of the certification or follow-up audits, or the regulatory authorities, during an inspection or during a regulatory control, may identify violations of the regulations or applicable standards and demand that they be corrected by performing corrective actions that could interrupt the manufacture and supply of the Group's products. The suspension, total shutdown or total or partial ban on the activities of the Group and/or its subcontractors could significantly affect the Group's business, financial position, results and reputation. Moreover, the Group is liable in its position as a manufacturer for injuries caused by its defective products. Although an action seeking indemnity remains possible against its defaulting subcontractors, on a contractual basis, a liability claim against the Group could prove to be particularly harmful to the Group, mainly in terms of public recognition.

In the event of non-conformity of products with regulatory and quality control standards, sanctions could be imposed on the Group. Those sanctions could include fines, injunctions, damages, a block on production, the suspension or withdrawal of the authorisations and certificates obtained, the revoking of licenses, the seizure or recall of its products, operational restrictions or restrictions on use and criminal prosecution; all such measures could have an adverse impact on the Group's business, outlook, and its financial position.

3.3.2. Risks related to third-parties

3.3.2.1. Risks related to failures or defects of the Group's suppliers or subcontractors

The choice and management of subcontractors are key factors in the Group's development. In order to limit any risk of defects in, or non-compliance of all or part of the subcontracted components of the Artus, Kalios or Epygon medical devices, the Group has established rigorous procedures with its manufacturing subcontractors, including validation of the manufacturing process, quality control, inspection, traceability and non-compliance.

However, if products manufactured by suppliers fail to comply with the regulations or standards in force, sanctions could be levied on the Group. Those sanctions could include fines, injunctions, damages, the refusal by regulatory bodies to allow future clinical trials, the suspension or withdrawal of the authorisations and certificates obtained, the seizure or recall of its products, operational restrictions or restrictions on use and criminal prosecution; all such measures could have a very serious adverse impact on the Group's operations.

In the event of the failure or bankruptcy of or a shutdown at its production and research and development subcontractors, which could be due in particular to the restrictions imposed as a result of the Covid-19 pandemic such as lockdown or travel restrictions, the Group may not be able to quickly sign new contracts with other service providers under commercially acceptable terms and therefore may no longer be able to implement preclinical and clinical trials, develop, test, manufacture and market its products, within expected time frames and at an acceptable cost. The Group holds regular discussions with its partners, service providers and suppliers in the current context related to the Covid-19 pandemic to plan for any risk of delay or interruption of operations.

Moreover, subcontractors may not wish to commit beyond the production runs for clinical studies. The materialisation of one of the risks listed above could have a material adverse impact on the business, its financial position, or the development of the Group.

3.3.2.2. Risks related to the Group's dependence on certain suppliers or subcontractors

The Group is dependent on third parties in the context of the process to produce its various medical devices. It subcontracts the manufacture of sub-assemblies, intermediate products and finished products

to around fifteen subcontractors. These directly manage their sources of raw materials and components.

Given the highly innovative nature of the Artus, Kalios and Epygon medical devices, the high level of specialisation of the suppliers and subcontractors, and the regulatory requirements, the number of qualified suppliers or subcontractors is relatively limited. The replacement of one of them would require the Group to identify new qualified suppliers or subcontractors and there can be no assurance that this would be successful.

Nevertheless, if the Group were to encounter difficulties in the supply of these specific raw materials, possibly due to the consequences of the restrictions imposed in certain countries by the Covid-19 pandemic, if it were unable to maintain its supply agreements in force or to sign new agreements in the future, its business, outlook, ability to achieve its objectives, financial position and/or its development could be significantly affected.

The Group has identified as essential critical raw materials to be procured: the bovine pericardium, used for the Epygon product, for which the Group is only supplied by a single supplier as at the date of approval of the Registration Document. Other raw materials such as biomaterials – fabrics and polymers – are not considered critical in terms of availability on the market. The stents used for the Epygon and Kalios products are also critical in terms of supply and are currently limited to a single supplier.In addition, the Group is dependent on subcontractors for the performance of its preclinical and clinical trials, for the performance of controls and tests on its products, and for the manufacture and assembly of components of some medical devices of the Group. A portion of the preclinical tests on the products is entrusted to shared subcontractors, in particular for the Epygon and Kalios products and the Kardiozis technology, notably in the context of animal tests, tests of biocompatibility and resistance on the implants. In this respect, the Group is planning to develop more of such synergies, particularly in the context of pivotal studies for Kalios and Epygon with a view to obtaining the CE marking for these two medical devices for the treatment of mitral insufficiency.

Dependence on subcontractors leads to additional risks that the Group would not be exposed to if it were responsible for all the manufacturing phases of the various components of its products, namely:

- a violation by these third parties of their agreements with the Group;
- the termination or non-renewal of these agreements for reasons beyond the control of the Group; and
- a more difficult reactivity to be implemented given the contingencies of manufacture or supply.

As the Group is dependent on its suppliers and subcontractors, it may not be able to negotiate competitive prices with them, which would compromise its profitability. The Group is indirectly exposed to the risks of fluctuations in prices, particularly with regard to stents and bovine pericardium used for Kalios and Epygon medical devices, as well as the costs of subcontracting necessary for the manufacture of medical device components. In particular, in this sector, the regulatory standards imposed on suppliers as well as the availability of products may lead to fluctuations in the prices of materials and components that do not allow supply prices to be maintained for the Group and potentially an adjustment of its own prices to maintain its level of profitability.

The materialisation of one of the risks listed above could have a material adverse impact on the business, its financial position, or the development of the Group.

3.3.3. Risks related to the implementation of the Group's marketing strategy

As at the date of approval of the Registration Document, the Group does not have the required authorisations or the internal organisation and infrastructure necessary for selling (marketing, direct and indirect sales via the creation of a distribution network) of its Artus, Kalios and Epygon medical devices.

As part of the implementation of its commercial strategy, the Group will be required to set up a dual direct sales organisation in certain European countries (notably in Germany, France, Italy and the United Kingdom) with its own infrastructure for the marketing of its Artus, Kalios and Epygon medical devices as well as indirect sales through the creation of a distribution network and partners in other countries or key areas for the Group, such as the United States, Southern Europe (Spain / Portugal where the Group has already signed an exclusive marketing agreement with Palex Medical, a recognised distributor in the fields of urology and cardiology in the Iberian peninsula, thus promoting the conduct of clinical trials in Spain.), Northern Europe and China where the Group has formed joint ventures with Shanghai Zuquan Investment Management Company Limited (see section 5.3.6 of the Registration Document). The Group will also have to set up business development, marketing and compliance teams, which will support the sales teams and interact with the distributors and partners selected by the Group. With regard to Kardiozis, the Company intends to license this technology to one of the players already involved in the cardiovascular sector for the treatment of abdominal aortic aneurysm.

Direct marketing will therefore require an adaptation of the Group's structure and the recruitment of qualified personnel, leading to an increase in structural costs. Any delay or significant difficulty in the implementation of such tools and organisations and in the recruitment and training of dedicated teams could have a significant negative impact on the Group, its outlook and its ability to achieve its objectives, as well as its financial position, and/or results.

As part of the indirect sales strategy, the Group will have to rely on new partners with the necessary resources and means as well as the experience required to market innovative medical devices for various medical sectors (urology, structural heart, cardiovascular). In this context, the Group could be confronted with risks, the occurrence of which will depend in whole or in part on its partners (see section 3.3.4 below).

Moreover, such distributors might not accomplish their task within the deadlines set or meet their commitment, particularly in terms of regulations and Materiovigilance. As a result, a failure by a distributor that does not transmit the information on incidents or accidents that have occurred or could potentially occur, would compromise the Materiovigilance procedures established by the Group, which could engage the Group's contractual and civil liability.

Finally, a wrongful breach of such contracts, at the initiative of either of the parties, could generate substantial damages and have a general negative effect on the distribution of the Group's products, which would have a negative impact on its financial position.

3.3.4. Risks related to the maintenance and performance of collaboration agreements signed with existing or future partners

The Group relies on and intends to continue to rely on strategic partnerships to ensure the development and marketing of its products in the targeted geographical markets.

In this context, Epygon and MyoPowers have entered into a partnership agreement with Shanghai Zuquan Investment Management Company Limited to ensure the development and marketing of their products in China (see section 20.1 of the Registration Document).

With respect to the American market, the Group could enter into a partnership with a leading local player for the clinical and commercial development of Artus. Depending on the opportunities, the Group could also enter into a similar partnership for the development of Kalios and/or Epygon in the United States.

The development of its medical devices in these markets, in the indications concerned, is thus based on the willingness of these industrial partners to collaborate with the Group to dedicate to their research and development programmes the human, material and financial resources that will allow the continuation and successful completion of the clinical trials required by regulations. The Group's

current partners could experience operational or economic difficulties which would put into question the continuation of ongoing programmes with the Group. These partners could also fail to implement all the resources necessary to obtain the results expected under the agreements signed with the Group. Budget restrictions within these partners or the priority given to other development programs could delay the development and marketing of the products in question.

The Group can not rule out the possibility that some of the partners with which it is currently working may reduce or interrupt their relations with it. A conflict of interest could arise between some of their activities and those they dedicate to the Group, depriving the Group of their expertise. In particular, the Group's partners may seek to implement a commercial activity using a technology that competes with that of the Group. This would cause a loss of know-how and financial resources for the Group, and could even result in the disclosure of important confidential information on the Group's research and development process even when the partners in question were contractually bound by an obligation of confidentiality to the Group.

Therefore, if the Group did not achieve its objectives, or if one or more of these agreements were terminated or not renewed, for any reason, this could have a significant adverse impact on the Group's business, outlook, and results.

The Group also aims to find new partners and establish new partnership agreements for the development and marketing of some of its products, in particular with regards to a license agreement for its Kardiozis technology. If the Group were unable to enter into such agreements, or to conclude them under favourable economic terms, it would then have to find the necessary financial and material resources and develop its own internal expertise for the development, production and marketing of the medical devices concerned or, failing that, may have to interrupt the development of certain programmes. In addition, its new partners may not comply with the quality standards in force in their respective fields of activity or encounter difficulties that may delay or even restrict the marketing of the products concerned. Even if the Group succeeded in establishing said partnerships, they could be terminated or not renewed by its partners. Such partners might not comply with their agreements, in whole or in part, or have disputes with the Group about these agreements or the implementation strategy applied to them, or suffer regulatory, financial or operational obstacles to their activity, which would have the result of delaying or ending the development of the programmes in progress or reducing the sales volumes of the Group's products.

The inability of the Group to set up new fruitful partnerships or to maintain them could thus have a significant negative effect on the Group, its business, and its development.

3.3.5. Risks related to dependence on qualified personnel and key executives

The Group's success depends heavily on the expertise and involvement of its executive team as well as the technical expertise and know-how of its production and scientific staff, in particular with regard to the production of the valves, the assembly of the Artus artificial urinary sphincter and the design of the software part of this device.

The development and implementation of the strategy is highly dependent on the Group's ability to retain its qualified personnel, capable of mastering cutting-edge techniques needed to produce various medical devices, and key executives. The temporary or definitive unavailability of these persons would deprive the Group of their non-patented know-how, their experience and their technical abilities, which the Group may not be able to replace.

In addition, in the future, the Group will need to recruit new senior executives and qualified personnel to assist in and support the development of its operations during the clinical, industrial and commercial phases. The Group competes with other companies, research organisations and academic institutions to recruit and retain highly qualified scientific, technical, commercial, marketing and management

personnel. Faced with this competition, the Group could be unable to attract and retain them under conditions acceptable from an economic standpoint.

Although the Group has implemented a policy to retain its key personnel (see section 19.1.4 of the Registration Document), difficulties in retaining key personnel and/or attracting new talent could slow down the deployment of its multi-product strategy and have a significant adverse effect on its business, its medium- and long-term prospects, its financial position and its results and/or its development.

3.4. Financial risks

3.4.1. Liquidity risk

The Group has carried out a specific review of its liquidity risk and estimates that, as of the date of approval of the Registration Document, it would be able to finance its activities until the end of May 2021, given its current available cash resources. As part of the proposed listing of its shares on the regulated Euronext Paris market, the Company intends to carry out a capital increase in order to finance its activities beyond the above-mentioned deadline.

On the basis of the consolidated financial statements, as at 31 December 2020, the Group's cash and cash equivalents amounted to €5,650 thousand. The operating cash flows over financial year 2020 totalled €8,936 thousand.

The total gross amount of financial debt and net financial debt of the Group as of 31 December 2020, taking into account repayable advances and innovation loans under Bpifrance aid contracts and loans guaranteed by the State taken out by the Group amounted to €22,131 thousand and €16,481 thousand respectively (see to Notes 11 and 8 to the Group consolidated financial statements under IFRS for the financial year ended on 31 December 2020 presented in section 18.1.1.1 of the Registration Document):

(Amounts in thousands of euros)	Carrying amount at 31/12/2020
Lease liabilities	957
Repayable advances	9,489
Loans guaranteed by the State	2,155
Kreos bond loan	5,483
OCA Head Leader bond loan	2,684
Derivative liabilities (mainly linked to the Head Leader	1,351
Other loans and liabilities	10
Bank overdrafts	2
Total gross financial debt	**22,131**
Cash and cash equivalents	5,650
Total net financial debt	**16,481**

The Group should not be exposed to an immediate liquidity risk on the Bpifrance subsidy agreements and on the loans guaranteed by the State insofar as the latter only provide for the implementation of a mandatory early repayment clause in the event of judicial liquidation, amicable liquidation, dissolution or cessation of activity.

On 29 October 2018, the Company entered into a venture loan agreement with Kreos Capital V in the form of non-convertible bonds in several tranches totalling a maximum of €8 million (see section 18.1.1, note 11.3.1). As at 31 December 2020, the outstanding principal amounted to €5.5 million (see sections 8.1.3 and 20.4 of the Registration Document for a detailed description of the venture loan agreement). This loan repayable monthly matures in November 2022. On 25 February 2021, Head Leader Limited notified the Company of its request for redemption of the OCAs in the event of the

listing of the Company's shares on the regulated Euronext Paris market. This reimbursement totalling approximately €4.1 million (including accrued interest) will be made within 60 business days of the completion of the admission of the Company's shares to trading on the regulated Euronext Paris market (see section 19.1.4.3).

Kreos/Head Leader pledges

Kreos benefits from first-ranking security interests on the Company's main tangible and intangible assets, in particular on its goodwill, the intellectual property rights relating to its main medical devices, as well as a pledge over the Company's bank accounts and receivables until all non-convertible bonds are repaid in November 2022. Head Leader benefits from first-ranking security interests on the intellectual property rights on the Artus and Epygon medical devices in China until repayment of the convertible bonds as mentioned above. In the event of the failure to repay the Kreos non-convertible bonds and the Head Leader convertible bonds, the Group could lose its rights to its tangible and intangible assets.

If the Company's shares are admitted to trading on the regulated Euronext Paris market, the schedule for the Company's debt and interest repayments under its main financing agreements should be as follows in the financial years 2021 and 2022:

	2021	2022
OCA Head Leader bond loan	€ 4.1m	-
Kreos bond loan	€ 3.9m	€ 2.3m
Bpifrance innovation loan	€ 0.0m	€ 0.1m
Repayable advances (Piave Artus, Mivana Project)	€ 0.0m	€ 0.0m
Loan guaranteed by the State	€ 0.0m	€ 0.4m
TOTAL	**€ 8.0m**	**€ 2.8m**

The audit report by the Company's statutory auditors on the Group's consolidated financial statements prepared in accordance with IFRS for the financial years ended 31 December 2019 and 2020 presented in section 18.3.1 of the Registration Document features the following observation: "*Without calling into question the opinion expressed above, we draw your attention to Note 2.1 "Principles applied to the preparation of the financial statements" to the consolidated financial statements, which specifies the assumptions underlying the application of the going concern principle for the closing of the consolidated financial statements and the measures implemented by management to ensure the financing of the company*".

For the period ends 31 December 2019 and 31 December 2020, the Company has obtained a financial support letter from the primary shareholders of the company managed by Truffle Capital for the financial years 2020 and 2021 respectively.

The Company's financial statements at 31 December 2020 were prepared on a going concern basis (see note 2.1 ongoing concerns and note 25 on liquidity risk to the consolidated financial statements of the Group under IFRS for the financial year ended on 31 December 2020 presented in section 18.1.1.1 of the Registration Document) with regard to the data and assumptions below and the measures implemented by the Company's management to ensure the financing of the company beyond May 2021. As such, they do not include any adjustments related to the amount or classification of assets and liabilities that might be necessary if the Company is not able to continue its activities on a going concern basis. The Board of Directors has decided to adopt the following measures to ensure the financing of the Company beyond its liquidity horizon:

- preparation of the Registration Document for the needs of a capital increase as part of the planned admission of its shares to trading on the regulated Euronext Paris market;
- alternatively, the Company could finance its future cash requirements through a combination of public or private capital increases, bank or bond financing, collaboration agreements, licenses and development or other forms of non-dilutive financing.

At the date of closing of the financial statements, the Board of Directors considers that it has reasonable assurance that it will find adequate financing. However, the Company cannot guarantee that it will succeed in obtaining this. The continuation of the activity is therefore conditional on the success of the Company's IPO and the search for investors in the event that the project is postponed.

The Company believes that it should have to continue to record losses in the medium term.Additional financing resources will therefore be necessary. A capital increase in the context of the admission of the Company's shares to trading on the regulated Euronext Paris market is therefore planned to cover medium-term cash requirements. If market conditions do not permit the Group to list its shares on the regulated Euronext Paris market, the Company is considering other funding alternatives.

In addition, the development of the Group's products and the continuation of its clinical development programmes will continue to generate significant financing needs in the future. The Group may be unable to self-finance its growth, which would lead it to search for other funding sources, particularly via capital increases.

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

- costs related to potential demands to modify studies or increase the number of patients;
- costs to prepare, file, defend and maintain its patents and other intellectual property rights; and
- higher costs and longer times than the costs and times anticipated for the different development phases and obtaining the regulatory marketing authorisations for its products and access to reimbursement, including the time to prepare application files with the competent authorities.

The Group may not be able to raise additional capital when it needs it, or under favourable financial conditions. The Group may then have to:

- delay, reduce or eliminate the number and scope of its research, pre-clinical and clinical trial programs;
- grant licenses for its technologies to partners or third parties, and/or sign new collaboration agreements under conditions less favourable for the Group than those that the Group might have obtained in a different context.

Debt financing, to the extent that it is available, could also include stringent commitments for the Group (such as the existing pledges of intellectual property as collateral for Kreos Capital and Head Leader bond financings – see section 8.1.3 of the Registration Document) and could generate additional financial expenses or the loss of pledged assets.

The materialisation of one or more of these risks could have a material adverse impact on the Group, its ability to achieve its objectives, and its financial position.

3.4.2. Risks related to the default or increase in insurance coverage costs

The Group is exposed to a significant liability risk in the context of the development, manufacture and potential marketing of its medical devices. Among the other potential risks, the occurrence of side effects or unexpected interactions that could result in legal action, and disputes concerning its

intellectual property could make it liable for damages that are not covered or exceed the coverage amounts provided by its insurance policies. The Group has implemented a policy to cover its primary insurable risks with amounts of coverage it believes are appropriate to the nature of its operations. It cannot guarantee that it will always be able to maintain, and if necessary obtain, insurance coverage at an acceptable cost, which could lead it to assume a higher level of risk and/or subscribe to insurance policies at a higher cost, particularly as it expands its activities. If the Group were unable to maintain such coverage, this could have a material negative effect on its activity, outlook, its ability to achieve its objectives, its credibility or reputation, its ability to raise new funds, its financial position, cash or operating income.

The main insurance policies put in place by the Group are as follows:

- a policy covering the civil liability of corporate officers subscribed by Affluent Medical with AIG with a total amount of cover of €7.5 million per year;
- civil liability for operations:

Group entity	Type of insurance	Insurer	Principal terms of the insurance cover	Term/End of validity date
Kephalios	Civil liability for operations	CHUBB	€5,000,000 per claim of which: - Inexcusable misconduct: €1,000,000 per victim of which a maximum of €3,000,000 per year; - material and immaterial damage: €1,500,000 per claim, including: o non-consequential immaterial damage: €200,000 per claim o damage to entrusted property: €50,000 per claim; - accidental damage to the environment: €400,000 per year.	Annual renewal
MyoPowers	Civil liability for operations	Generali	€8,000,000 per claim of which: - Inexcusable misconduct/Accidents at work/ Occupational diseases: €1,500,000 per year; - tangible and intangible damage: €1,500,000 per claim; - accidental damage to the environment: €750,000 per year.	Annual renewal
Epygon Italie	Civil liability for operations	Generali	- €1,000,000 per claim; - €1,000,000 per victim.	22 February 2022

- an insurance for business travel subscribed by Affluent Medical with AIG and including an overall amount of cover of €5 million per claim in the event of bodily injury following an accident with a maximum of €500 thousand per insured person (employee, non-salaried executive or director);

- professional multi-risk insurance for the offices of Affluent Medical in Aix-en-Provence as well as those of MyoPowers in Besançon and Epygon Italie in Colleretto:

Group entity	Type of insurance	Insurer	Principal terms of the insurance cover	Term/End of validity date
Kephalios	Professional multi-risk for the Aix-en-Provence site	Allianz	- Fire, similar events/Water damage/Storm: o Premises - Content: €200,000 /Goods: €40,000 - Theft & Vandalism: o Premises - Content: €100,000 /Goods: €40,000 - Electrical damage: €70,000 - Breakdown of electronic equipment: €50,000 - Additional operating costs: €100,000	Annual renewal

Group entity	Type of insurance	Insurer	Principal terms of the insurance cover	Term/End of validity date
MyoPowers	Professional multi-risk for the Besançon site	Generali	- Fire, similar events and vandalism, collapse, natural disasters, climatic events, terrorist attacks or acts of terrorism: o Premises: Unlimited - Content: €350,000 - Theft: property damage (unlimited)/contents (€50,000) - Electrical breakdown and damage to IT and operating equipment: €33,300 - Necessary costs for business continuity: €60,000	Annual renewal
Epygon Italie	Professional multi-risk for the Colleretto site	Generali	- Fire: Equipment (€500,000)/Recourse by third parties (€1,00,000)/rental risk (€35,000)	27 February 2022

- various insurance policies relating to the Group's clinical trials:

Group entity	Type of insurance	Insurer	Principal terms of the insurance cover	Term/End of validity date
Epygon	Insurance relating to the Minerva clinical trial of the Epygon medical device in: Austria, Spain and Italy	HBI Global	- Austria: o €3,500,000 for clinical studies o €500,000 per patient - Spain: o €2,500,000 per year o €250,000 per patient per year - Italy: o €5,000,000 for clinical studies o €1,000,000 per patient	1 January 2026 31 March 2026 31 March 2026
Kephalios	Insurance for the Optimise II clinical study of the Kalios medical device in: Austria, Germany, Switzerland and Italy	HBI Global	- Austria: o €3,500,000 for clinical studies o €500,000 per patient	1 January 2025
		CNA Hardy	- Germany: o €5,000 per year o €500,000 per patient per year - Switzerland: o CHF 10,000,000 for the clinical study o CHF 1,000 per patient - Italy: o €5,000,000 for clinical studies o €1,000,000 per patient	31 December 2024 31 December 2024 31 December 2024
MyoPowers	Insurance for the Dry clinical study of the Artus medical device in Spain and the Czech Republic	HBI Global	- Spain: o €2,500,000 per year o €250,000 per patient per year - Czech Republic: o CZK 60,000,000 for the clinical study o CZK 6,000,000 per patient	30 September 2032 30 September 2032

3.4.3. Dilution risk

Since its creation, the Company has issued and allocated convertible bonds (CBs), series of share subscription warrants (BSAs) and founders' share warrants (BSPCEs) (see section 19.1.4 of the Registration Document). On the date of approval of the Registration Document, the full exercise of all instruments giving access to the share capital (including BSA-2018 Kreos) would allow the issue and subscription of 3,572,280 new ordinary shares, thus generating a dilution equivalent to 18.97% of the share capital on a fully diluted basis, excluding convertible bonds that will be redeemed in cash in the event of the listing of the Company's shares for trading on the regulated Euronext Paris market (see section 19.1.4.3 of the Registration Document). The exercise of a major part of the BSAs and BSPCEs is conditional, on the one hand, on the holders remaining within the Group with vesting periods and, on the other hand, on the achievement of clinical, regulatory or financial objectives. The number of new shares issued through the exercise of BSA-2018 Kreos share subscription warrants could reach a maximum of 400,000 new shares.

In the context of its policy to motivate and incentivise its executives and employees, and in order to attract additional talent, the Company could also in the future issue or allocate shares or new financial instruments giving rights to capital that could result in additional, potentially significant, dilution for current and future shareholders of the Company and weigh on the future stock market price of the Company's shares.

In the event that the Group raises capital through the issuance of new shares, in particular through the implementation of the delegations of authority granted by the General Meeting to the Board of Directors (see section 19.1.5 of the Registration Document), the shareholding of its shareholders could be diluted.

3.4.4. Risks related to access to public subsidies and funding

- ***Innovation loans – Bpifrance grants/repayable advances:***

The Group has obtained various grants, repayable advances and innovation loans granted by Bpifrance in the context of:

- the development of a disruptive medical device (adjustable mitral ring) to combat recurrent mitral insufficiency (Innovation Loan – Research & Development granted to Affluent Medical) for an amount of €1 million at 8 April 2020;
- the Industrial Project of the Future for the development of an artificial urinary sphincter for the treatment of severe incontinence (PIAVE Artus) granted on 21 July 2016 by Bpifrance to MyoPowers and providing for a maximum amount of €200,589 in grants and €7,795,560 in reimbursable advances depending on the achievement of key milestones;
- the Structuring Research and Development Project for Competitiveness for the development of cardiac implants (PSPC Mivana) granted on 28 September 2015 by Bpifrance to Kephalios, Epygon, MDB Texinov and the *Institut Français du Textile et de l'Habillement*, a research partner whose role is to provide know-how and technologies for textile structures and the assembly of textile components for the Epygon and Kalios membranes. This project provides for maximum grant payments of €965,382 for Kephalios and €992,009 for Epygon as well as maximum reimbursable advances of €1,049,488 for Kephalios and €3,462,598 for Epygon depending on the achievement of key milestones.

As at 31 December 2020, the Company and its Subsidiaries benefited from the following grants:

As at 31 December 2020 (in €)	Recipient entity at origin	Date obtained	Amount granted at 31 December 2020	Amount received at 31 December 2020	Amount still outstanding	Amount repaid at 31 December 2020	Amount to be repaid at 31 December 2020
R&D innovation loan	Affluent Medical	16 April 2020	€1,000,000	€1,000,000	€0	€0	€1,000,000
PIAVE Artus (Grant portion)	MyoPowers	21 July 2016	€200,589	€117,000	€83,589 (2)	-	-
PIAVE Artus (Reimbursable advances portion)			€7,795,560	€3,659,000	€4,136,560 (2)	€0	€1,000,000
PSPC Mivana (Grant portion)	Kephalios	28 September 2015	€965,382	€820,000	€145,382	-	-
	Epygon		€992,009	€833,537	€158,472	-	-
PSPC Mivana (Reimbursable advances portion)	Kephalios		€1,049,488	€892,000	€157,488	€0	€892,000(3)
	Epygon		€3,462,598	€2,318,558	€1,144,040	€0	€2,318,558 (3)
TOTAL			**€15,465,626**	**€9,640,095**	**€5,825,531**	**€0**	**€7,869,558**

(1) Repayment in 20 quarters after a deferred amortisation period of nine quarters – i.e. a repayment on a quarterly straight-line basis between 30 September 2022 and 30 June 2027.

(2) Maximum payments.
(3) Corresponding to the amounts of repayable advances received as at 31 December 2020.

Given the stage of completion of the various projects, the key stages remaining to be completed and the conditions of the contracts, the balance of grants and reimbursable advances of the PIAVE Artus and PSPC Mivana programmes as well as the repayments to be made to Bpifrance should be as follows, assuming the receipt of all reimbursable advances still to be obtained:

As at 31 December 2020 (in €)	Recipient entity at origin	Future payments (+) and repayments (-) of aid programs						
		2021	2022	2023	2024	2025	2026	2027
R&D innovation loan	Affluent Medical	-	-€100,000	-€200,000	-€200,000	-€200,000	-€200,000	-€100,000
PIAVE Artus (Grant Part)	MyoPowers	+€28,000	+€55,589	-	-	-	-	-
PIAVE Artus (Reimbursable Advances Portion)		+€2,575,000	+€1,561,560	-€2,055,000	-€2,055,000	-€2,056,000	-€2,058,000	-
PSPC Mivana (Grant Portion)	Kephalios	-	-	+€145,382	-	-	-	-
	Epygon	-	-	+€168,472	-	-	-	-
PSPC Mivana (Reimbursable Advances Portion)	Kephalios	-	-	+€157,488	-€100,000	-€250,000	-€350,000	-€450,000
	Epygon	-	-	+€1,144,040	-€500,000	-€800,000	-€1,100,000	-€1,350,000
TOTAL		**+€2,603,000**	**+€1,517,149**	**-€639,618**	**-€2,855,000**	**-€3,305,000**	**-€3,605**	**+€2,603,000**

In addition, additional payments are planned for MyoPowers at the end of the repayment of the initial reimbursable advance (discounted maximum value of €8,224 thousand) during the next four years, on the basis of 1% of the annual revenues of MyoPowers generated above €20 million in cumulative revenue. The total amount of the payments is capped at €4 million.

Additional reimbursements are planned:

- for Kephalios after reimbursement of the initial advance (discounted value of €1.15 million) during the next five (5) years above €10 million in cumulative revenue generated by the project on the basis of 2% of annual revenue generated; the total amount of the payments is capped at €3 million;
- for Epygon after reimbursement of the initial advance (discounted value of €3.75 million) during the next five (5) years above €20 million in cumulative revenue generated by the project on the basis of 2% of the annual revenue generated by the project; the total amount of the payments is capped at €6 million.

Information on the PIAVE Artus and PSPC Mivana contracts is presented in Sections 20.2 and 20.3 of the Registration Document.

For Bpifrance reimbursable advances, in the event that MyoPowers, Kephalios and Epygon do not comply with the contractual conditions provided for in the subsidy agreements entered into, they may have to repay the amounts advanced early. Such a situation could deprive these companies of the financial resources necessary for their development projects and they could not guarantee that they would find the necessary additional financial resources to replace these financial resources with others, which could have a material adverse effect on the Group, its ability to achieve its objectives, and its financial position.

- ***Research Tax Credit (CIR):***

To finance their activities, the Group's subsidiaries have also opted for the Research Tax Credit (*Crédit d'Impôt Recherche*, "**CIR**"), which provides for a tax incentive to develop the scientific and technical research efforts of French companies located in France by awarding a tax credit. The research expenses eligible for the CIR include the salaries and compensation of researchers and research technicians, the amortisation and depreciation of assets assigned to the performance of research operations, services subcontracted to approved research organisations (public or private) and the costs to obtain and maintain patents.

The amounts received by the Group in respect of the CIR are respectively €1,951 thousand and €1,087 thousand for the 2018 and 2019 financial years. The amount of the CIR reimbursement requested by the Group amounts to €380 thousand for financial year 2020, the decrease in the value of the RTC for the financial year 2020 compared to previous years is explained by the fact that in 2020 the Group received a part of the Bpifrance repayable advances and subsidies which are deducted from the calculation base of the RTC.

Companies must prove, at the request of the Tax Administration, the amount of the CIR receivable and the eligibility of the work recorded to benefit from the mechanism. The Tax Administration recommends that companies create a scientific dossier that contains the supporting documentation necessary to control this tax credit. It cannot be excluded that the tax authorities may question the methods used to calculate research and development expenses used by the Group to determine the amounts of the CIR. The risk of a dispute about these CIR cannot therefore be eliminated, it being specified that the right of recovery is exercised until the end of the third year following the year in which the special declaration provided for the calculation of the CIR is filed.

If the CIR were challenged by a change in regulations or by a challenge from the tax services, this could have a significant negative effect on the financial position and results of the Company.

- ***Loans guaranteed by the State (PGE):***

In addition, to cope with the financial consequences of the Covid-19 pandemic, the Company and its Subsidiaries have taken out various loans that meet the conditions set out in Article 6 of Amending Finance Law for 2020 No. 2020-289 of 23 March 2020, and by the decree of 23 March 2020 as amended by the decree of 17 April 2020 granting the State guarantee to credit institutions and financing companies (the "**PGE**"). In accordance with the possibilities offered by the state guaranteed loan, the Company and its subsidiaries have chosen to repay these over a period of five years (four years of amortisation after a one-year delay in repayments, i.e. repayments starting from the financial year 2022):

Group entity	Lending Bank	Loan amount
Kardiozis	Société Générale	€160,000(as of 31 December 2020)
Kephalios	Société Générale	€890,000 (as of 31 December 2020)
Epygon	Société Générale	€90,000 (as of 31 December 2020)
Affluent Medical	BNP Paribas	€1,000,000 (as of 31 December 2020)
MyoPowers	CIC	€394,790 (obtained in 2021)
TOTAL		€2,534,790

In 2020, no accrued interest was recognised in respect of PGEs.

In the future, the Group intends to continue to seek public aid and funding to finance its development. In the absence of such sources of financing, this could force the Group to seek alternative funding solutions that are more dilutive or under less favourable borrowing conditions, or delay or terminate

some of its research and development projects, which could have a material adverse effect on the Group, its ability to achieve its objectives, and its financial position.

3.4.5. Risks related to past and future losses

Since their creation, the Company and its Subsidiaries have recorded net and operating losses each year. Over the last three financial years, the Group's consolidated net losses for the financial years ended on 31 December 2018, 2019 and 2020 amounted to -€11,248 thousand, -€16,589 thousand and -€14,319 thousand, respectively. These losses mainly result from investments in research and development as well as preclinical and clinical studies.

The Group did not generate any revenue from sales, suffered net and operating losses and had to finance its growth through successive capital increases, through the issue of convertible bonds, through the issue of non-convertible bonds, by obtaining reimbursable advances, grants, by the reimbursement of CIR receivables (see section 3.4.3 below) as well as by bank indebtedness through PGEs.

Until the marketing launch of its first product, the Group should experience higher net operating losses than in the past, in particular due to:

- planned preclinical and clinical studies scheduled in Europe and the United States for its Artus, Kalios and Epygon medical devices;
- all procedures to obtain marketing authorisations and access to reimbursement for its Artus, Kalios and Epygon medical devices in Europe or the United States;
- a possible strengthening of regulatory requirements governing the manufacture of its products;
- potential marketing and sales expenditures to be made depending on the degree of progress and development of the products in the different target markets; and
- the continuation of an active research and development policy that can, if applicable, include the acquisition of new technologies, products or licenses.

The Group may not generate sufficient revenues in the future to offset past, present and future losses and achieve its profitability threshold, which could affect the Group's ability to continue its operations. In addition, even if the Group reaches a satisfactory profitability threshold, such profitability may not be lasting. Any inability to generate sustainable profits could have a material adverse effect on the Group, its outlook, ability to achieve its objectives, and its financial position.

3.4.6. Risks related to the depreciation of the Group's intangible assets

The Group was formed as a result of the contributions of Kardiozis, Kephalios, Epygon and MyoPowers by the shareholders of these companies to Affluent Medical in accordance with contribution agreements signed on 16 March 2018. These contributions were made taking into account the actual value of the shares contributed in accordance with regulatory provisions.

A portion of the goodwill recognised was allocated to the patents held for the development of each of the products or technologies of the Group's subsidiaries and thus appears under the item "Other intangible assets" of the Group's financial statements, the remainder was allocated to "Goodwill" item. These patents are depreciated over a period of 15 years.

At 31 December 2020, the amount of goodwill and other intangible assets amounted to €32,203 thousand and €22,566 thousand respectively in the Group's consolidated financial statements prepared in accordance with IFRS, respectively accounting for 49.68% and 34.81% of all the assets.

In accordance with note 4 to the Group's consolidated financial statements prepared in accordance with IFRS for the financial years ended 31 December 2019 and 2020 (see section 18.1.1.1 of the Registration

Document), goodwill and intangible assets with an indefinite useful life are not depreciated and are subject to an annual impairment test. Fixed assets undergoing depreciation are tested for impairment whenever there is an internal or external indication that they may have suffered a loss in value.

For the financial years ended 31 December 2020, 2019 and 2018, with regard to depreciable intangible assets, the Group did not identify any indication of loss of value. With regard to goodwill, the Group has carried out annual impairment tests (see notes 3 and 4 to the Group consolidated financial statements for the years 2019 and 2020 appearing in section 18.1.1.1 and in section 18.1.1.2 of the Registration Document) which did not lead to the recording of any depreciation on the latter in the financial statements.

In the future, should the impairment tests carried out by the Group reveal recoverable amounts lower than the carrying amounts, in particular due to the discontinuation or significant delay in the development of a product, a technology or a significant deterioration in its business prospects, the Group should record a depreciation for its goodwill and/or its intangible assets. Due to the significant amount of goodwill and other intangible assets recorded on the Group's balance sheet, these potential depreciations could have a material adverse effect on the Group's results for the financial year of their recording, it being specified that this would have no cash impact for the Group.

4. INFORMATION ABOUT THE ISSUER

4.1. Company name

The Company name is: Affluent Medical.

4.2. Company's place of registration, registration number and Legal Entity Identifier (LEI)

The Company is registered with the Aix-en-Provence Trade and Companies Registry under number 837 722 560.

The Company's NAF [French business classification] code is 6420Z.

The Company's Legal Entity Identifier (LEI) is 969500N30CO4B5N2GN67.

4.3. Date of incorporation and term

The Company was incorporated on 23 February 2018 for a term of 99 years that will expire on 22 February 2117 unless early dissolution or extension.

4.4. Registered office of the Company, legal form and applicable law

The Company registered office is located at:
320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France
Telephone: +33 (0)4 42 95 12 20
Email address: investor@affluentmedical.com
Website: www.affluentmedical.com

The Company is a French corporation (*société anonyme*) with a Board of Directors. Its financial year closes on 31 December of each year.

The Company, governed by French law, is mainly subject for its operation to Articles L. 225-1 *et seq.* of the French Commercial Code.

It is specified that the information included on the Company's website is not part of the Registration Document, unless this information is incorporated by reference in the Prospectus.

5. OVERVIEW OF BUSINESS ACTIVITIES

5.1. General presentation of Affluent Medical

5.1.1. A new generation of minimally invasive medical devices for the treatment of severe pathologies in urology and structural heart

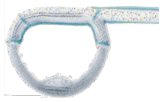
Affluent Medical is a company developing next-generation minimally invasive medical devices, at a clinical stage, with the aim of saving the lives and improving the quality of life of millions of patients around the world affected by severe pathologies in the fields of urology and structural heart.

Affluent Medical is developing a portfolio of products and a technology offering disruptive and effective solutions to regulate urethral, cardiac or aortic flows, by restoring the natural physiology of patients, while simplifying the surgical procedure (optimal precision, speed and safety) and by reducing the total cost of short- and long-term care:

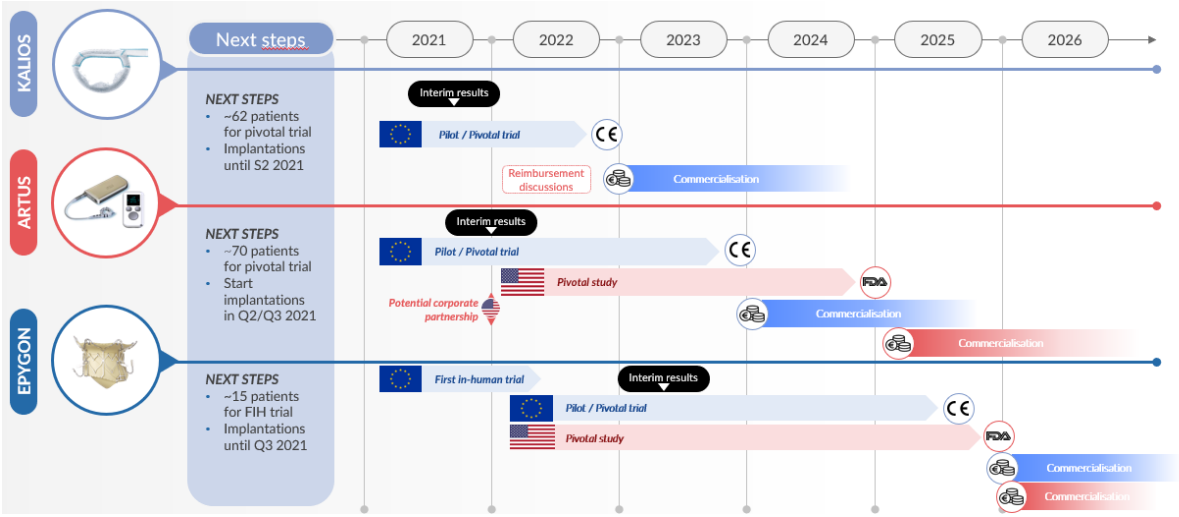
- three innovative implantable best-in-class prostheses:
    - Artus: artificial sphincter for the treatment of moderate to severe urinary incontinence restoring complete control of the bladder, by closing or opening the urinary flow at the will of the patient using a simple remote control and designed both for men and women.
    - Kalios: the only ring designed for mitral valve repair optimised for minimally invasive cardiac surgery and allowing multiple post-operative readjustments via the transcatheter route-without invasive reoperation. It is therefore a unique hybrid technology.
    - Epygon: the only physiological mitral valve bioprosthesis implanted via a transcatheter route capable of mimicking the native mitral valve.
- The Kardiozis technology based on thrombogenic fibres that fits on an endoprosthesis (stent-graft) for the treatment of the abdominal aortic aneurysm and ensures a natural embolisation allowing to reduce the risk of endoleaks* generating a risk of rupture of the aneurysm.

Affluent Medical's strategy aims to complete all of the clinical studies (pilot and pivotal) to obtain regulatory marketing authorisations (CE marking in Europe, FDA approval in the United States) for Kalios, its most advanced product, in Europe and for Artus and Epygon in Europe and the United States, it being specified that in the United States, the Group may enter into partnerships with leading players in the field of medical devices in urology and cardiology for the completion of clinical studies with a view to marketing in the United States.

Concerning its Kardiozis technology, the Group aims to negotiate a partnership agreement with one of the main players in the treatment of AAA with a view to the marketing of stents incorporating thrombogenic fibre technology and negotiations are underway with several potential partners.

Product / Technology		Indication	Clinical development[2]	CE marking[2]	FDA approval[2]
Kalios (Section 5.2.3.2)		Mitral valve repair	<u>In Europe:</u> Clinical Stage - Optimised II Study - Pilot study successfully completed in 2018 - Pivotal study underway in Austria, Germany, Switzerland and Italy and to be completed in the 2nd half of 2022: 15 patients have been recruited out of the planned 62	4th quarter of 2022	-
Artus (Section 5.2.2)		Moderate to severe urinary incontinence	<u>In Europe:</u> Clinical stage - Dry Study - Successful feasibility study in 2018 - Pilot / pivotal study launched between the 2nd and 3rd quarters of 2021 in Spain, Italy, Czech Republic and France: expected recruitment of 70 patients <u>In the United States:</u> Pivotal study launched in the 1st half of 2022 for recruitment starting in the second half of 2022	4th quarter of 2023	4th quarter of 2024
Epygon (Section 5.2.3.3)		Mitral valve replacement	<u>In Europe:</u> Clinical stage - Minerva study - Pilot study launched in the 2nd quarter of 2021 in Austria, Spain and Italy with the expected recruitment of 15 patients - Pivotal study in the 2nd half of 2022 <u>In the United States:</u> Work required launched in the 1st half of 2022 to conduct a feasibility study followed by a pivotal study	2nd half of 2025	4th quarter of 2025
Kardiozis (Section 5.2.4)		Abdominal aortic aneurysm	Technology validated by clinical trials and in vivo studies. Search for a partnership	-	-

Next key stages in the development of the Kalios, Artus, and Epygon medical devices up until their commercialisation



These four products or technologies have in common that they can be perfectly adjusted to the specific needs of each patient in the context of minimally invasive procedures with optimised solutions,

[2] Subject to the impact of the Covid-19 pandemic and regulatory developments (see sections 3 and 9 of the Registration Document) and the obtaining of the necessary financing for the development of the Company, which must be provided in the context of a share capital increase on the occasion of the listing of the Company's shares on the regulated Euronext Paris market and, as necessary, further capital increases (see also section 3.4.1 of the Registration Document).

biocompatible components and mimic the human anatomy or restore human physiology for medical indications:

► **The Artus implant for the treatment of moderate to severe urinary incontinence:**

The Artus implant is an implantable electro-mechanical artificial sphincter that targets moderate to severe urinary incontinence. Artus is an adjustable ring implanted around the bladder neck that controls, by optimised pressure, the opening and closing of the patient's urethra. This ring is controlled by an electromechanical control unit implanted in the abdomen and whose expected battery life is more than ten years. The patient can open or close their urethra at will using a simple remote control to ensure simplicity, efficiency, comfort and discretion. Artus closely respects the physiology of the urinary sphincter, thereby seeking to limit the risks of vascular complications and tissue erosions in the ureter. The inability to control the normal functioning of the bladder has major consequences for the quality of life, mental health and social life of patients and their families. Currently, the consequences of urinary incontinence are mainly treated by the use of adult diapers, sales of which are expected to represent an annual market of $28.7 billion in 2025[3]. Medical devices used in the treatment of moderate to severe incontinence are mainly the surgical implantation of strips, neurostimulators or artificial urinary sphincters. For the latter, the Boston Scientific AMS 800 (hydraulic artificial sphincter for which the model currently marketed dates from 1987) is the main medical device authorised for the treatment of men in Europe and the United States and for the treatment of women only in France. Affluent Medical believes that these treatments are not sufficiently effective, or cause significant discomfort for the patient. Artus meets all the recommendations for an ideal artificial sphincter established by an international group of urologists (ease of use, simplicity, everyday comfort, adaptation of the pressure on the urethra, robustness, all associated costs)[4]. Artus was the subject of a successful feasibility study in 2018 and is due to launch a pilot study followed immediately by a pivotal study in 2021 with a view to obtaining CE marking in the 4th quarter of 2023 for marketing in 2024. In parallel with the studies carried out in Europe, Affluent Medical intends to launch a clinical study in the United States, alone or with a local partner, in the first semester of 2022 to register the device with the FDA in the 4th quarter of 2024 for marketing in 2025.

► **Kalios and Epygon implants for the treatment of mitral regurgitation:**

The Kalios implant and the Epygon implant relate to the treatment of mitral insufficiency, a disorder in which the mitral valve is no longer sealed, which leads to partial regurgitation of blood from the ventricle to the atrium. This is one of the most frequent heart conditions and one of the most difficult to treat. The current conventional treatment consists either of repairing the mitral valve, in particular by annuloplasty*, or in replacing it with a biological or mechanical valve by an open surgery, of the aortic type which is not adapted to the physiological blood flow between the atrium and the left ventricle, mitral valve surgical techniques, open surgery with cardiopulmonary bypass surgery* or so-called minimally invasive techniques remain very invasive and burdensome for the patient, require a relatively long hospital stay and have an impact on public healthcare costs. This is explained among other things by the anatomical complexity of the mitral valve, human physiology, the surgical approach, the pathologies associated with this valve as well as by the technological and regulatory requirements for marketing. However, a few so-called transcatheter devices have appeared or are under development for mitral valve repair and replacement. The valve is thus compressed and introduced into the heart by a catheter that enters the body through a small incision in the chest or via a peripheral artery. It is then deployed under imaging guidance into the heart in fewer than 30 minutes. This technique appeared first for the treatment of the aortic valve (TAVI - *transcatheter aortic valve implantation*) and is now

[3] Grand View Research - 2019 - Adult Diapers Market Size, Share & Trends 2019 - 2025

[4] X. Biardeau, S. Aharony, The AUS Consensus Group, L. Campeau and J. Corcos (Department of Urology, Jewish General Hospital, McGill Univerty, Montreal, Québec, Canada) - Artificial Urinary Sphincter : Report of the 2015 Consensus Conference – Neuroulogy and Urodynamics 35:S8-S24 (2016)

intended for application to the mitral valve. As a result, Affluent Medical anticipates that the treatment of mitral valves (a larger market than that of aortic valves) could also benefit from major technological innovations representing a global market estimated at $4.7 billion in 2027[5]. Affluent Medical is developing two complementary products in this therapeutic area:

- a mitral ring, Kalios, unique to date for the repair of the mitral valve as the only one that can be adjusted several times by the transcatheter route after its implantation. Mitral valve closure can thus be optimised and recurrences of mitral regurgitation can be anticipated and treated without repeated invasive surgical procedure. A clinical trial is already underway in Europe with preliminary results considered to be very satisfactory by the Company. A pilot study was successfully carried out in 2018 on Kalios, a pivotal study is underway with a view to obtaining CE marking in the 4th quarter of 2022 for marketing in 2023. Development in the United States could be considered in the event of a partnership with a local key player to conduct the necessary clinical studies and market the product.

- a mitral valve, Epygon, which is the only valve, by transcatheter replacement, that mimics the physiological functioning of the native mitral valve. The blood circulates effectively from the atrium to the ventricle, then to the aorta with the most physiological flow and the minimum energy consumption by the ventricle. Other projects currently in development in this field significantly change the circulation of blood in the ventricle, inducing a less effective flow and a greater, potentially excessive, energy consumption in a ventricle that is already weakened potentially causing heart failure. The same Epygon valve should be able to be implanted transapically* or transeptally*, both being minimally invasive. Epygon will be the subject of a pilot study in the 2nd semester of 2021, which should be followed by a pivotal study starting in the 2nd semester of 2022 with a view to obtaining CE marking in the 2nd semester of 2025 for marketing in 2026. In parallel to Europe, Affluent Medical intends to launch a global study to meet the FDA's requests including an initial feasibility study followed immediately by a pivotal study in the United States also in the 2nd semester of 2022 for registration with the FDA at the end of 2025 and marketing in 2026. Depending on opportunities, development in the United States could be carried out through a partnership with a key player.

► **Kardiozis technology for the treatment of abdominal aortic aneurysm:**

► The Kardiozis technology relates to the non-invasive treatment of abdominal aortic aneurysm (**AAA**). AAA* is an abnormal dilation of the largest artery in the body that can cause a dramatic and unpredictable rupture of the vessel leading to sudden death of the patient in 80% to 90% of cases. Conventional invasive preventive surgery presents many risks. The minimally invasive stents currently on the market to treat AAA (sales of which in 2016 represented a global market of $1.7 billion[6]) are of limited effectiveness because they frequently allow continued dilation of the aneurysm that remains supplied by secondary collateral vessels (type II endoleaks). This often leads to a wait-and-see approach by clinicians, which can be a source of anxiety for patients. The Kardiozis technology of thrombogenic fibres on the stent makes it possible to generate a natural coagulation, controlled inside the aneurysm sac, which binds the prosthesis to the aorta and blocks the development of the aneurysm by eliminating endoleaks and reducing the size and volume of the aneurysm. Its concept has already been validated in clinical and in vitro studies demonstrating the benefits of the technology compared to the existing state of the art. Affluent Medical aims to negotiate a partnership agreement with one of the main players in the treatment of AAA with a view

[5] Transcatheter Mitral Valve Implantation Market Size (Emergen Research - September 2020)
[6] Infoholic Research – 2017: Global Aortic Aneurysm Market – Drivers, Opportunities, Trends and Forecasts 2017-2023

to the commercialisation of stents incorporating Kardiozis thrombogenic fibre technology (see section 5.2.4.2 - Strategy and objective for the commercialisation of the Kardiozis technology**).**

Thanks to its technological expertise in control of urological, cardiac and vascular flows by biocompatible implants and minimally invasive medicine, Affluent Medical aims to design and develop other potentially best-in-class medical implants or implantation systems for related medical indications or other major medical needs.

5.1.2. Competitive advantages and Development strategy

Affluent Medical's objective is to become a major European player in medtech in the fields of urology and structural heart by relying on differentiated geographical and commercial development as well as on an improvement and expansion of its portfolio of minimally invasive implants that reproduce or respect the physiology of the human body.

To do so, Affluent Medical will rely on the following strengths and competitive advantages:

- a positioning on three products for two indications and one technology with large markets each representing several billion dollars and rapid growth for which there are unmet medical needs (global addressable market of approximately $11 billion in 2027[7]);

- recognised know-how in the development of implantable medical devices mimicking human physiology in the field of flow management;

- unique implants with disruptive characteristics according to the Company (see sections 5.2.2.2, 5.2.3.1 and 5.2.3.2 of the Registration Document) to improve the quality of life of patients by offering a medical alternative given the expected medico-economic benefits with the only minimally invasive ring for mitral valve repair that can be adjusted over time, the only physiological mitral valve bioprosthesis implanted via a transcatheter, and the only artificial sphincter designed for men and women that can be activated by a remote control for the treatment of moderate to severe urinary incontinence;

- implants facilitating surgical procedures in the urological and cardiovascular fields and without modifying current surgical procedures, encouraging rapid adoption of the devices by practitioners;

- the first stages of clinical development already completed with interesting results in terms of safety profile as well as conclusive efficacy data;

- the support of key opinion leaders* (or "**KOL**") and a world-renowned international scientific committee;

- a clear growth strategy thanks to an agile industrial and commercial plan conditional on the search for suitable partners, suppliers, subcontractors and distributions and financing for industrialisation and marketing:

    - a dual organisation with proprietary production and the use of subcontracting;

[7] Urinary Incontinence (UI) Devices (Optima Insights, September 2020) / Transcatheter Mitral Valve Implantation MarketSize (EmergenResearch, September 2020) / Global Aortic Aneurysm Market (Infoholic Research 2017)

- a commercial strategy combining its own sales, marketing and clinical support forces in strategic European countries, in particular, Germany, France, Italy and the United Kingdom, with the aim of achieving high gross margins and local distributors and partners for other European countries;

- anticipation of the future marketing of Affluent Medical Artus and Epygon products in China, Macao, Taiwan and Hong Kong through two joint-venture agreements with Shanghai Zuquan Investment Management Company Limited, which support their development. These agreements provide for full financing by Shanghai Zuquan Investment Management Company Limited of the clinical development, registration and commercialisation until the profitability of the two Chinese joint ventures. Such a partnership from financing to profitability (and not until market launch) is extremely rare, underlining the confidence of the Company's partners in the products developed by Affluent Medical and their prospects;

- the signing of distribution agreements or partnerships with key players in the United States and the rest of the world to achieve the rapid gain of significant market share;

- the intensification of the policy of publishing the results of the various studies carried out by Affluent Medical in recognised scientific journals and of presentations at major medical conferences in the urological and cardiovascular fields, as the Group has done in the past (*EACTS, Oxford Academic, AATS Mitral Conclave 2017, ASAIO Journal, AATS 2020*);

- initial marketing of products expected in the short term, starting in 2023, for Kalios;

- a risk diversification strategy based on the development of three implants and the licensing of the Kardiozis technology, it being understood that Affluent Medical believes that, given the potential of its products and the targeted markets, the future success of only one of its medical devices could ensure its development and growth;

- a broad and strong collection of intellectual property, which further supports the advantage of Affluent Medical in the field of flow physiology. A portfolio of 31 patent families (29 in full ownership and two under exclusive licenses) covering around 300 patents and patent applications in Europe, the United States and other major markets, covers the implants under development through 2037 (Artus and Kalios) or 2038 (Epygon) or 2041 (Kardiozis);

- experienced and recognised management. Affluent Medical has brought together a talented team of professionals with complementary skills who have demonstrated their ability in recent years to develop, industrialise, obtain reimbursement for and market complex implants for interventional medicine (see section 5.3.1 of the Registration Document);

- the intense merger and acquisitions activity in the four markets targeted by the Group, offering Affluent Medical the possibility of selling or licensing each of its products or technologies or entering into major commercial partnerships that could in the medium term secure substantial revenue and cash inflow.

To grow and with the aim of rapid value creation, Affluent Medical will target:

- the demonstration of the clinical superiority and medico-economic benefits of its implants;

- fast regulatory approval of its products;

- support from KOL and the early adoption of its products by surgeons;
- assessment of the selling price and optimal reimbursement of the product;
- manufacturing at optimum cost and quality and rapid and sustainable penetration of the four markets; and
- support for practitioners in the use of its medical devices currently under development with a view to improving operating techniques, technical characteristics of products (durability, resistance, sealing, etc.) and ergonomics (positioning and implant delivery system, minimally invasive characteristics, human-machine interface for Artus, etc.) to obtain the best clinical results.

With a view to longer-term development, Affluent Medical intends to continue its efforts in the development of disruptive technologies for medical needs that are currently unsatisfied. In contact with practitioners, the Group benefits from leading-edge knowledge and skills and is organised to detect new unsatisfied needs, identify therapeutic issues and adapt its technologies or develop new ones to respond to these indications.

As Artus, Kalios and Epygon are all at a clinical stage, the listing of the shares for trading on the Euronext market could provide the Company with the necessary funds to finance its clinical studies, as obtaining regulatory approvals for the marketing of the Group's medical devices remains subject to the success of the clinical studies. The implementation of the Group's strategy is subject to the raising of the necessary financing given the Company's current cash flow horizon to the end of May 2021.

5.2. A strategic positioning based on disruptive solutions for key indications in urology and structural heart

Affluent Medical is developing a portfolio of products and a technology offering disruptive and effective solutions to regulate flows in the fields of urology or structural heart. The different implants were designed on the basis of a common DNA:

- treating critical pathologies by providing major and innovative solutions for which existing treatments are not satisfactory;
- used in the context of minimally invasive surgery;
- replicating human physiological flows;
- saving lives and improving quality of life for patients;
- simplifying surgical procedures by developing tools enabling precise, rapid implantations with an optimal level of safety; and
- reducing the total cost of short- and long-term care.

5.2.1. Affluent Medical: the synergistic combination of three best-in-class medical devices and one technology

Affluent Medical was created in 2018 with the aim of concentrating a synergistic offer (shared skills and know-how in the management of urological and cardiac flows, clinical trials conducted in shared centres with shared investigators, pooling of costs with complementary management and shared and harmonised functions within the parent company) with best-in-class medical devices and technologies designed by four pre-existing companies: MyoPowers, Kephalios, Epygon and Kardiozis. The Group's history is as follows:

2011
- Creation of Kephalios, company specialised in reversible and minimally invasive correction of mitral regurgitation.
- Creation of Kardiozis, company specialised in the long-term treatment of abdominal aortic aneurysm.

2012
- Creation of Epygon, company specialised in mitral valve replacement.

2014
- Creation of MyoPowers, company specialised in the development of artificial muscles for the treatment of moderate to severe incontinence.
- Capital increase of Epygon for an amount of €1,240,000 subscribed mainly by funds managed by Truffle Capital.
- Kalios and Epygon enter into in-vivo preclinical phase (animal).

2015
- Capital increase for MyoPowers for an amount of €4,500,000 subscribed mainly by funds managed by Truffle Capital and Novartis Bioventures Limited.
- Signature of a consortium agreement relating to the "Mivana" project "*Innovative medical devices and techniques derived from the textiles industry for the creation of a national cardiovascular sector*" between Kephalios, Epygon, MDB Texinov and the Institut Français du Textile et de l'Habillement with financing provided by Bpifrance.
- Capital increase of Kephalios by contribution of tangible and intangible assets relating to a development and marketing project of a medical device by Mitraflex at Kephalios.

2016
- Bpifrance support granted to MyoPowers for the "Artus" PIAVE program.

2017
- Signature of joint venture agreements between Shanghai Zuquan Investment Management Company Limited and Epygon and MyoPowers.

2018
- Creation of Affluent Medical via the contributions in kind of all shares and convertible bonds issued by Epygon, Kephalios, Kardiozis and MyoPowers
- "Innovative Company" label awarded by Bpifrance.
- Successful completion of the clinical feasibility study of the Kalios medical device demonstrating the surgical safety of the implant.
- Positive results of the first clinical study on the Artus device with the verification of the safety of the implant and the successful validation of the surgical technique of the device by celioscopy and by the open approach.
- Financing in the form of non-convertible bonds subscribed for by Kreos Capital with the drawdown of a first tranche of €4 million.

2019
- Launch of the pivotal Optimise II study of the Kalios medical device with regulatory approval to begin patient inclusions in Austria (Vienna) and Italy (Florence).
- Successful completion of the first key stage of the PIAVE Artus project with the payment to MyoPowers of subsidies and repayable advances by Bpifrance totalling €3.7 million.
- Strengthening of the management team with the appointment of Michel Finance as Chief Executive Officer, Professor François Laborde as Chief Medical Officer.
- Drawdown of a second tranche of €4 million from Kreos Capital.

- Positive results of the Scope clinical study validating the clinical benefit of embolisation and the genesis of the Kardiozis technology.

2020
- Strengthening of Affluent Medical's equity with the completion of private placements of €10.2 million (conversion of convertible bonds) and €4.0 million (2019 CB).
- Affluent Medical obtains a €1 million Bpifrance innovation loan and a €2.14 million PGE loan.
- €2.3 million in subsidies and repayable advances obtained from Bpifrance by Kephalios and Epygon as part of the PSPC Mivana project with the achievement of new key milestones.
- Launch of the Minerva pilot clinical study of the Epygon medical device with authorisation from the competent Austrian authority to start the recruitment of patients at the Vienna General Hospital.
- Strengthening of the management team with the recruitment of Olivier Pierron as Director of Operations and Jérôme Geoffroy as Chief Financial Officer.

2021
- Authorisation from the competent Spanish and Italian authorities for the launch of the Minerva pilot clinical study in the Murcia and Florence centres.
- Reinforcement of the management team with the arrival of Wenzel Hurtak as Vice-President (Operations) for the Epygon medical device and Eric Jague as Director of Regulatory Affairs.

5.2.2. Artus: a unique artificial sphincter for urinary incontinence

5.2.2.1. Moderate to severe urinary incontinence: a potential multi-billion dollar market lacking in innovations

► Urinary incontinence

Urinary incontinence is defined as the accidental or involuntary loss of urine through the urethra and represents a major social, medical and economic problem.

Urinary continence requires a correctly functioning pelvic floor*, integrity of the sphincters and control of the nerves acting on these muscles and on the detrusor*. Any change in one of these structures can lead to incontinence. Traditionally, a distinction is made between three types of urinary incontinence:

- Stress incontinence characterised by involuntary urine leak by the urethra (urethral meatus) occurring during physical effort, coughing and sneezing. This is a sparse jet leak that occurs abruptly during exercise, most often in a standing position, without prior feeling of need (51% of cases of urinary incontinence in women and 10% in women[8]);
- urge incontinence, characterised by an involuntary urine leak, accompanied or immediately preceded by an urgent and irrepressible need to urinate resulting in micturition that cannot be withheld (11% of cases of urinary incontinence in women and 23% in men [8]); and
- mixed urinary incontinence combining the two types of incontinence defined above (17% of cases of urinary incontinence in women and 11% in men[8]).

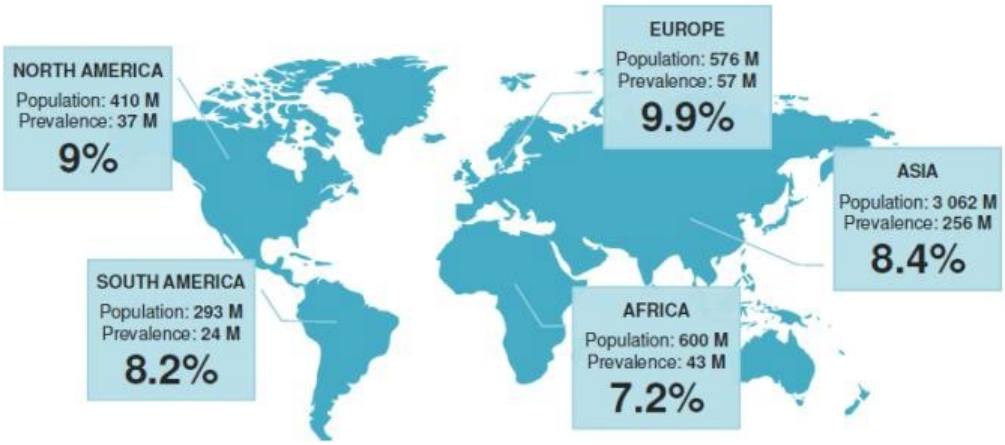
One of the most disabling stages or forms of urinary incontinence is severe urinary incontinence. The latter may be triggered by several factors such as age, anxiety, obesity, neurological disorders, an infection (cystitis), prolapse*, family history, menopause, or loosening of the sphincter or pelvic floor muscles, for example. Wide ablation surgery of the prostate (prostatectomy) can also cause

[8] Irwin et al. "Worlwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction" BJU Int. 2011 Oct, 108 (7): 1132-8

incontinence. The Cleveland Clinic indicates that a proportion of men undergoing a prostatectomy are subject to long-term incontinence and recommends the use of an artificial sphincter in this context[9]. This type of procedure has developed over the last two decades with the development of robotic and video-assisted surgery, which has led to a significant increase in the number of urological procedures, particularly in men[10].

Urinary incontinence is estimated to affect approximately 8.7%[7,11] of the general population aged over 20 worldwide (12.4% of women and 5% of men)[7] i.e. more than 423 million people (303 million women and 121 million men)[7,12], which is a major public health problem, especially since more than 50% of these people are not treated[12] and among those who receive treatment, many do not recover[12]. 5% to 15% of the population aged between 40 and 70 [12] apparently suffer from urinary incontinence on a daily basis and for people over the age of 70, this rate is higher than 15%[12]. The Company focuses on moderate to severe urinary incontinence which affects 25%[13] of people suffering from urinary incontinence, i.e. an estimated target population of around 107 million[13].

Prevalence of urinary incontinence by continent



Source: Milsom I. "How big is the problem? Incontinence in numbers", Gothenburg Continence Research Center

Europe and North America, the Group's main target markets, have the highest prevalence rates with respectively 9.9% and 9% of the general population aged over 20, i.e. 94 million people.

According to the National Association For Continence (NAFC), this disorder affects approximately 25 million people in the United States. The global annual cost of urinary incontinence in the United States was estimated at 65.9 billion dollars in 2007 with a projection of 82.6 billion dollars in 2020[14]. In France, urinary incontinence affects around three million[15] people with an estimated total cost of €4.5 billion[16].

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[9] Cleveland Clinic - Treatments & Procedures "Incontinence After Prostate Surgery" - 31 October 2020

[10] Descotes JL, Rebillard X., Long J., Fiard G. "The reasons for the success of robot-assisted surgery in urology", Bulletin de l'Académie Nationale de Médecine, *201* , nos. 7-8-9, 1059-1070, meeting of 19 September 2017

[11] Irwin DE., Milsom I, Hunskaar S, et al. "Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: results of the EPIC study" Eur Urol 2006; 50: 1306–14

[12] Milsom I. "How big is the problem? Incontinence in numbers", Gothenburg Continence Research Center

[13] Company estimates based on the study "New Artificial Urinary Sphincter Devices in the Treatment of Male Iatrogenic Incontinence and Severity of Urinary Incontinence and Effect on Quality of Life in Women by Incontinence Type".

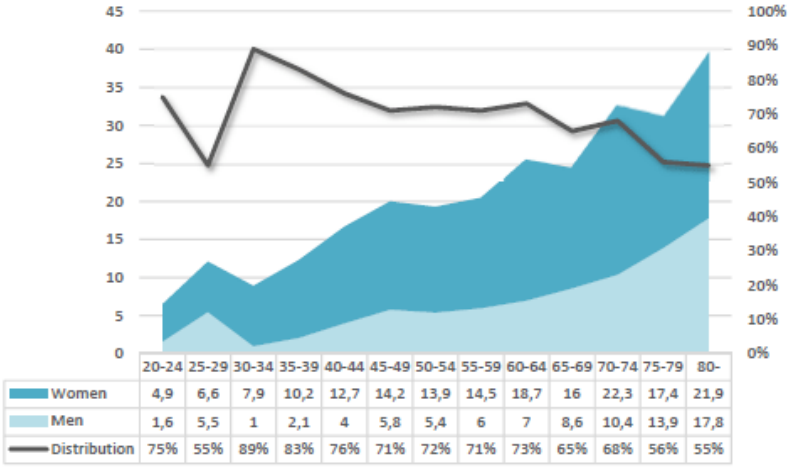
[14] Karin S Coyne 1 , Alan Wein, Sean Nicholson, Marion Kvasz, Chieh-I Chen, Ian Milsom "Economic burden of urgency urinary incontinence in the United States: a systematic review" - J Manag Care Pharm. 2014 Feb; 20(2):130-40 doi: 10.18553/jmcp.2014.20.2.130.

[15] Ministère de la Santé et des Solidarités [French Ministry of Health] Rapport sur le thème de l'incontinence urinaire [Report on the topic of urinary incontinence] François Haab, April 2007

[16] L'incontinence urinaire en chiffres [Urinary incontinence in figures] – Passeport Santé.

The prevalence of urinary incontinence also varies greatly depending on the individual and increases with age. This prevalence is much higher in people over the age of 65 and can even reach between 49% and 77% of people who are hospitalised or living in a medico-social establishment[17].

Prevalence of urinary incontinence by age group and gender



	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-
Women	4,9	6,6	7,9	10,2	12,7	14,2	13,9	14,5	18,7	16	22,3	17,4	21,9
Men	1,6	5,5	1	2,1	4	5,8	5,4	6	7	8,6	10,4	13,9	17,8
Distribution	75%	55%	89%	83%	76%	71%	72%	71%	73%	65%	68%	56%	55%

Source: Milsom I. "How big is the problem? Incontinence in numbers", Gothenburg Continence Research Center

While the prevalence of urinary incontinence affects nearly three times as many women as men, this gap tends to narrow with age, in particular due to the consequences of surgical treatment of the prostate cancer that may be the cause of many cases of severe urinary incontinence.

Severe urinary incontinence, which is defined as the occurrence of leaks at least several times a week, affects up to 10% of all women and up to 20% of men who have undergone surgery or prostate cancer[18], it being specified that more than 1.4 million cases of prostate cancer were recorded worldwide in 2020[19] and that surgery remains the standard treatment.

This prevalence should logically increase, particularly in Western countries, as populations age. It is therefore important to make every effort to prevent, recognise and treat urinary incontinence.

The overall number of people suffering from urinary incontinence is probably underestimated; these individuals take on average 6.5 years[20] to ask for care according to the NAFC and experience this as a real handicap.

A study carried out in Canada showed that among 3,364 female employees aged 18 to 60 suffering from severe urinary incontinence, 2% had to change their type of work[21]. According to the same study, 15.5% of incontinent women suffer from depression. This rate rises to 30% among women aged between 18 and 44 and contrasts with the rate of depression of 9.2% among women not suffering from incontinence. The fact of needing to anticipate, plan and prepare all of their movements can end up discouraging these individuals from venturing from their homes. Even when these people allow themselves to go out, long trips are greatly compromised due to the difficulty of access to bathrooms at any time of the trip. Exercising is also often reduced because of the urinary leakage that can occur during exertion, thus 64%

[17] Saxer S, Halfens, R.J., De Bie, R.A., Dassen, T. “Prevalence and incidence of urinary incontinence of Swiss nursing home residents at admission and after six, 12 and 24 months." Journal of clinical nursing. 2008 Sept.; 17 (18): 2490-6

[18] ISS AG, 2018; Nygaard, Thom, Calhoun Urinary Incontinence in Women, 2007; Stothers, Thom, Calhoun Urinary Incontinence in Men, 2007.

[19] The Global Cancer Observatory - December 2020

[20] NAFC - Facts and Statistics

[21] Vigod SN, Stewart DE, Major depression in female urinary incontinence, Psychosomatics, 2006

of women suffering from severe to very severe urinary incontinence find it difficult to maintain normal physical activity.

People with incontinence often live with anxiety, which is reflected by a certain degree of isolation in daily life. Due to fear of unpleasant odours and of being publicly embarrassed in the event of an accident, incontinent individuals have a tendency to withdraw into themselves. Whether linked to stress, urge or mixed, urinary incontinence often has a particularly negative impact on patient quality of life, especially their psychological equilibrium.

The causes of urinary insufficiency may involve multiple factors:

- Genito-urinary causes:
  - Sphincter insufficiency: loss of tone of the pelvic musculature and connective tissue supporting the bladder and urethra (vaginal delivery, history of pelvic surgery, neurological lesions or pelvic radiation). This leads to a decrease in urethral pressure with subsequent loss of urine as soon as the pressure in the abdomen exceeds the urethral pressure;
  - Bladder or prostate cancer;
  - Post-surgical or postactinic bladder denervation: observed during abdominoperineal amputation, hysterectomy or radiotherapy including the small pelvis in the field; or
  - Interstitial cystitis: more common in young female patients, urinary incontinence may be an atypical manifestation.

- Systemic causes:
  - Neurological disease: stroke, Parkinson's disease, multiple sclerosis, herniated disc, etc.;
  - Long-term insulin-dependent diabetes; or
  - Lesion or intervention on the dorsal spine.

- Potentially reversible causes:
  - Drugs (oral contraceptives, alpha and beta blockers, ACE inhibitors, psychotropic drugs);
  - Chronic constipation;
  - Excessive consumption of certain liquids (coffee, alcohol, etc.); or
  - Change of mental state.

In men, problems of urinary incontinence are most often related to more specific situations resulting from a pathology of the prostate and often due to medical procedures or therapies (removal of the prostate), which explains the better management of this pathology in men, in particular through the fitting of an artificial sphincter.

The various factors favouring urinary incontinence are:

- pregnancy: urinary incontinence is common and worsens during pregnancy, then usually resolves spontaneously after childbirth;
- Menopause (due to the drop in oestrogen plus progestin hormones);
- ageing;
- excess weight and obesity;
- chronic constipation;
- chronic cough;
- hygiene-dietary errors (excessive consumption of caffeine, alcohol, tobacco, etc.);
- taking of certain drugs, especially if taken in combination (e.g. diuretics, sedatives, etc.);
- reduced mobility due to physical or mental illness; or
- intensive physical activity and in particular sports that put repeated pressure on the perineum.

► Treatment of urinary incontinence

The first actions to treat urinary incontinence consist of a conservative approach with:

- the change of behaviours and lifestyles and the strengthening of the sphincter musculature:
  - reducing water intake and eliminating the consumption of certain types of liquids (coffee, lemon juice, alcoholic or carbonated drinks) or spicy food;
  - diet in case of excess weight;
  - treatment of constipation;
  - strengthening of the pelvic floor and bladder muscles.

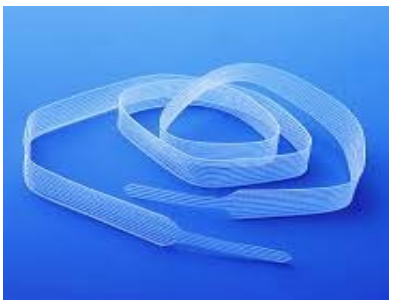
The second line of treatment consists of a pharmacological approach, which is, however, almost exclusively reserved for the urgent treatment of urinary incontinence:

- anticholinergics, which block muscarinic receptors at the detrusor level, thus reducing bladder contractility, which nevertheless generate side effects (dry mouth, constipation);
- a new beta-3-adrenergic receptor agonist, mirabegron, which reduces detrusor tone, with lesser side effects (less than 2% of dry mouth and constipation referred).

For stress urinary incontinence, only duloxetin has been prescribed in recent years, when surgery could not be offered. Prescribed at doses lower than the psychotropic dosage, it is rarely used because of the potential side effects on mood.

If these conservative treatments prove ineffective, surgery may be proposed to avoid palliative measures such as pads and adult diapers. There are several possible surgical procedures:

- With regard to stress urinary incontinence:
  - positioning of slings: this surgery is often recommended in cases of urethral hypermobility, a synthetic suburethral sling is placed by transobturator (TOT: trans-obturator tape) or externalised by retropubic approach (TVT: tension-free vaginal tape)



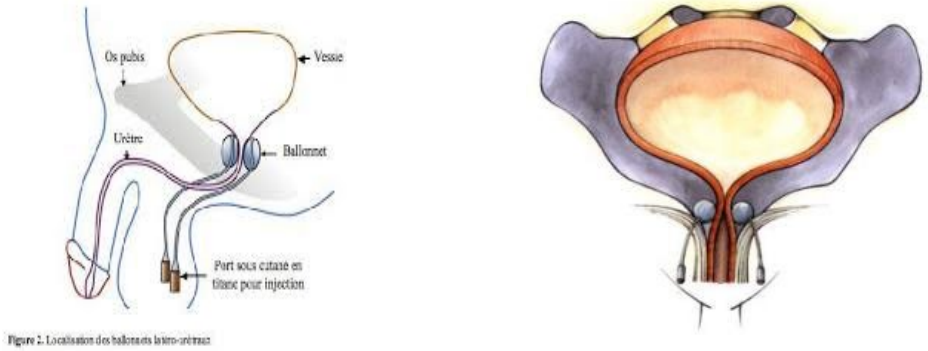
Support bands

The TVT or TOT intervention is intended to treat stress or mixed urinary incontinence with predominance of stress leakage. This surgery consists of placing a small strip under the urethra to replace the failing support structures. The operation is performed under general or local anaesthesia. The procedure can be done on an outpatient basis or during a short hospital stay (one day). The procedure lasts between approximately 15 and 30 minutes.

  - the peri-urethral injection of fillers is a minimally invasive technique to inflate the wall of the urethra, increase resistance to the flow of urine and improve the closure of the sphincter. This type of treatment for urinary incontinence is currently a possible and reasonable choice in certain cases where other surgical techniques are contraindicated.

  - peri-urethral balloons very close to the urethra, just under the neck of the bladder. The essential contribution made by this device is to be able to adjust urethral compression post-operatively, without a new operation being necessary. Each balloon is in fact connected by tubing to a subcutaneous titanium port. Through this subcutaneous port, which can be

installed without surgery, the volume of liquid in each balloon can be adjusted. Balloons are deflated in the event of difficulty in urinating or inflated if leaks persist.



Source: Urofrance

FR	EN
Os pubis	Pubic bone
Vessie	Bladder
Urètre	Urethra
Ballonnet	Balloon
Port sous-cutané en titane pour injection	Titanium subcutaneous port for injection

- the fitting of an artificial sphincter which is the standard treatment for the most difficult cases and cases of sphincter insufficiency. As of the date of approval of the Registration Document, the main device marketed is Boston Scientific's AMS 800, which is authorised for implantation in men only (with a few exceptions), mainly after prostate surgery.

- Urge urinary incontinence for which the surgery is more rarely indicated:

  - injections of toxin A ("**TBA**") into the bladder wall. TBA reduces uncontrolled contractions of the bladder and reduces the urgent need to urinate by acting on nerve endings contained in the wall. Urine leakage and urgent urges are thus eliminated or considerably reduced. The effect of TBA begins two to ten days after the injection. It acts temporarily for an average of six to nine months. When the effect wears off, re-injection is possible as many times as necessary, leaving a minimum of three months between two injections. The major drawback of this technique is the risk of post-operative urinary retention*.

  - sacral neuromodulation: this technique stimulates the sacral nerves located just above the coccyx in the lower back using low-intensity electrical impulses. These sacral nerves control the urinary systems as well as the pelvic floor muscles. The system consists of: an implantable neurostimulator, similar to a cardiac pacemaker, implanted under the skin, an electrode that conveys low-intensity electrical impulses to the nerve controlling the pelvic floor and in particular the intestines and bladder, and a patient remote control to adjust the intensity of the stimulation and to activate and deactivate the system. This technique has a success rate of 40 to 80%[22] and has the advantage of being reversible in the event of failure. The disadvantage of the peripheral stimulation method is the frequency of treatments, which must be almost daily (sessions of 30 minutes).

[22] Renard J. & al. "Prise en charge initiale de l'incontinence urinaire chez la femme par l'interniste généraliste" [Initial treatment of urinary incontinence in women by the general registrar] - RevMed Suisse 2014 volume 10. 2322-2327

Source: Medtronic and Axonics

- the ultimate solution is cystectomy combined with a non-continent (Bricker type) or continent urinary diversion.

► The urinary incontinence treated using medical devices market:

The artificial sphincter market is currently dominated by a single player, Boston Scientific, with a medical device, the AMS-800, which was developed in the 1970s and whose version currently on the market dates back to 1987. It is almost exclusively implanted in men to treat severe urinary incontinence after prostate surgery. This market is estimated at $436.34 million in 2020 and could reach $643.43 million in 2026, i.e. an average annual growth rate of 6.6%[23].

One of the main paradoxes of this disorder is that men who have undergone prostate ablation or who are being treated for this form of severe incontinence are more easily treated by the implantation of an artificial sphincter; while women who are the main victims of this pathology are treated rarely or not at all because of lack of a product suited to their anatomy. Only 3% of artificial sphincter implantations involved women in Western countries while 97% involved men[24].

According to Optima Insights, the global market for medical devices to treat urinary incontinence (strips, neurostimulators, artificial sphincters) is expected to reach $4.3 billion by 2027, i.e. an average annual growth rate of 11% between 2019 and 2027, with a market of $2.2 billion in 2019[25].

ISS AG estimates that the number of procedures worldwide using medical devices for the treatment of urinary incontinence for men and women was in the order of 500,000 in 2016 and 684 thousand in 2019, and that this number could reach as many as 1,152,000 procedures in 2024 and 1,420,000 by 2027, i.e. an average annual growth rate of 11% over ten years[26].

The urology sector is a sector of interest for a large number of major players in the medical devices sector, with nearly twenty transactions completed since 2015, five of which are more specifically related to the treatment of urinary incontinence for a cumulative amount of approximately €3.5 billion[27]:

- acquisition of Nine Continents Medical by Coloplast in 2020 for €124.0 million (implantable tibial nerve stimulation treatment for overactive bladder)
- acquisition of Neotract by Teleflex Medical in 2017 for €672.1 million (minimally invasive surgery in case of prostatic hypertrophy);
- acquisition of PureWick by CR Bard in 2017 for €8.5 million (urine collection system to

[23] ISS AG 2020
[24] IMS Consulting Group: US Market Opportunity Assessment for Artus
[25] Optima Insights - Urinary Incontinence (UI) Devices - September 2020
[26] ISS AG 2020; Allied Market Research. Global Urinary Incontinence Devices Market. Opportunity Analysis and Industry Forecast 2017-2023
[27] Merger Market – Opérations réalisées dans le secteur de l'urologie et notamment liées au traitement de l'incontinence urinaire depuis 2015 [Transactions completed in the urology sector and linked in particular to the treatment of urinary incontinence since 2015]

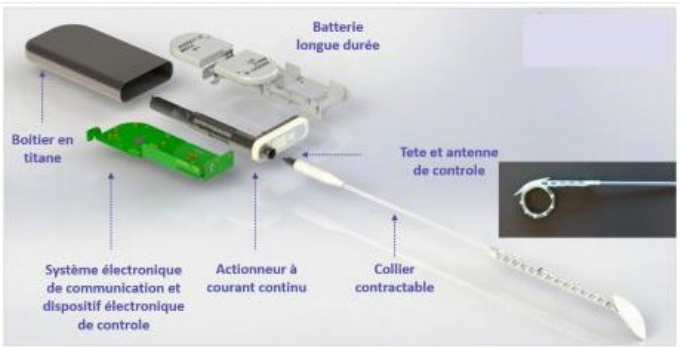
improve the management of urinary incontinence);

- acquisition of a 19.95% stake in ConvaTec Group by Novo Holdings A/S in 2017 for €1.170 billion (diversified group supplying medical devices for continence); and
- acquisition of American Medical Systems by Boston Scientific in 2015 for $1.475 billion (treatment of the prostate).

5.2.2.2. The Artus implant: a fully implantable and easy-to-use device that addresses an unmet need for the treatment of moderate to severe urinary incontinence.

► The Artus implant

With a view to meeting the unmet medical need of moderate to severe urinary incontinence and providing comfort for both men and ultimately for women, Affluent Medical has developed the Artus medical device, a minimally invasive active implant which restores complete control of the bladder, closing and opening urinary flow at the will of the patient via a simple remote control.



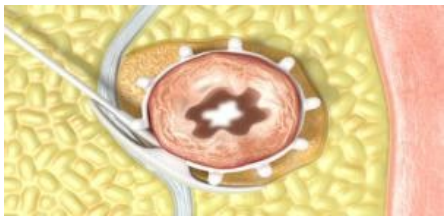
FR	*EN*
Boitier en titane	**Titanium case**
Batterie longue durée	**Long-life battery**
Système électronique de communication et dispositif électronique de contrôle	**Electronic communication system and electronic engine control system**
Actionneur à courant continu	**Direct current actuator**
Collier contractable	**Contractible necklace**
Tête et antenne de contrôle Tête et antenne de contrôle	**Head and Control Antenna**

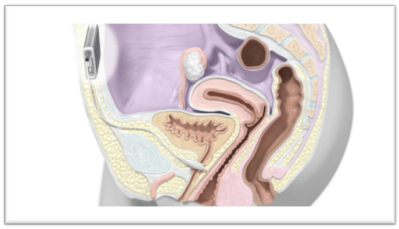
Artus has an optimised pressure profile adaptable post-operatively on the urethra, reducing the risk of ischemia and erosion. The objective of the device is:

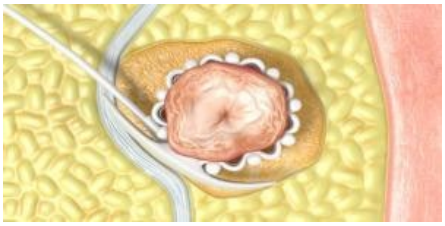
- to be invisible (compact implantable device);
- to be reliable (battery life of ten years - acceleration tests on the test bench currently indicate a battery life of more than ten years);
- to be secure (security system integrated into the device with data analysis, dual remote control for the patient);
- to be easy to use thanks in particular to an easy-to-use remote control including in-built software to remotely operate the urinary flow controls;
- to guarantee to put a stop to urinary incontinence with adaptation to both male and female anatomy; and
- to adapt so that the patient regains a normal rhythm and comfort with three positions adjustable by the patient himself via the remote control according to the time of day and level of activity

(Day closed position / Night closed position with a less tight collar / Sport closed position with a tighter collar due to the increased risk of stress incontinence).

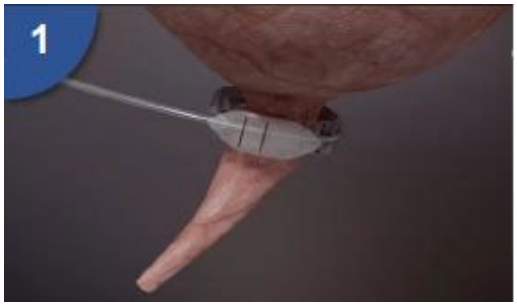
Artus cuff (pre-adjustable silicone collar) and implantation diagram



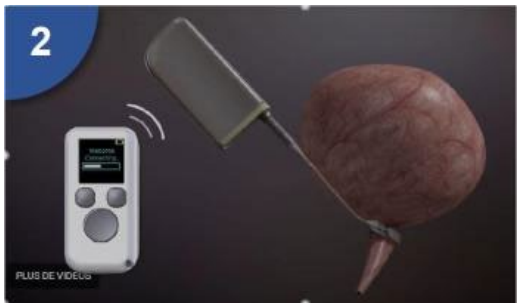




Artus can be implanted thanks to minimally invasive surgery and is faster than conventional surgery (around 30 minutes). This surgery can be a celioscopy or laparoscopy, which is less invasive than the open surgery currently used. This operation will reduce the length of hospitalisation. The cuff on the urethra is adjusted by the surgeon at the time of insertion. The Artus system is activated one month after implementation.



The adjustable cuff is positioned around the neck of the bladder and locked



The cuff is connected to the control unit which communicates with the remote control to adapt the cuff pressure (closing/opening).

The cuff is adjusted according to the severity of the incontinence.

Urination is achieved by pressing the main button on the remote control.

The Artus implant has been designed to offer solutions to the main difficulties existing in medical devices for the treatment of urinary incontinence:

- complex and lengthy surgeries;
- significant pressure on the tissues that can cause strictures* (the cuff does not completely surround the urethra - no permanent pressure);
- patient dexterity required to activate the device;
- adaptation of the implant for women as well;
- existence of hydraulic leaks; and
- secondary operations in 30% of cases.

A consensus report by international urologists was published in 2015[28] aiming in particular to list the ideal characteristics of an artificial urinary sphincter as detailed below. Artus meets all of these requirements.

Ideal characteristics of an artificial urinary sphincter	Artus
- Easy handling of the device by the patient or caregiver and ability to inactivate it	✓
- Possible change in cuff pressure after implantation	✓
- Adjustment of the cuff pressure in real time to mimic normal physiology	✓
- Simple and robust design	✓
- Safe implantation via a minimally invasive procedure	✓
- Competitive costs for the procedure as a whole	✓

► Preclinical and clinical studies carried out - Artus clinical development plan

Several studies of the technical feasibility, safety and tolerability and efficacy have been conducted on animals in laboratories with follow-up studies lasting up to six months, the longest time frame for the in situ Artus implant. These studies show that the Artus medical device does not cause any immediate post-operative urinary retention. In addition, due to its design and the materials used, no chronic inflammatory reaction that could generate strictures has been recorded along the transmission line ("cable") between the control unit box and the cuff placed around the urethra. The urethra was surrounded by granulation tissue with no signs of acute inflammation, abnormal compression or necrosis. This tissue did not block the opening or closing process but, on the contrary, made it possible to cushion interactions with Artus making the system perfectly tolerable.

The Artus implant was tested on a simulation bench in accelerated cycling of openings and closings of the cuff surrounding an artificial urethra. The number of cycles performed represents more than 20 years of life of the implant in normal use in the patient, without any material fatigue detected. During the validation phase of the implant design, several hundred thousand cycles of twisting and multidirectional repetitive movements imposed on the cuff and the transmission line confirm that the movements of the patient's everyday life do not alter in any way the performance and reliability of the contractile part of Artus.

[28] X. Biardeau, S. Aharony, The AUS Consensus Group, L. Campeau and J. Corcos (Department of Urology, Jewish General Hospital, McGill Univerty, Montreal, Québec, Canada) - Artificial Urinary Sphincter : Report of the 2015 Consensus Conference – Neuroulogy and Urodynamics 35: S8-S24 (2016)

Simulation bench to test the tensile strength of the cuff

The mechanical components and the miniaturised motor inserted in the control unit box and connected to the cuff via the transmission line ("cable") have also been tested and qualified following accelerated fatigue resistance and stress tests, simulating more than ten years of normal functioning in the implanted patient.

All the biocompatibility tests required by ISO 10993-1:2018 were conducted on the Artus implant in laboratories approved for this type of preclinical assessment, such as Namsa, a laboratory globally recognised in the medical device industry and by certifying bodies. The results obtained through studies on cytotoxicity, irritation, sensitisation, genotoxicity, endotoxin and intramuscular implantation demonstrate the total biocompatibility of the various components of the Artus implant.

Electrical testing was also conducted on Artus implants by the Laboratoire National d'Essai (LNE, National Laboratory for Testing), a certified French laboratory. The conclusions show that the implant fully complies with the standards for electrical safety and electromagnetic compatibility:

- compliance with standard EN 45502-1 by demonstrating consistent results with a current below the current limit of 0.75 µA / mm²;
- dielectric strength compliant with standard EN 45502-1;
- temperature elevation of the externally-accessible parts compliant with standard EN 45502-1 with a temperature value below the 2° C required by the standard;
- compliance with standard EN 60601-1-2 in tests relating to electromagnetic compatibility.

In 2018, Affluent Medical conducted a first clinical study on humans (*FIH - First in Human*) as part of an acute test, i.e. with removal of the device after testing. This first study aimed to validate the surgical technique of implantation of the device by celioscopy and by open approach, and to verify its intraoperative safety. This clinical study was conducted in France, at the Cochin Hospital (Paris), and in the Czech Republic, at the Thomayer University Hospital (Prague), under the responsibility of Professors Barry Delongchamps and Zachoval respectively. Three patients received the Artus device on a temporary basis during a planned pelvectomy by celioscopy or open surgery. The functionality of the device, opening and closing the urinary canal in situ, was also verified and confirmed.

As part of its clinical development, Affluent Medical plans to conduct a clinical study, called Dry, of its Artus device for the treatment of urinary incontinence in men, comprising two phases:

- a first pilot phase involving ten patients and which should take place between the 2nd/3rd quarter of 2021 and the 2nd semester of 2021 in two centres in Spain (Hospital Germain Trias y Pujol

Barcelona - Hospital Clinico San Carlos Madrid) and one in the Czech Republic (Faculty Hospital Prague);

- a second pivotal phase to obtain CE marking, which should take place immediately after the pilot study through the 2nd quarter of 2022 by integrating four additional centres in Spain, the Czech Republic, Italy and France and including 60 patients with follow-up at six months and one year.

The characteristics of the studies have already been determined with a submission file submitted to the competent authorities in February 2021 for approval expected in the 1st semester of 2021. A partnership with a Spanish distributor Palex Medical was signed to obtain ethics committee approvals. Affluent Medical has also signed a distribution agreement in Spain and Portugal with this major player in the cardiology sector.

These studies should enable the CE marking application to be submitted in the 2nd quarter of 2023 for anticipated awarding in the 4th quarter of 2023.

At the same time, Affluent Medical intends to carry out additional animal studies in the 2nd semester of 2021 in accordance with the FDA recommendations for a pivotal clinical study in the United States starting in 2022 (FDA filing to conduct the pivotal study potentially as part of a 510 (k) (see section 9.1.2 of the Registration Document) in the 1st semester of 2022 for patient recruitment in the 2nd semester of 2022) for potentially obtaining approval during the 2nd semester of 2024.

► Competitive positioning of Artus

- Positioning of Artus compared to other treatments for urinary incontinence

	Drug Treatments	**Strips (Boston Scientific / Coloplast / Caldera)**	**Filling agent injections**	**Peri-urethral balloons**	**Artus Affluent Medical**
PRODUCTS					
COMPARISON	Heavy and binding treatment. Limited efficiency	Limited efficiency for severe urinary incontinence and intrinsic sphincter deficiency Recurrent complications after surgery	Treatment for women only Requires several injections / to be repeated over time	Complex positioning surgery to properly position the balloons	
ADVANTAGE	No surgery Treatment for Men and Women	Treatment for Men and Women Launched on the market in 2008 - current generation of products from 2014	Benefit in case of more complex surgery contraindicated	Post-operative adjustment of urethral compression Treatment for Men and Women	Less invasive & simple surgery Modifiable post surgery Easy to use regardless of patient's dexterity Adapted for both men and women
STATUS	Approved	Approved	Approved	Approved	In clinical phase

- Positioning of Artus compared to other artificial sphincters:

The Artus medical device, which is currently in the clinical phase, is positioned in the artificial urinary sphincter market with simple and less invasive surgery, a system modifiable post-operatively, suitable for men and women and an easy-to-use system regardless of the patient's dexterity.

To date, only two devices are marketed:

- Boston Scientific's AMS 800, the first product marketed in 1983, the version currently marketed was developed in 1997 - it is approved for women in France but used in very few procedures. The surgery to implant the device is complex because the AMS 800 is composed of three elements. The device is not activated by a remote control and requires patient dexterity. The product may show hydraulic leaks requiring secondary operations in 30% of cases; and

- Zephyr Surgical Implants' ZSI375 which is a product relatively comparable to AMS 800 and marketed since 2009 in Europe but which does not have FDA approval and is not available for women.

There are also other artificial urinary sphincter development projects developed for men and women (Uromems with a pressure sensor system and Implantica with its product Uricontrol) for which little information is available in terms of clinical progress or technical characteristics.

Summary diagram of the competitive positioning of the Artus product[29]

	UroMems	ZSI	Boston Scientific	affluent MEDICAL
Product offering	Electronic artificial urinary sphincter	ZSI 375	AMS 800™	ARTUS™
CE Approval	×	✓	✓	4th quarter 2023
FDA Approval	×	×	✓	4th quarter 2024
Launch date	-	-	1987	2024
User friendly	✓	×	×	✓✓✓
Efficiency	-	-	✓	✓✓✓
Targets men and women	✓	×	×	✓
Surgery type	-	✓	✓	✓✓
Remote control	-	×	×	✓
* Potential selling average price depending the market				Price: €8,000 - €10,000*

The Boston Scientific AMS 800 is a hydraulic implant made up of three elastomer components: a peri-urethral occlusion cuff, a pressure-regulating balloon in the abdominal position and a scrotal control pump for men or in the labia majora for women. The various elements are connected by tubes and filled with a saline solution or contrast medium. Given its difficulty of use and its impracticality for use by women, it is not widely implanted in women. Its use by women is, moreover, only authorised in France. The FDA in the United States has only granted its approval for men.

► Strategy and objectives for the development of Artus

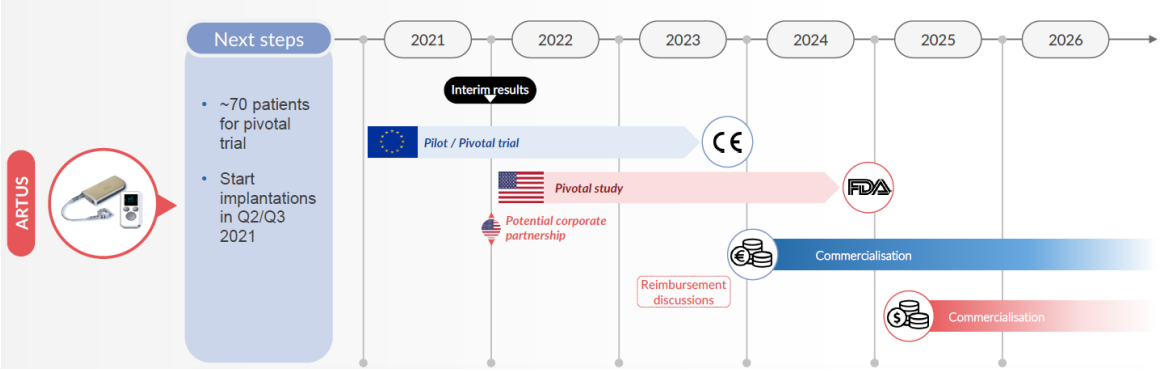
Affluent Medical's objective is to be able to market Artus in Europe by 2024 after obtaining CE marking and in the United States by 2025 after obtaining the necessary regulatory approval (refer to section 9 of the Registration Document). Affluent Medical is initially targeting the male moderate to severe urinary incontinence market insofar as to date it is mainly men who are treated even if the Artus device has

[29] Comparative table drawn up using the Company's estimates on the basis of the publicly-available information

been designed to adapt to men as well as women.

Affluent Medical intends to take advantage of the 2023 financial year to initiate discussions regarding the reimbursement of the Artus device in Europe (see section 5.3.6 of the Registration Document) on the basis of the publication of interim results after six months for the patients included in the European pivotal study.

At the same time, to address the American market more effectively and ensure faster market penetration, Affluent Medical may decide to enter into a partnership with a local key player.



Affluent Medical benefits from intellectual protection for its Artus system until 2037.

The reference to the price of the AMS 800 artificial sphincter (product reimbursement price of €5,200 in France in 2020) must be taken into account in setting the price of Artus, as must the significant technological breakthrough provided by the latter in the treatment of moderate to severe sphincter insufficiency. Artus' advantages (ease of use, simple and robust design, real-time adaptation mimicking physiological functioning) and its minimally invasive implantation procedure, as well as the clinical benefits that can be demonstrated in the context of clinical trials (better clinical results, reduction in length of operations, lower rate of complications and reoperation) with a reduction in the associated implantation costs should enable a premium positioning of this medical device. Affluent Medical thus envisages an average potential selling price to the customer which could be between €8,000 and €10,000 depending on the geographical areas of marketing. For information, this price level is corroborated by the reimbursement price of implantable neuromodulators such as Medtronic's Interstim II (€7,200 in France).

5.2.3. Kalios & Epygon: complementary innovations to effectively treat mitral regurgitation in a minimally invasive way

5.2.3.1. Mitral insufficiency: the most promising Structural Heart market

► Mitral insufficiency

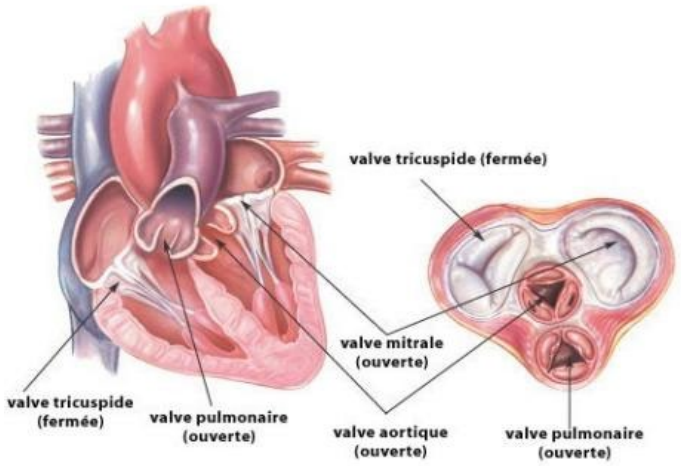
According to data from the World Health Organization, cardiac pathologies are the main cause of death worldwide with nearly 17.9 million deaths per year worldwide[30].

Among the most important cardiac pathologies are heart valve disease* corresponding to malfunctioning of the cardiac valves. In the absence of treatment, the heart gradually becomes exhausted and no longer provides sufficient flow resulting in generalised heart failure.

[30] World Heath Organization - Health topics - Cardiovascular diseases - Overview

The valves of the heart separate the various chambers of the heart in order to ensure good blood circulation among the various heart chambers. These valves are composed of two or three leaflets called valvules which open to allow blood to pass and then close to prevent backflow. There are 4 major heart valves:

- the aortic valve between the left ventricle and the aorta;
- the pulmonary valve between the right ventricle and the pulmonary artery;
- the tricuspid valve between the right atrium and the right ventricle; and
- the mitral valve between the left atrium and the left ventricle.



Anatomy of the heart and the heart valves

FR	EN
Valve tricuspide (fermée)	Tricuspid valve (closed)
Valve pulmonaire (ouverte)	Pulmonary valve (open)
Valve tricuspide (fermée)	Tricuspid valve (closed)
Valve mitrale (ouverte)	Mitral valve (open)
Valve aortique (ouverte)	Aortic valve (open)
Valve pulmonaire (ouverte)	Pulmonary valve (open)

These valves can be impaired in several ways: either they do not open enough and prevent blood circulation known as valve stenosis (in 46% of cases)[31]; or they do not close and the lack of continence causes a leak called insufficiency (in 12% of cases); or, finally, they can have both types of malfunction (in 42% of cases)[31].

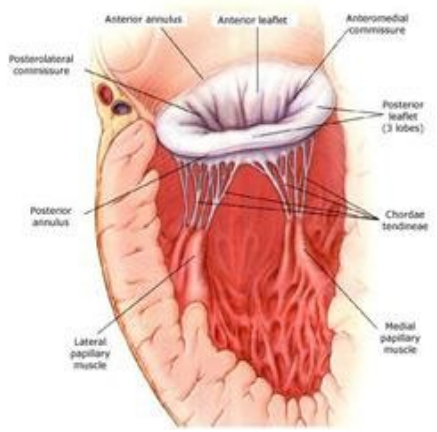
The mitral valve is a bicuspid valve—with two leaflets—which separate the left atrium from the left ventricle. The mitral system is comprised of three components:

- a veil consisting of two valvules:
    - The mitral valve has two valvules: the large valvule (or septal valvule, or anterior leaflet), which is very mobile, and the small valvule (or parietal valvule or posterior leaflet) which serves as an abutment for the large valvule to provide coaptation and provide continence during ventricular contraction (systole). Two faces can be distinguished: the superior or atrial face (i.e. giving onto the left atrium) or the inferior or ventricular face.
- a mitral ring:
    - The two mitral valvules are attached to a fibrous ring, of which the anterior part (one third of its circumference) corresponds to the insertion of the large valvule under the

[31] Institut Mutualiste Montsouris - Prof. François Laborde

aortic annulus, and the posterior part (two thirds of its circumference) corresponds to the insertion of the small valvule.

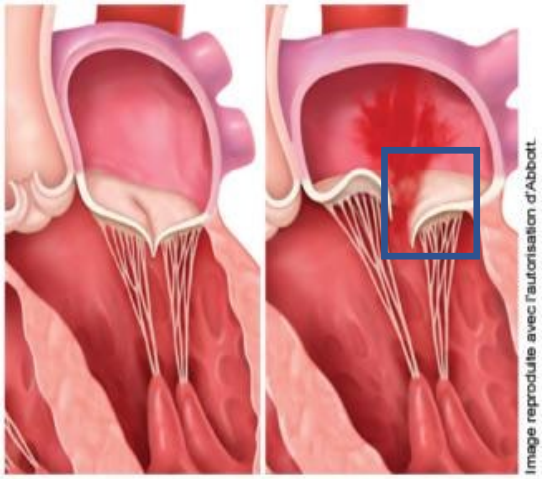
- a subvalvular device, consisting of chordae tendinae and pillars:
    - The subvalvular apparatus comprises two pillars and chordae tendineae. The cordae tendineae, made up of elastic (non-muscle) tissue connect the tip of the papillary muscles to the two valvules. The primary chordae insert on the free margin of the valvules and the secondary chordae insert on the lower (or ventricular) face of the valvules. The pillars are also called "papillary muscles". Their insertion and the number of chordae attached to them varies.



Anatomy of the mitral valve

Mitral stenosis consists of a reduction in the opening of the mitral valve, caused by incomplete opening of the valvules. An obstacle to blood circulation from the left atrium to the left ventricle can then be formed. This is mitral stenosis. This disease can lead to pulmonary oedema. If the mitral valvular disease is severe, the recommended treatment is most often medical, by the use of diuretics. The pressure in the left atrium can thus be decreased. However, if the stenosis is symptomatic, severe or poorly tolerated, surgery becomes necessary.

Mitral insufficiency or regurgitation occurs when the mitral valve no longer closes correctly and an abnormal reflux of blood between the left ventricle and the left atrium occurs during contraction. It results from a defect in closing of the mitral valve which is generally caused by progressive damage of the mitral valvular apparatus. This disease is commonly treated by a surgical procedure. The surgeon then proceeds with a mitral valve repair (preservation of the native valve and repair by plastic surgery of the elements responsible for the leak: valvular tissue, valve suspension device, etc.), or mitral valvular replacement (replacement of the damaged valve by a valvular prosthesis).



Mitral valve regurgitation

The prevalence of regurgitation is around 2% and increases with age[32]. Mitral insufficiency is the first or second most prevalent valvular disease with aortic stenosis[33] depending on the country. It affects up to 13.3% of the population aged over 75[34].

Mitral insufficiency can also be of ischemic origin* and is linked to poor contractility of the ventricle in the region where the mitral subvalvular system is inserted, either chronically when the diameter of the coronary arteries is reduced, or due to acute complication of a myocardial infarction.

Mitral insufficiency can be:

- functional by dilatation of the left ventricle that is found in many heart diseases;
- organic by defect of the chordae tendineae and papillary muscle system or the anterior or posterior leaflets of the mitral valve; or
- infectious by destruction of the valve by bacteria (infectious endocarditis).

Mitral insufficiency can remain asymptomatic for a long time. The main symptom is shortness of breath, which appears belatedly because it is linked to the failure of the left ventricle as a result of the leak, first only during exertion, then when lying down and at rest. Heart rhythm disorders (palpitations, tachycardia), pulmonary congestion and sudden death are also common.

Mild forms of mitral insufficiency are often discovered during echocardiograms and are generally without consequence. Severe forms require a thorough examination and even a surgical operation in some cases.

In the absence of surgery for severe forms of mitral regurgitation, the risks of death and hospitalisation due to heart failure are high, with up to 50% of death at five years and up to 90% of hospitalisation for surviving patients.

<u>Patients with severe mitral regurgitation not operated on:</u>

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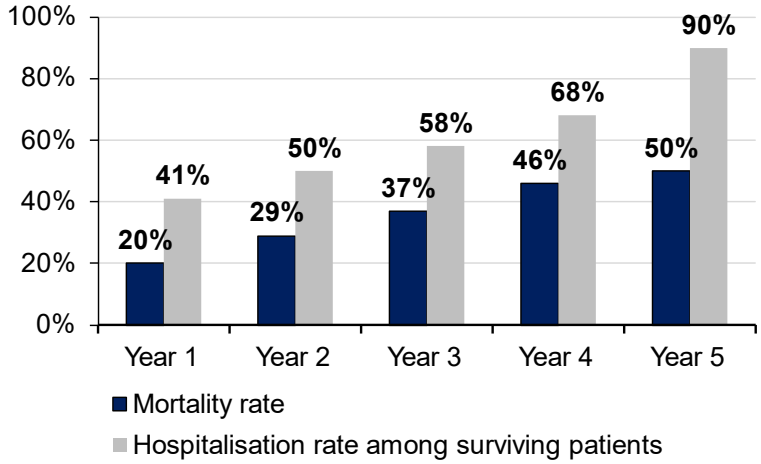
[32] S. Douedi - H. Douedi - August 2020 "Mitral Regurgitation"

[33] Panagiotis A. & al. "Insuffisance Mitrale : Mise au point en 2016" - Rev Med Suisse 2016; 12: 1042-8 / Grave C. & al "Hospitalisations pour Valvulopathie en France : Caractéristiques des patients et évolution 2006-2016" [Hospitalization for Valvulopathy in France: Patient characteristics and developments 2006-2016] Santé Publique France - July 2019 / Dziadzko V. & al. "Outcome and undertreatment of mitral regurgitation: a community cohort study" Lancet. 2018 Mar 10; 391 (10124): 960–969

[34] Vuyisile T Nkomo, Julius M Gardin, Thomas N Skelton, John S Gottdiener, Christopher G Scott, Maurice Enriquez-Sarano: Burden of valvular heart diseases: a population-based study

Mortality and hospitalisation rates



Source: Department of Cardiovascular Medicine Cleveland Clinic Foundation
Journal of the American College of Cardiology

In developed countries, the main causes are mitral prolapse, coronary heart disease, and cardiomyopathy.

The main cause of mitral insufficiency is mitral prolapse, which is related to either an excess of tissue at the valve leaflet or a chordae rupture, leading to excursion beyond the normal closing plane. This prolapse can be congenital or degenerative.

Moreover, mitral insufficiency can occur in other congenital heart malformation contexts or in congenital connective tissue diseases.

Acute severe mitral insufficiency, occurring as a complication of myocardial infarction or inflammation of the heart valves is rare. It requires emergency treatment, which often can only be controlled by a surgical procedure.

Depending on the cause and the severity, the sometimes urgent surgical procedure can be a surgical heart valve repair or a valve replacement.

► Treatment of mitral insufficiency

Depending on the stage of development of the disorder, medical treatment may be indicated as a first line (vasodilators, diuretics, anticoagulants) and should be adapted at the mitral insufficiency stage.

If the mitral insufficiency is asymptomatic and does not fulfil the criteria for surgery at the echocardiogram, the patient is generally put under surveillance every six months with an echocardiogram and cardiology consultation.

Surgical treatment is indicated if mitral insufficiency is symptomatic, or according to echocardiography criterias if it is asymptomatic.

Two types of surgical procedures can be considered: mitral valve repair or replacement.

- Mitral valve repair (indication targeted by the Kalios implant)

The surgical procedure consists of preserving and repairing the existing valve. This technique allows anticoagulant treatment to be avoided.

This procedure is done under general anaesthesia and requires cardiopulmonary bypass. When possible, access is done by a small opening between the ribs (minimally invasive surgery by video-assisted minithoracotomy*) and allows sternotomy* to be avoided.

In most cases, surgical repair of the mitral valve leads to implantation of an annular prosthesis to remodel and reinforce the annulus*.

A check of the mitral repair by transoesophageal echocardiography is then routine in order to ensure a good result at the end of the procedure and with beating heart.

- Mitral valve replacement (indication targeted by the Epygon implant)

When the valve is too damaged and cannot be preserved, or if the mitral valve repair fails, surgeons can perform a valve replacement.

The treatment consists of replacing the defective valve with a valvular prosthesis which can be of two types:

- The mechanical valve is made up of two leaflets of pyrolytic carbon in a titanium or pyrolytic carbon cage. It is indestructible but requires anticoagulant treatment for life. This valve is recommended in patients below age 65[35].

- The biological valve is composed of previously treated and sterilised porcine or bovine tissue. It deteriorates over time and may require a new valve replacement because its average lifespan is 10 to 15 years[18]. However, it does not require long-term anticoagulant treatment. It is recommended from age 60 or 65, or for young women who may be pregnant[18].

The valve replacement is performed under general anaesthesia, by opening the sternum and requires the establishment of a cardiopulmonary bypass which makes it possible to stop the heart and to protect it. Techniques under development allow the performance of this type of surgery by a smaller incision on the chest, or in aortic stenosis and contraindication for a sternotomy, the valve replacement can be done by peripheral access and without cardiopulmonary bypass, via the positioning of an implant transapically or transeptally.

These techniques of replacement or repair by the transcatheter route, which initially concerned the aortic valve, the first having been carried out in 2002, using the TAVI (*transcatheter aortic valve implantation*) or TAVR (*transcatheter aortic valve repair*) technique, began to emerge with some clinical studies for the mitral valve with techniques called TMVI (*transcatheter mitral valve implantation*) like the Epygon implant (see section 5.3.3.3 of the Registration Document) or TMVR (*transcatheter mitral valve repair*).

Research regarding TMVI is one of the most active fields in medical technology. Several European and American companies are seeking to position themselves on this market and are trying to reproduce the success of the TAVI technique in the mitral valve field.

[35] Chirurgiens cardiaques associés : Mitral insufficiency and its treatment - https://www.chirurgien-cardiaque.com/chirurgie-des-valves-cardiaque/remplacement-valvulaire/

Affluent Medical believes that more than 4 million patients in Europe, the United States and Asia suffer from the most severe form of mitral regurgitation, rendering them eligible for heart surgery, while only around 150,000 patients actually undergo this type of procedure each year (i.e. less than 4%).

The development of the Kalios and Epygon implants by Affluent Medical will address this currently unmet need, respectively in the fields of mitral valve repair and replacement.

► The markets for repair and replacement of the mitral valve:

The mitral valve repair and replacement market is one of the most promising markets in the medical device industry. According to Emergen Research, the size of market for mitral valve repair and replacement by the transcatheter route was estimated at $1.8 billion in 2019 and is expected to reach $4.7 billion by 2027, i.e. an average growth rate of 14.4%[36].

Several factors underlie this dynamic, notably an increased number of patients with mitral insufficiency, ageing of the population, development of minimally invasive device technology (in particular using transcatheter implantation) to include patient populations that are not currently treated, regulatory device approvals and more widespread knowledge of mitral regurgitation issues. Increasing expenditures allocated by payer and reimbursement systems for cardiac devices and valves is also a factor for growth, notably in developed countries.

The expansion of TMVI (*transcatheter mitral valve implantation*) therapy technologies to lower risk patients or patients with functional mitral regurgitation is made possible by new technologies developed by established players in another segment of heart valves (TAVI for aortic valves) such as Edwards Lifesciences, Medtronic, Abbott Laboratories and Boston Scientific, who continue to invest significant sums in the development of new valves.

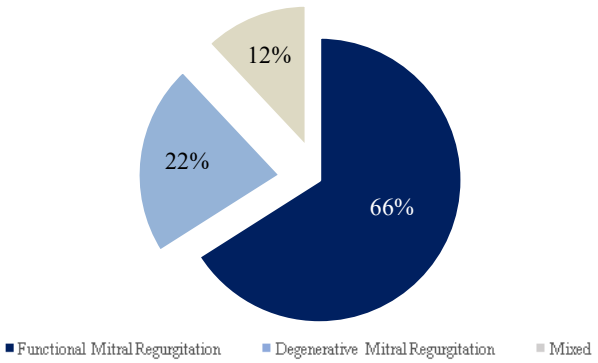
Percutaneous mitral valve repair with the MitraClip system developed by Abbott Vascular, is the first and only device currently available for transcatheter treatment of mitral regurgitation globally. Mitral valve repair by catheter via this device was done for the first time in 2003. The device received CE marking in 2008. The FDA approved its use in 2013 for degenerative mitral regurgitation in patients with major surgical risk for open repair or replacement surgery. MitraClip has been marketed in nearly 90 countries around the world since the end of 2016 and is estimated to have generated nearly $700 million in sales in 2019, an increase of 30% compared to 2018[37].

According to some studies, the size of the TMVI market is expected to surpass the TAVI market in the coming years (estimated at $8 billion in 2025[38]) and become the largest market for heart valves[39].

Globally and all mitral therapies together, therapies for functional mitral regurgitation treatment represent nearly two thirds (66%) of the market, followed by treatments for degenerative mitral regurgitation at 22% of cases and 12% for mixed therapies (degenerative and functional).

[36] Transcatheter mitral valve implantation market size (Emergen research - September 2020)
[37] Medtechive - CMS proposes major market expansion in potential boost for Abbott's MitraClip - July 2020
[38] Global Transcatheter Aortic Valve Implantation (TAVI) Market - Allied Market Research - June 2018
[39] Azoth Analytics – 2017: Transcatheter Mitral Valve Repair and Replacement (TMVR) Market – Opportunities and Forecast 2017-2022

Market breakdown by type of mitral regurgitation (%)



Source: ASECHO, Azoth Analytics Estimates, May 2017

The development of technologies respecting flow physiology such as those developed by Affluent Medical with the Epygon valve could increase the size of the replacement market and treat patients that currently do not have implants.

The development of minimally invasive therapies for mitral valve repair relies on the same principles as open-heart surgery for the mitral valve, but limiting the surgical impact. Several devices are in the process of development and in the clinical phase to reduce the risk of failure or limit residual mitral valve regurgitation that occurs in 40% of cases[40]. The majority of transcatheter approaches are transapical or transseptal. The Group believes that the transcatheter approach should therefore become the most common approach in the coming years since this approach is less risky and less invasive.

According to the American Heart Association, cardiovascular pathologies could lead to 23.6 million deaths per year in 2030. The main causes of this increase are estimated to be 55% aging of the global population and 25% increase in the global population according to Institute for Health Metrics and Evaluation. The remainder is attributed to lifestyle (smoking, obesity, for example) or disease (diabetes)[41].

The new technologies, which can be implanted for patient categories that only have less-severe or less-advanced mitral regurgitation, contribute to the development of the mitral valve repair and replacement market. The spread of better-controlled technologies will also permit treating patients that are already diagnosed and eligible but not treated.

For example, in the United States, 2% of the population has a form of mitral regurgitation (around 7 million people) 600 thousand of whom have degenerative mitral regurgitation. However, around 50% of people concerned by degenerative mitral regurgitation cannot be eligible for open-heart surgery due to an exacerbated comorbidity risk. The development of transcatheter therapies could permit treating these patients.

[40] Journal of American College of Cardiology: Percutaneous approaches to valve repair for mitral regurgitation. May 2014

[41] Virani S. & al "Heart Disease and stroke statistics 2020 update: A report from the American Heart Association" Circulation 2020 141: e139 – e596

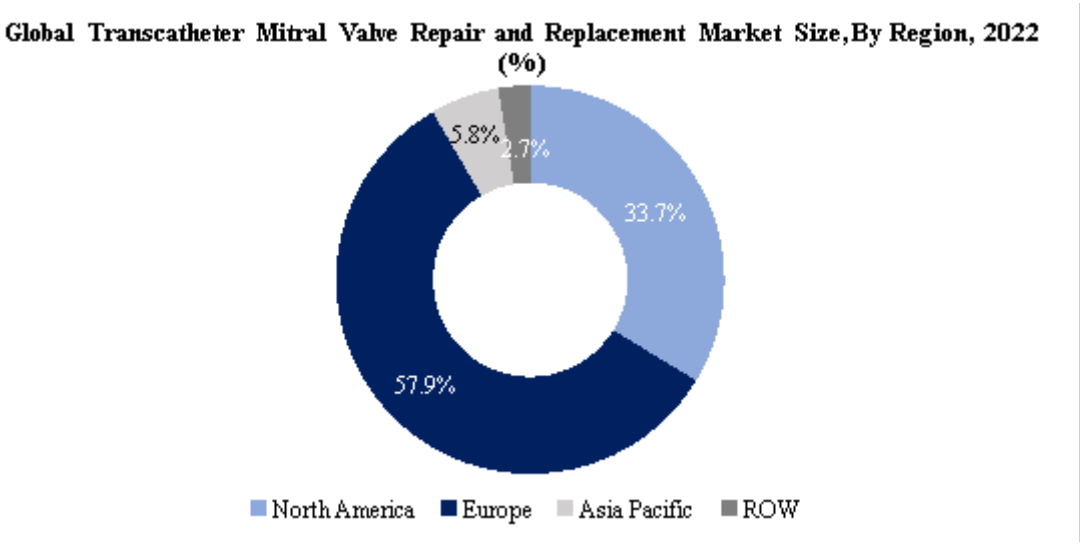
2016 mitral regurgitation statistics in the United States

Mitral regurgitation	Patient population in the United States	Number of patients currently treated	% Treated
Moderate to severe	2,300,000	48,000	2.10%
Severe	220,000	48,000	22%

American Heart Association

Finally, the increasing expenditures of healthcare systems in developed countries that better reimburse this type of procedure and the development of more systematic diagnosis of at-risk patients will help support this emerging market.

In geographical terms, the largest market for mitral valve repair or replacement therapies is Europe, which represents nearly 58% of the global market, followed by North America and Asia Pacific.[42]



Azoth Analytics Estimates, May 2017

Overall, the cardiology medical devices sector is one of the most active sectors in terms of mergers and acquisitions, with:

- significant acquisitions (St-Jude Medical for €26.3 billion or Sorin for €1.3 billion), or
- acquisitions of companies highly specialised in mitral valve repair or replacement, most often carried out shortly after the first patient implantations, as presented below, for an amount of around €2 billion:

Target	Purchaser	Year	Transaction value	Stage of development
Cephea	Abbott	2019	Not available	First human trials
Millipede	Boston Scientific	2018	$90M + option to acquire the remaining capital for $450M	Several patients implanted in clinical studies
Harpoon Medical	Edwards Lifescience	2017	$20M including milestones	CE marking and marketing
Caisson Interventional (51% stake)	LivaNova	2017	$72M including $18M paid upon completion of the transaction	3 patients implanted
Neovasc	Boston Scientific	2016	$75M for the acquisition of 15% of the share capital	70 patients implanted as part of the clinical study and the feasibility study
Valtech Cardio	Edwards	2016	$690M	CE marking

[42] Azoth Analytics - Estimates, May 2017

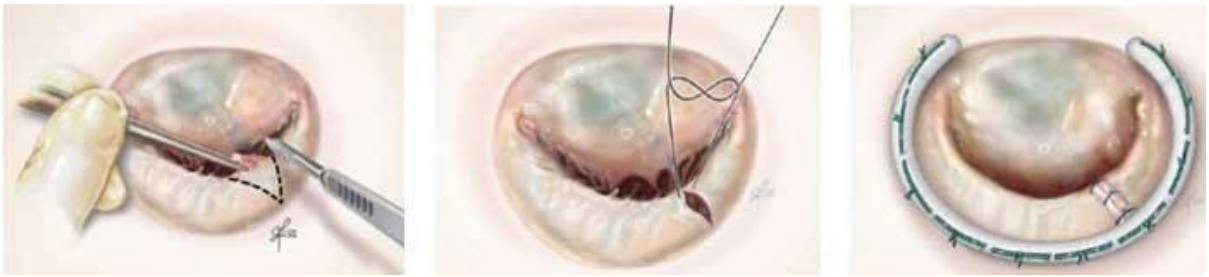
	Lifescience			
CardiAQ Valve Technologies	Edwards Lifescience	2015	$400M including $350M paid upon completion of the transaction	10 patients implanted
Tendyne	Abbott	2015	$250M including $225M paid upon completion of the transaction	Several patients implanted as part of the feasibility study
Twelve	Medtronic	2015	$458M including $408M paid upon completion of the transaction	10 patients implanted as part of the feasibility study
MValve	Boston Scientific	2015	$200M	1 patient implanted

Source: Transactions completed since 2015 in the field of mitral valve repair or replacement extracted from the Merger Market database.

5.2.3.2. The Kalios implant: the only minimally invasive adjustable ring for mitral valve repair

► **The Kalios implant**

Mitral valve repair has historically been treated by annuloplasty. This surgical technique reduces the calibre of the mitral annulus through shortening by plication* the attachment of the small valve, the support point being taken on both commissures.



The rings designed by Professor Alain Carpentier, member of the Scientific Committee of Affluent Medical, with the Edwards Lifesciences laboratory are repair devices implanted in humans for more than 30 years as part of open-heart surgery and establishment of extracorporeal blood circulation. These rings allow the repair of the mitral valve by restoring the size and anatomical shape of the mitral valve and thus preventing recurrent regurgitation.

Carpentier Edwards ring

Source: Edwards Lifesciences

The core, often of solid titanium, provides strength and durability.

The polyester fabric suture ring promotes tissue growth and anchoring of the ring and minimises the risk of dehiscence.

The D-shaped mitral ring re-establishes the anteroposterior and transverse diameters of a normal mitral valve for optimal hemodynamic performance.

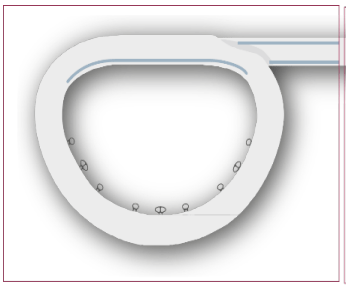
Based on this annuloplasty technique, which is the gold standard for mitral valve repair, but which has limitations related to those of invasive surgery and new regurgitation in the event of further deterioration of the mitral valve, Affluent Medical has developed the Kalios adjustable ring which is the only ring that can be adjusted in stages in the days or months after implantation, in order to adapt percutaneously the size and shape of the ring to the specific needs of the patient, the severity of the disease and its progression. Kalios will be available in several sizes to cover the majority of the market.

Kalios is the only mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral regurgitation at any time after implantation, repeatedly and with a beating heart,

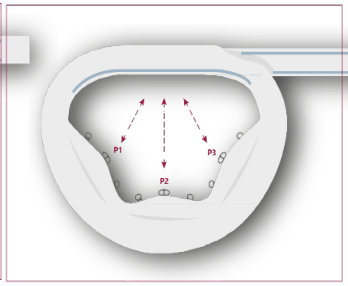
thus avoiding a new operation. Affluent Medical estimates that Kalios would avoid a new procedure for potentially 40% of patients. Kalios thus improves the effectiveness of mitral valve repair with an adjustment of the ring at the time of implantation and an improvement in the patient's quality of life in the short and long term in the event of progression of the pathology with a new percutaneous adjustment of the ring and therefore no new intervention.

In the shape of a capital D, this chromium-cobalt alloy ring can be precisely adjusted to the anatomy, if necessary several times in the months following the operation, by means of a balloon catheter.

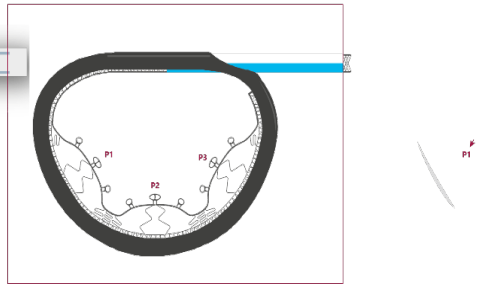
This percutaneous adjustment of the ring is carried out by a balloon catheter with connectors, similar to balloons for angioplasty: the balloon is inserted into the connection line of the ring through a subcutaneous entry that can be retrieved by a small incision of the skin, most often in the subclavian region.



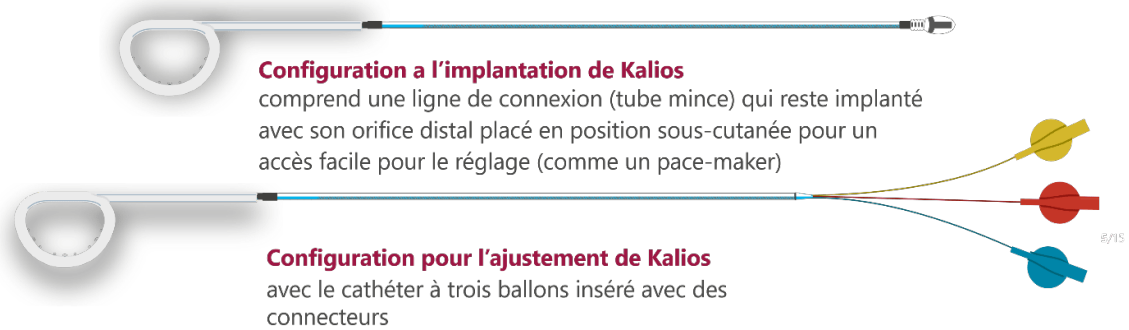
The Kalios implant is in the shape of a traditional Carpentier ring



Zones P1, P2 and P3 can be extended after implantation to move two edges of the valve ring closer



The extension is enabled by the use of a technology developed by Affluent Medical



FR	EN
Configuration à l'implantation de Kalios	Configuration at the Kalios implant
comprend une ligne de connexion (tube mice) qui reste implanté avec son orifice distal placé en position sous-cutanée pour un accès facile pour le réglage (comme un pace-maker)	consists of a connection line (thin tube) that remains implanted with the distal orifice placed in a sub-cutaneous position for easy access in order to adjust it (like a pace-maker)
Configuration pour l'ajustement de Kalios	Configuration for the Kalios adjustment
avec le cathéter à trois ballons inséré avec des connecteurs	with the three-balloon catheter inserted with the connectors

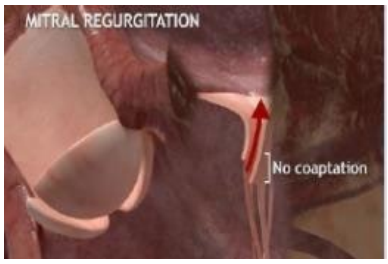
The innovative adjustment option offered by Kalios has many advantages for the monitoring of this disease, which remains progressive and may subsequently recur in mitral regurgitation.

With traditional non-adjustable rings, surgeons tended to implant rings smaller in size than required so as to anticipate the progressive risk at the risk of creating a narrowing of the mitral orifice. With Kalios, choosing the size that is necessary to correct the leakage is sufficient, while retaining the option of adjusting the ring according to changes. The echocardiographic monitoring of the patient makes it possible to anticipate the adjustment decision as soon as there are signs of change and to protect the ventricle from the risk of deterioration and to avoid having to redo a long and serious open-heart procedure with serious consequences.

The Kalios ring is implanted in the heart in a similar way to other rings. It takes about 20 to 30 minutes for an operation that lasts between one and a half to two hours. The incision is more or less long thanks to the use of minimally invasive techniques. Adjustment is infinitely simpler: a one-centimeter incision on the end of the subcutaneous line under local anaesthesia allows the balloons to be introduced to make the necessary adjustment under ultrasound control. This manoeuvre makes it possible to anticipate the evolving risks of this condition. It can be performed in 15 to 20 minutes, does not require hospitalisation and can be performed again as long as the adjustment possibilities are not fully used. Kalios thus significantly reduces the risks for patients and the costs for the healthcare system.

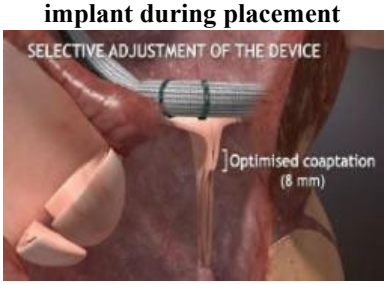
Implantation procedure for the Kalios ring

Before surgery

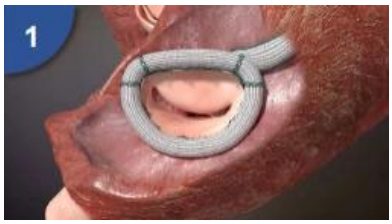


Placement of the Kalios implant

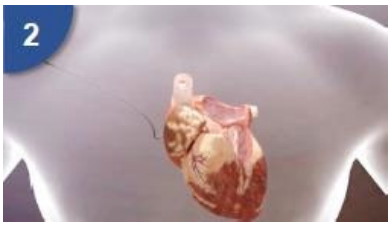
Adjustment of the Kalios implant during placement



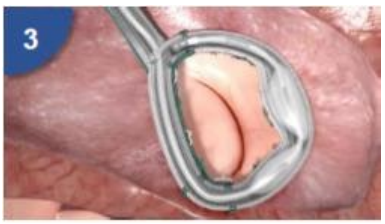
Post-operative adjustment of the Kalios ring



The Kalios ring enables annuloplasty and makes other percutaneous adjustments possible in the event of recurrent mitral regurgitation.



The distal end of the connection line routed to the subcutaneous subclavian region will be used for any necessary secondary adjustments.



The adjustment is performed by inserting a three-balloon catheter that can be inflated into three pre-defined areas to correct recurrent mitral regurgitation. The adjustment is checked under ultrasound.

► **Preclinical and clinical completed studies - Kalios clinical development plan**

The Kalios ring has undergone numerous preclinical tests on animals, aimed at demonstrating:

- the perfect biocompatibility of the device;
- the safety of the surgical implantation;
- proof of concept; and
- efficiency and ease of adjustment.

Under certified Good Laboratory Practice (GLP) tests, several animals were implanted, with chronic implants of differentiated duration according to the protocol, of maximum duration of 150 days. The results of this last test, carried out in an internationally renowned French laboratory, the Institut

Mutualiste de Montsouris Recherche (IMMR), met all expectations and allowed authorisation from the competent authorities for the launch of the clinical phase.

A 90-day preclinical study on six *Ile de France* breed ewes weighing 60/65 kg was carried out. Five ewes had a perioperative adjustment:

- without technical problems;
- with an effective adjustment controlled by ultrasound;
- average gradient: 0.8 +/- 0.45 mmHg versus 2.3 +/- 0.50 mmHg
- orifice area: 7.3 +/- 1.00 cm² versus 4.1 +/- 0.35 cm²
- coaptation height 7.1 +/- 0.7 mm versus 8.7 +/- 0.9 mm

These in vivo preclinical results confirm, in healthy animals without any pre-existing mitral pathology:

- the safety of the implanted device;
- the performance of the adjustment;
- ease of use;
- proof of concept.

Affluent Medical conducted a first study on humans (*FIH - First in Human*), called Optimise, with the implantation of the Kalios ring on five patients between January and May 2018 by Professor Martin Andreas, principal investigator of this feasibility study, at the Vienna General Hospital (AKH) in Austria. A one-year follow-up was carried out. The results of the study show that the primary endpoint was met, thus confirming the surgical safety of Kalios.

This FIH study was carried out with the help of five patients: mean age 74.4 (+/- 6.2 years)/NYHA* Class 2 (+/- 2)/Euroscore* 2.1 (+/- 0.9).

No mortality was observed and no adverse event due to the device was observed. Four patients (80%) had a perfect result with no residual leaks and one patient had a minimal trace of leakage with no hemodynamic consequences. The co-adaptation height of the two valves increased from 3 (+/- 1) mm pre-operatively to 6 (+/- 1) mm post-operatively, testifying to the quality of the result. All the patients had simple post-operative consequences (one of them, due to his pre-operative state, remained in intensive care for a longer period of time), and all patients were asymptomatic on discharge.

The purpose of this study was to demonstrate the safety of the device and did not include any adjustment of the post-operative band, unlike the ongoing Optimise II study.

Following the positive results of the Optimise study, Affluent Medical initiated a pivotal Optimise II clinical study of its Kalios device with a view to obtaining CE marking.

This study, which provides for the recruitment of 62 patients, was launched in November 2019. As at the date of approval of the Registration Document, 15 patients had benefited from the implantation of the Kalios device, including three for whom the band had been adjusted, with Affluent Medical planning to finalise recruitments in the 2nd semester of 2021 subject to the impact of the Covid-19 pandemic, which led to the extension of the study by around one year with the delay in the recruitment of around fifty patients (see to section 3.11 of the Registration Document). Patient recruitment has in fact been slowed down by this pandemic which has considerably reduced the number of patients implanted in 2020 and early 2021. However, patient monitoring was carried out normally. The clinical study is taking place in nine centres, one in Austria (Vienna), two in Germany (Passau, Leipzig), one in Switzerland (Lausanne) and five in Italy (Florence, Palermo, Cotignola, and two in Milan). Interim results for the first 15 patients could be published in the course of the 2nd semester of 2021. The patients will be followed up over one year. The final results of the study should therefore be published in the 2nd semester of 2022.

This study should make it possible to submit the CE marking application in the 3rd quarter of 2022 for anticipated awarding in the 4th quarter of 2022.

► **Competitive positioning of Kalios in the mitral valve repair market**

As part of its technology monitoring, Affluent Medical has identified around twenty players operating in the field of mitral valve repair with technologies based on rings, ropes or clips.

The most advanced entities are as follows (it being specified that no device other than Kalios offers a post-operative transcatheter adjustment that can be performed multiple times):

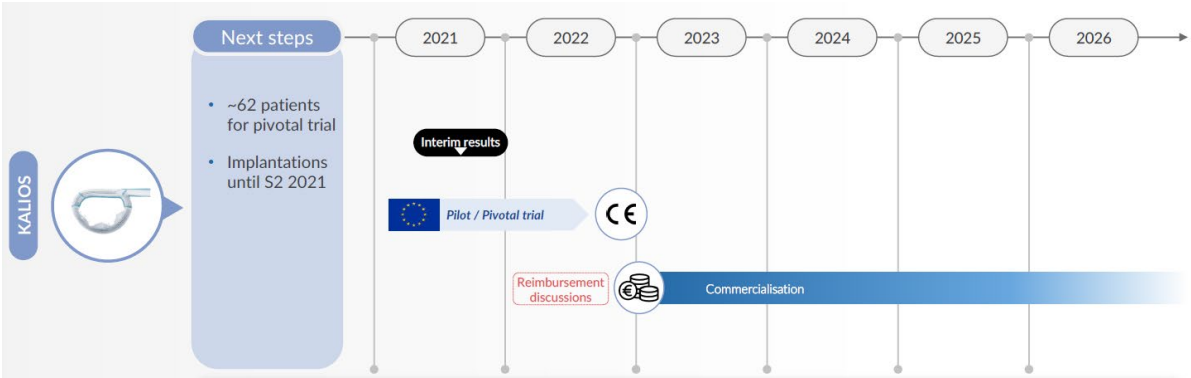
Device		Description	Status
Mitraclip Abbott		Percutaneous mitral repair using a clip system	CE marking FDA authorisation
Pascal Edwards LifeScience		Percutaneous mitral repair using a clip system	CE marking
Cardioband Edwards Lifescience / Valtech		System for mitral valve reconstruction via annuloplasty Adjustment during beating heart surgery	CE marking FDA authorisation
Cardinal Edwards Lifescience / Valtech		System for mitral valve reconstruction via annuloplasty Adjustment during beating heart surgery only	CE marking FDA authorisation
Attune Abbott		System for mitral valve reconstruction via annuloplasty Adjustment possible during stopped heart surgery only	CE marking FDA approval
Kalios Affluent Medical		Annuloplasty with adjustable ring during the operation and several times after the operation	Pivotal European study in progress

The various medical devices presented have complex implantation techniques, requiring a long and expensive learning curve. The majority of implants have intraoperative adjustments. The Kalios implant has the advantage of being able to be implanted using traditional minimally invasive cardiac surgery, as practised all over the world, even in the poorest countries. The adjustment, which is performed without further invasive surgery, can be performed several times, without requiring very sophisticated equipment or involving a full intervention team. The adjustment requires the use of a simple ultrasound machine.

Summary diagram of the competitive positioning of the Kalios product compared to the most comparable rings[43]

► **Strategy and objectives for the development of Kalios**

Affluent Medical's objective is to be able to market Kalios in Europe by 2023 after obtaining CE marking in the 4th quarter of 2022.



Affluent Medical benefits from intellectual protection for its Kalios device until 2037 with various components protected both on the ring, the fact that it can be adjustable and the surgical method for its placement.

The Group does not intend to conduct clinical studies on its own in the United States with a view to marketing in this region. The Group could enter into a partnership with a major player in cardiology to conduct clinical studies and eventually market the Kalios ring in the United States.

The added value of the Kalios ring permits Affluent Medical to seek to establish a unit selling price of around €4,000, compared to the selling price of the best non-adjustable conventional rings that range from €1,000 to €2,000. For Affluent Medical, this premium on the price is justified given the differentiating aspect of Kalios residing in its ability to significantly improve the immediate results of surgery and facilitate re-operations in case of recurrence without having to operate on the patient again. In fact, the post-operative adjustment of the ring can replace a second surgical procedure, which in the majority of cases would be necessary and have a major economic impact of €20,000 to €40,000 per repeated surgery for insurers.

[43] Comparative table drawn up using the Company's estimates on the basis of the publicly-available information

Taking into account these improvements and the importance of the therapeutic and economic value provided by Kalios, the only mitral ring that can be readjusted multiple times post-operatively and without repeat surgery, Affluent Medical intends to rely on the publication of the interim results of the Optimise II study to initiate discussions in 2022 for the coverage of the cost of the Kalios ring in Europe (see Section 5.3.6 of the Registration Document) through a pharmaco-economic study conducted in the 1st semester of 2022. The Company intends to select and sign distribution contracts in Eastern and Northern Europe during the same period and to set up a sales and marketing team in the 2nd semester of 2022 for the commercial launch of Kalios in the 1st semester of 2023.

5.2.3.3. The Epygon implant: the only physiological mitral valve bioprosthesis implanted via a transcatheter route capable of mimicking the native mitral valve.

► **The Epygon implant**

In a certain number of cases, the mitral valve cannot/can no longer be repaired. Therefore, it must be replaced to treat mitral regurgitation. Until now, this replacement has only been done by open-heart surgery, requiring a sternotomy (opening of the ribcage through a vertical incision in the sternum) and the establishment of extracorporeal blood circulation.

Following the example of the development of TAVI for the replacement of the aortic valve by the percutaneous route, that is to say without open surgery, many projects have been developed to design a transcatheter mitral valve (TMVI - *Transcatheter Mitral Valve Implantation*). To date, several devices are at the clinical or preclinical stage. Only the Tendyne system by Abbott Vascular for implantation via the transapical approach obtained CE marking in 2020, enabling it to start marketing the product.

Epygon is the only transcatheter valve bioprosthesis under development that aims to imitate the native mitral valve, restore physiological blood flow in the heart and minimise the ventricular work load.

Epygon implant

Where many transcatheter mitral valves have a design derived from an aortic valve or a tricuspid valve, Epygon is a D-shaped ring to attain a perfect match between the prosthesis and the native annulus:

- the D-shaped nitinol stent mimics the native annulus while minimising perivalvular leakage;
- the asymmetric ventricular stent ensures minimal interference with myocardial contraction and prevents obstruction of blood flow from the left ventricle;
- the ventricular stent has one leaflet only;
- a minimum atrial protrusion* guaranteeing a negligible thrombosis risk; and
- a reduced ventricular protusion avoiding acting as a mechanical obstacle to the ejection of blood into the aorta.

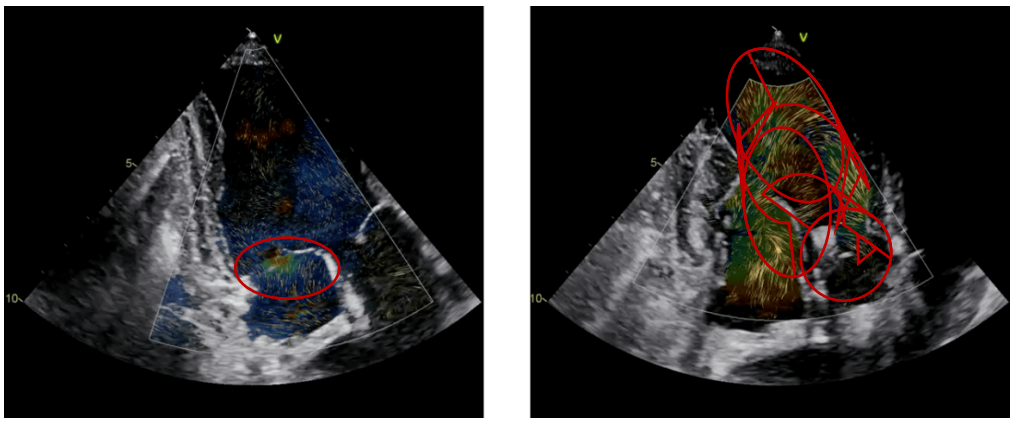
The Epygon physiological mitral valve adapts to the natural functioning of the heart with a physiological opening of the mitral valve, a normal systolic and diastolic functioning of the left ventricle, an absence of obstacle to ventricular ejection and an equally normal intraventricular vortex avoiding the risk of blood clots. The valve is made up of fully biocompatible elements, including bovine pericardium

specially treated to avoid any risk of calcification. Epygon is a monobloc implant that will be available in several sizes to cover the majority of the market.

In addition, the valve has a strong anatomical anchorage with engagement arms to maintain the papillary muscles and prevent left ventricular sphericity. There is no risk of bioprosthesis migration. As a monobloc device, Epygon is easier to implement than other devices.

Regarding optimised blood circulation to mimic the natural valve, Affluent Medical conducted an imaging study, with the support of GE Healthcare, of the pre-and post-implantation blood flow and demonstrated that the heart does not need to provide additional effort to evacuate blood and regain a normal rhythm. The Epygon valve restores the natural blood flow between the atrium and the left ventricle and eliminates mitral regurgitation.

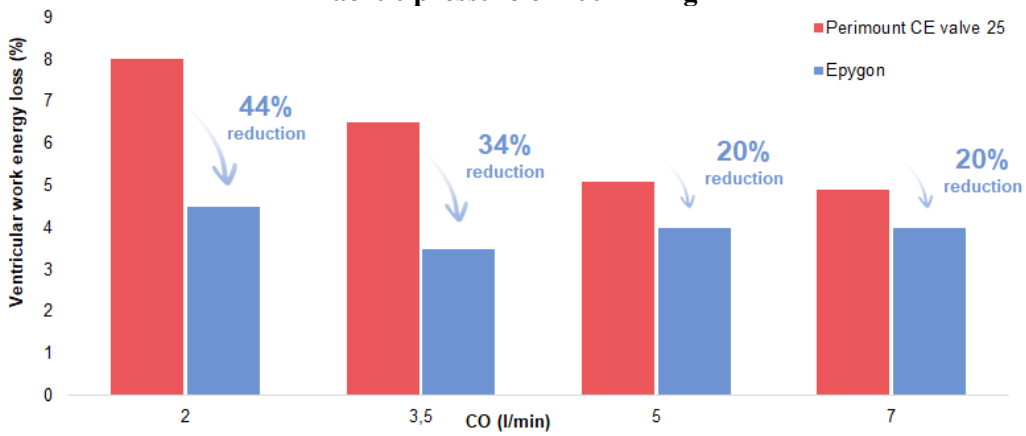
Imaging of the pre-and post-implantation blood circulation



Mitral regurgitation | Restoration of natural blood flow

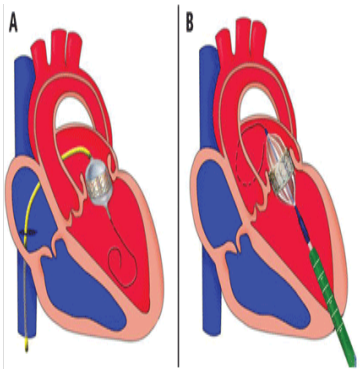
A comparison study relative to a tricuspid valve adapted for aortic indications (Perimount CE valve 25 from Edwards Lifesciences) has demonstrated that the Epygon valve reduces the effort furnished by the heart by 20% to 44% depending on the volume of blood pumped.

Energy loss (in % of ventricular work) in pre-clinical tests at 2 - 3.5 and 7 l/min at an average aortic pressure of 100 mmHg

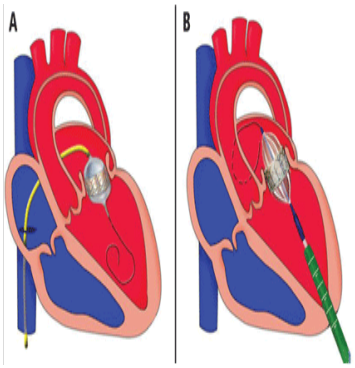


In many cases, this will permit recovering better cardiac function, especially in frail and weakened patients, with a very low ejection fraction (effective blood flow pumping). Restoring natural blood flow is key to recovering the functioning of the left ventricle and thus the patient's quality of life, thereby avoiding the risk of developing heart failure or re-hospitalisation for mitral regurgitation.

It is anticipated that the Epygon mitral valve bioprosthesis can be implanted via a transcatheter approach via the transapical route first, then via the transseptal route.



Transapical route



Transseptal route

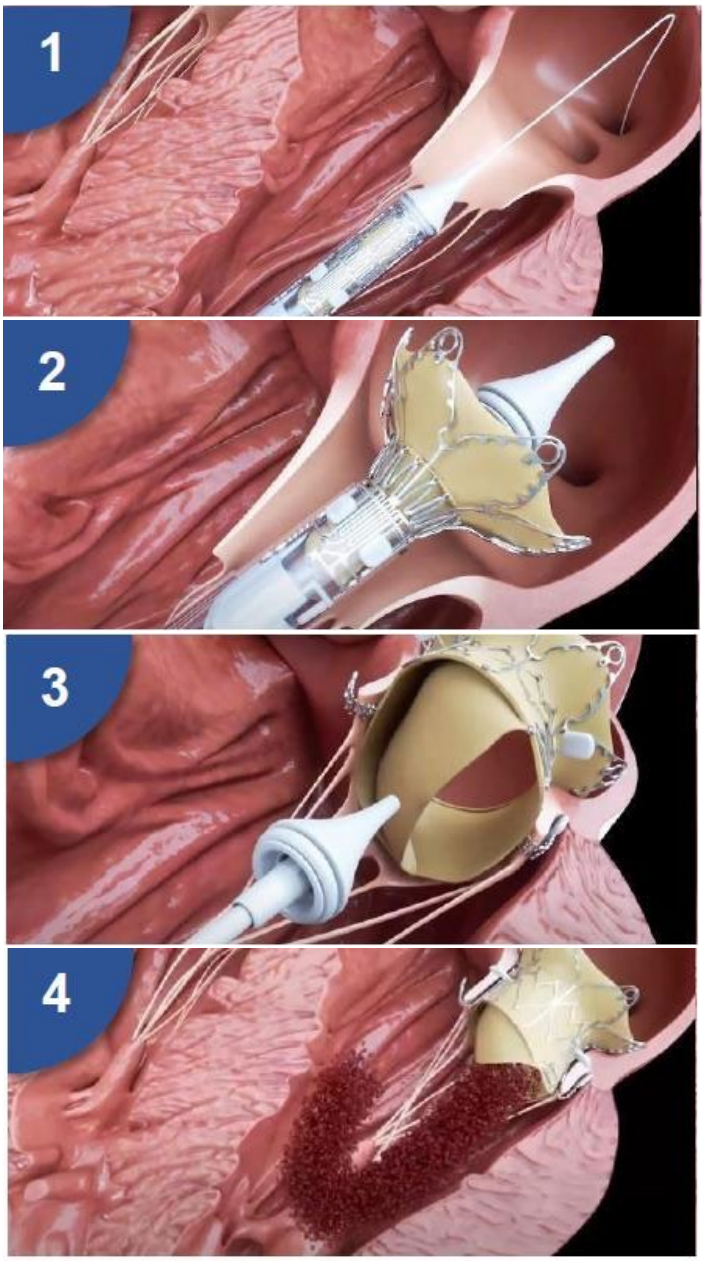
In this type of minimally invasive operation, the mitral valve is brought to the desired location via the large vessels of the body or through a slight incision in the chest without open-heart surgery or extracorporeal blood circulation. The positioning system or delivery catheter is adjusted to the approach considered. The transapical approach is the easiest but requires a chest incision near the heart to reach the apex* (tip of the heart). The implantation system is guided towards the left ventricle through the apex and reaches the mitral valve to be replaced.

Affluent Medical designed Epygon's transapical implantation and anchoring systems for one-handed use, with guidance speed control, safety devices, good ergonomics and ease of use. The patented anchoring system is one of the advantages of Epygon.

Epygon transapical implantation system

In 2020, Affluent Medical began developments to design a transseptal implantation system due to this being less invasive. In this case, the implantation catheter is inserted by the femoral or iliac vein and guided through the inferior vena cava to reach the right atrium of the heart. Here, the prosthesis delivery catheter crosses the interatrial septum to reach the left ventricle of the heart directly at the mitral valve. The surgeon, guided by fluoroscopy and a three-dimensional ultrasound system, reaches the correct implantation position for the bioprosthesis.

When the delivery position and orientation are optimal, deployment of the valve can be initiated with the use of a patented hydraulic system developed for the Epygon valve. The tube covering the valve is withdrawn gradually and the self-expanding bioprosthesis is positioned in the diseased native valve. The Epygon deployment process takes less than ten minutes.



The implantation system is advanced to ensure optimal central placement within the native mitral valve

The atrial part of the device is gradually released; the "petals" are deployed to obtain the desired D-shaped position

The valve is gently drawn towards the mitral annulus while two anchoring arms are attached to the posterior and anterior leaflets

The bioprosthesis is able to restore physiological blood flow in the ventricle and keep the native leaflets under traction

The implantation procedure is much faster than for open heart surgery and less disabling. Once the procedure is finished, the implantation system is removed from the patient's body.

► **Preclinical studies conducted - Epygon clinical development plan**

After the initial design phase of the valve and the delivery system, Affluent Medical conducted a comprehensive preclinical feasibility study to consolidate the final prosthetic design and set up test protocols.

Ex vivo and in vivo preclinical tests were launched to optimise the design of the bioprosthesis and delivery systems and to define and mimic the actual implantation technique.

In vitro tests carried out on Epygon valves prototypes of three different sizes have demonstrated in pulsatile flow tests a physiological fluid dynamic with pressure gradients and energy consumption significantly lower (up to 40%) than the best surgical bioprostheses, giving the left ventricle a greater possibility of recovery. The same optimal results were obtained with a representative number of Epygon prostheses that successively reached the 200 million required by ISO 5840 guidelines. The in vitro tests

(biocompatibility, cytotoxicity, pyrogenicity, haemocompatibility, mechanical fatigue tests, durability tests, corrosion tests) confirmed the quality of the materials composing the device.

Ex-vivo tests were performed in isolated animal and human hearts to assess anatomical adjustment and verify the prosthesis anchoring system. In parallel, a long-term preclinical campaign on animals (three to five months) was carried out with the aim of verifying in vivo the resistance and durability of the prosthesis and also its implantation on an animal model under operating conditions similar to those dedicated to humans as well as angiographic, radiographic and three-dimensional ultrasound checks. These tests made it possible to study the hemodynamic performance and, once explanted bioprostheses, their macroscopic aspects and the state of the metallic elements and the histology of the tissues.

The currently-defined implantation procedure is transapical access (direct access by the ventricular apex). Different sizes of Epygon bioprostheses have been tested in qualification studies aimed at collecting the necessary data for the first human implants.

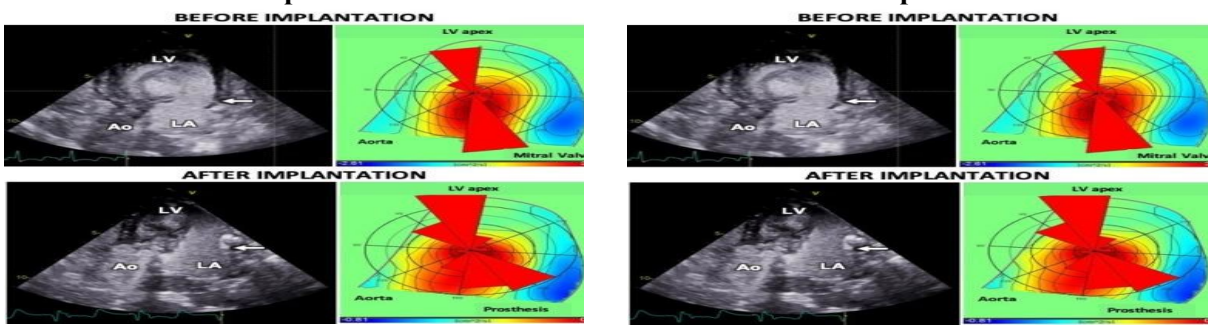
Developments for transseptal implantation were launched in 2020 and will continue in 2021 and 2022.

The results of the preclinical study were presented at the AATS Congress in New York in April 2020. The presentation entitled "*Preclinial results of innovative transacther mitral prothesis specially designed to maintain physiological left ventricular vortex flow*" showed that preclinical in vivo studies confirm the preservation of a physiological blood flow within the left ventricle (vortex) and an optimal adjustment to the anatomical structures, this favouring the recovery of the functions of the left ventricle after elimination of mitral regurgitation.

The Epygon mitral bioprosthesis, designed with a self-expanding D-shaped stent and a single-leaf bovine pericardium structure, provides physiological asymmetric intraventricular flow. The coaptation is not central, but against the posterior wall of the stent, in order to avoid any deformation induced by contraction of the left ventricle. In addition, the two anchoring systems capture and pull the native valves to reduce the protrusion of the device in front of the exit port of the left ventricle, which maintains traction on the papillary muscles preserving the shape of the left ventricle. Twelve juvenile sheep (age 10 ± 1 month, weight 41 ± 1 kg) were implanted consecutively by the transapical approach with mitral prostheses of sizes 34 mm and 38 mm. The post-implantation ultrasound was performed immediately after implantation and at three months. The procedure was successful in 100% of cases. The ultrasound analysis showed a normal intraventricular blood flow both in terms of volume and orientation of the vortex with preservation of the physiological anti-clockwise rotation. No obstruction of the left ventricular outlet, valvular thrombosis or haemolysis was observed. The explantations performed showed no intracardiac thrombus and a normal integration process between the prosthesis and the surrounding myocardial tissue.

Ultrasound analysis of intraventicular blood flow before and after implantation

Before implantation | **After implantation**



The clinical feasibility study of the Epygon implant, called Minerva, obtained all the necessary approvals from the regulatory authorities and also from ethics committees. The Minerva study is a single-arm non-randomised prospective study. The aim of the study is to ensure the safety and technical feasibility of implanting the Epygon mitral valve with a transapical trans-catheter system.

The Minerva study provides for the inclusion of around fifteen patients with a planned recruitment in four centres: one in Austria (Vienna), one in Italy (Florence) and two in Spain (Murcia and Madrid). The investigator in charge of this study in Austria also acts as investigator for the Optimise II study on Kalios.

Regulatory approvals have been obtained in all three countries and only the approval from one of its Spanish centres is still pending. As the training of investigators has been completed, recruitment should be launched in the 1st semester of 2021 and end in the 3rd quarter of 2021. Patients will be monitored over a period of 12 months. The Company intends to publish the interim results of the Minerva study in the course of the 1st semester of 2022 and full results in the 2nd semester of 2022.

Immediately after the Minerva feasibility study, Affluent Medical intends to launch, in the 2nd semester of 2022, a pilot study in four countries in Europe as well as a feasibility study and a pivotal study in the United States with a view to obtaining the various regulatory approvals in these geographical areas. These studies should take place in parallel between the 2nd semester of 2022 and the 1st semester of 2025. Concerning the United States, the Company intends to launch in the 2nd semester of 2021 the work required to conduct a preclinical study to be able to submit a dossier to the FDA for the conduct of a feasibility study.

► **Competitive positioning of Epygon in the mitral valve replacement market**

- Positioning of Epygon compared to traditional surgery:

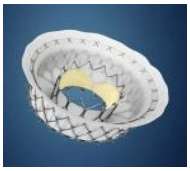
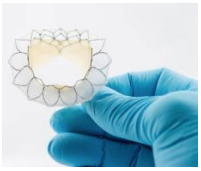
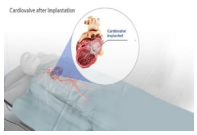
The traditional mitral valve replacement technique is performed by placing a mechanical or biological valve (depending in particular on the age of the patient) through open surgery which is onerous for the patient. The development of minimally invasive transcatheter mitral valve replacement surgery (TMVI) is expected to grow strongly, like TAVI for aortic valve replacement, given all of the advantages that this type of intervention offers.

	Conventional open heart surgery		**EPYGON AFFLUENT MEDICAL**
PRODUCTS	 Mechanical valve	 Biological valve	
ADVANTAGE	- The only intervention possible to date for the replacement of the mitral valve		- No sternotomy (minimally invasive surgery) - No extracorporeal blood circulation ► Time savings of approximately 50% to 60% over the total duration of the intervention - Operation less traumatic for the patient - Shorter hospital stay and faster recovery time ► Time savings of approximately 70% to 80% for hospital stay and recovery time - Lower risk of infection
STATUS	Gold standard with transactions carried out since the 1970s		In clinical phase

- Positioning of Epygon in relation to other transcatheter mitral valves:

The development of transcatheter mitral valves is currently being considered by a dozen or so players in medical devices. Only one valve has to date obtained CE marking: the Abbott Vascular Tendyne valve, but none has yet received FDA approval. Most transcatheter mitral valves are still in the development or clinical phase. The implantation approach predominantly studied by these players is transapical.

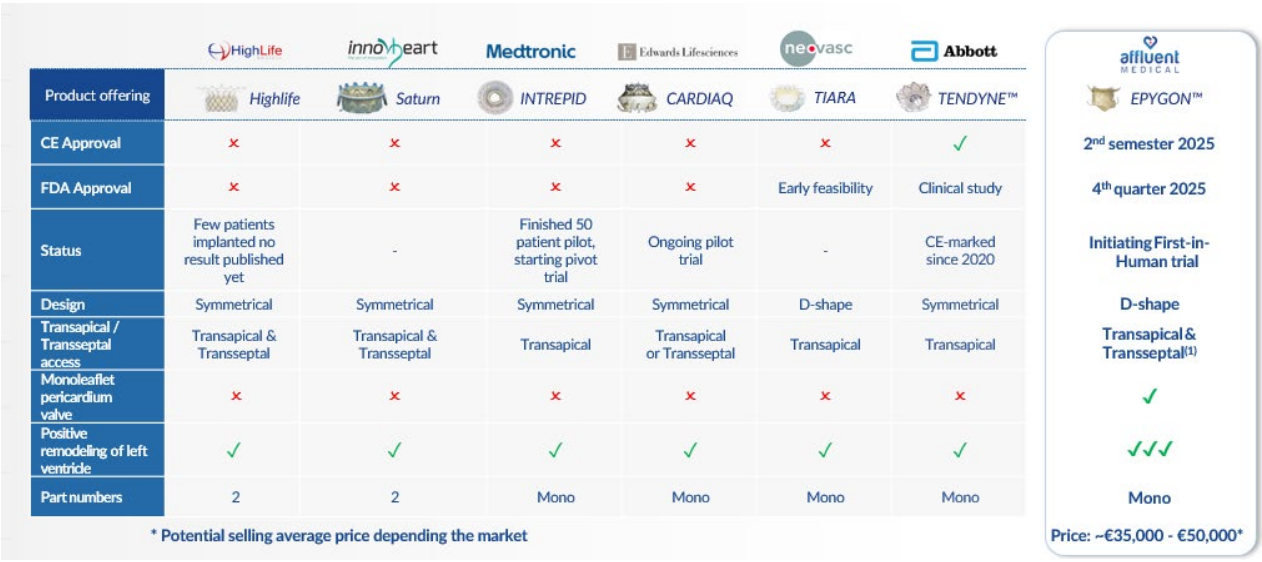
The main players in this market are:

Device		Description	Status
Tendyne Abbott		Symmetrical implant / self-expanding three-sheet of two nitinol stents covered with a treated porcine pericardium implanted transapically	CE marking obtained in January 2020
Intrepid Medtronic		Implant with a self-expanding nitinol structure and bovine pericardium leaflets implanted via a transapical and transfemoral delivery system Double symmetrical stent	Appolo randomised trial vs surgery with 1,600 patients in the United States and Denmark
Saturn InnovHeart		2 components Symmetrical shape Transapical and transseptal route	Ongoing feasibility study with 20 patients in Lithuania - Results expected in 2022
Tiara Neovasc		Self-expanding implant with bovine pericardium, D-shaped, tricuspid, implanted transapically	Ongoing Tiara II study with 115 patients Feasibility trial conducted in the United States Results January 2021
Cardiovalve		Transseptal and transfemoral* mitral valve replacement system	Feasibility study underway in Europe and the United States
Cardiaq Edwards Lifesciences		Self-positioning and self-docking symmetrical implant for transapical and transfemoral implantation	First in human clinical trials
HighLife Medical		Double components - 3 sheets transseptal route	Ongoing feasibility study on five patients
Epygon Affluent Medical		D-shaped valve, asymmetrical, one single leaflet Self-expanding stent with bovine pericardium	Ongoing feasibility study on 15 patients

		Physiological restoration	

If TMVI becomes the gold standard for mitral valve replacement, Epygon would be the only currently known medical device to reproduce the physiology of the filling of the ventricle in the same manner as the native mitral valve. This real difference allows the already failing ventricle to save its energy to perform its pumping function.

Summary diagram of the competitive positioning of the Epygon product compared to the most comparable transcatheter mitral valves[44]



	HighLife	innoheart	Medtronic	Edwards Lifesciences	neovasc	Abbott	affluent MEDICAL
Product offering	Highlife	Saturn	INTREPID	CARDIAQ	TIARA	TENDYNE™	EPYGON™
CE Approval	×	×	×	×	×	✓	2nd semester 2025
FDA Approval	×	×	×	×	Early feasibility	Clinical study	4th quarter 2025
Status	Few patients implanted no result published yet	-	Finished 50 patient pilot, starting pivot trial	Ongoing pilot trial	-	CE-marked since 2020	Initiating First-in-Human trial
Design	Symmetrical	Symmetrical	Symmetrical	Symmetrical	D-shape	Symmetrical	D-shape
Transapical / Transseptal access	Transapical & Transseptal	Transapical & Transseptal	Transapical	Transapical or Transseptal	Transapical	Transapical	Transapical & Transseptal(1)
Monoleaflet pericardium valve	×	×	×	×	×	×	✓
Positive remodeling of left ventricle	✓	✓	✓	✓	✓	✓	✓✓✓
Part numbers	2	2	Mono	Mono	Mono	Mono	Mono

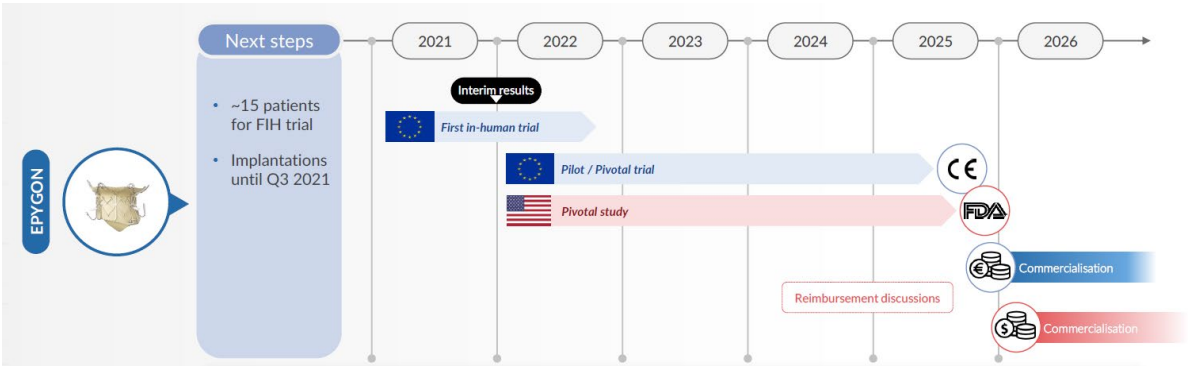
* Potential selling average price depending the market

Price: ~€35,000 - €50,000*

(1) Preclinical study

► **Strategy and objectives for the development of Epygon**

Affluent Medical's objective is to be able to market Epygon in Europe by the end of the financial year 2025 after obtaining CE marking in the 2nd semester of 2025 and FDA approval in the United States in the 4th quarter of 2025. The Epygon pivotal study in Europe is to be conducted at the same time as the feasibility study (*early feasibility study - EFS*) in the United States, followed by a pivotal study with a view to obtaining FDA approval. Affluent Medical does not rule out entering into a partnership with a leading local player in cardiology to ensure its commercial or even clinical development in the United States if the opportunity arises.



[44] Comparative table drawn up using the Company's estimates on the basis of the publicly-available information

Affluent Medical benefits from intellectual property protection for its Epygon device until 2038 with various components protected both on the unique structure of the physiological implant (shape of the valve, pericardium treatment, stent, etc.), the grip system and the operating method for its placement with a specific transcatheter.

The selling price defined for Epygon implants will depend on the implantation technique. The transseptal delivery system will have a higher price than the transapical system due to the complexity of the implantation device. Given its potential superiority over competing products as the only physiological mitral valve bioprosthesis implanted via a transcatheter route capable of mimicking the native mitral valve, early repayments (estimates based on existing repayments for aortic valves) and the implantation technique concerned, the average unit selling price to the end customer could be between €35,000 and €50,000 per implant.

The structural heart sector is a very active sector in terms of mergers and acquisitions with large-scale transactions carried out in recent years (such as for example the acquisition of St-Jude Medical by Abbott a price in the order of €26.3 billion) or very specific transactions in the context of the acquisition of a particular technology or product (acquisition of Cephea or Tendyne by Abbott, Harpoon Medical by Edwards Lifesciences, etc.) at a clinical stage with relatively few patients treated and for significant prices of several hundred million euros. In total, since 2015, ten transactions involving companies addressing the mitral valve market were identified for a total value of nearly two billion euros[45].

Affluent Medical intends to use the publication of the interim results of the pivotal study in 2023 to launch discussions in 2024 for the reimbursement of the Epygon transcatheter mitral valve in Europe and the United States (see section 5.3.6 of the Registration Document).

5.2.4. Kardiozis: a technology for the treatment of abdominal aortic aneurysm without open surgery

5.2.4.1. Abdominal aortic aneurysm: a degenerative pathology with fatal consequences in case of rupture

► Abdominal aortic aneurysm

The vascular system is an interconnected network of blood vessels (veins and arteries) connected to the heart and lungs in order to bring oxygen and nutrients to all the organs and tissues of the body. Diseases affecting the vascular system are the result of damage to the blood vessels and can have consequences for the body that are devastating or even fatal such as cerebrovascular accidents (CVA), thoracic or abdominal aneurysms.

Most vascular diseases occur due to prolonged exposure to vascular risk factors such as high blood pressure, diabetes, hypercholesterolemia and obesity, which slowly destroy and damage the vascular system. These factors are tending to develop in increasingly younger populations due to an unhealthy lifestyle and a diet too rich in fatty products and sugars causing premature vascular ageing.

Abdominal aortic aneurysm ("**AAA**"), a condition that can lead to death by massive internal bleeding in the event of a rupture in nearly 80 to 90% of cases, is characterised by an enlargement of the abdominal aorta so that the diameter is greater than three centimetres whereas the normal size is about two centimetres.

[45]Merger Market - Operations carried out since 2015 in the field of mitral valve repair or replacement

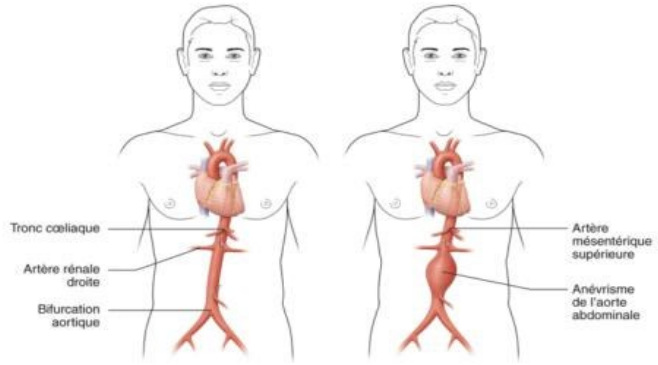


Figure 4.1. Anévrisme de l'aorte abdominale.

Source: Elsevier - Aortic aneurysm

FR	EN
Tronc cœliaque	Coeliac trunk
Artère rénale droite	Right renal artery
Bifurcation aortique	Aortic bifurcation
Artère mésentérique supérieure	Superior mesenteric artery
Anévrisme de l'aorte abdominale	Abdominal aortic aneurysm

People with AAA are most often asymptomatic. They are mainly diagnosed incidentally during medical examinations for other pathologies. Otherwise, the most common symptoms are abdominal or back pain and, when the AAA reaches a certain volume, a throbbing mass can sometimes be palpated in the abdomen.

All aortic aneurysms show continuous growth over the years. The main determinants of the risk of rupture[46] are:

- the diameter: the risk of rupture increases exponentially with the diameter;
- the speed of growth of the aneurysm: a high speed is associated with an increased risk and the larger an aneurysm, the faster it will grow;
- women: women are at three times greater risk than men.

AAA diameter (in cm)	Risk of rupture (in %/year)
< 4	0
4 - 5	0.5 - 5
5 - 6	3 - 15
6 - 7	10 - 20
7 - 8	20 - 40
> 8	30 - 50

Source: Brewster DC, Cronenwett JH, Hallett JW Jr et al. Guidelines for the treatment of abdominal aortic aneurysms. J Vasc Surg 2003; 37 (5): 1106-17

Surgical treatment is recommended when the diametre of an abdominal aortic aneurysm exceeds 5 centimetres or if it increases by more than one centimetre per year. For an aneurysmal diameter of between 3 and 5 centimetres, Doppler ultrasound monitoring of the growth of the aneurysmal diameter, with examinations at a rate depending on the diameter, is carried out with a global therapeutic approach aimed at amending the factors of risk and reducing co-morbidities.

[46] Brown LC, Powell JT. "Risk factors for aneurysm rupture in patients kept under ultrasound surveillance. UK small aneurysm trial participants" Ann Surg 1999; 230:289-96

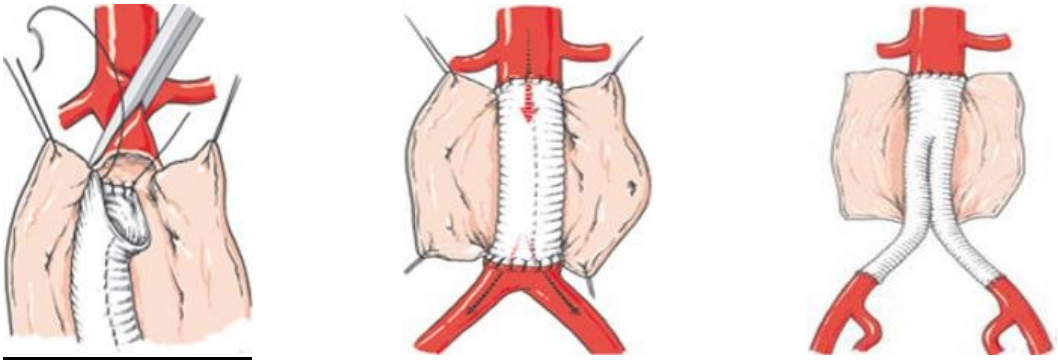
► **Abdominal aortic aneurysm treatment**

The curative treatment of AAA is either surgical or endovascular*.

The surgical treatment consists of the surgical flattening of the AAA and the placement of a synthetic tubular aortic prosthesis. It requires a laparotomy*, and is performed either during a planned surgery, or in emergency in case of aneurysmal rupture. The procedure is performed under general anaesthesia and lasts between two and four hours depending on the type of aneurysm. Patients stay at least one night in continuous care units and at least five days in hospital units. The convalescence period is at least three weeks.

The frequency of post-operative complications is 10 to 30%. These are mainly: cardiac (15%), pulmonary (5 to 12%) or renal (5 to 12%)[47]. Post-operative bleeding, gastrointestinal problems or ischemia of the lower limb are rarer.

Open surgery treatment



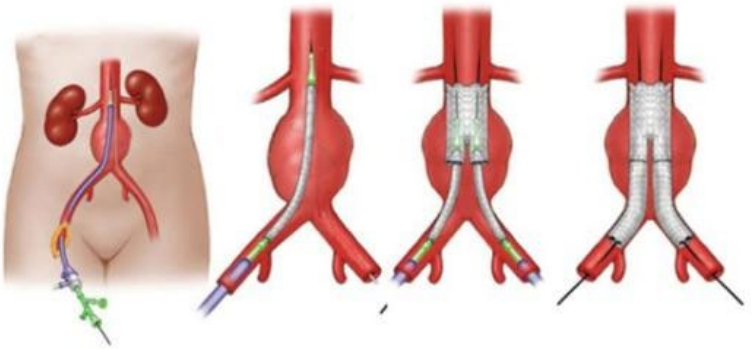
Source: CHIRVTT

Endovascular treatment is a less invasive treatment procedure (percutaneous) than open surgical repair. An incision is made in the groin to allow a catheter containing the stent graft to pass through the femoral artery. This technique of endovascular aneurysm repair, commonly known as EVAR*, consists of excluding the aneurysm from the bloodstream by endovascular implantation of a prosthesis in the AAA, thus creating a new passageway for the blood and strengthening the arterial wall. This technique is usually performed under local anaesthesia. The operation lasts between one and a half and three hours depending on the type of aneurysm. After this procedure, patients stay in a vascular surgery unit for two to three days.

Complications more specific to endovascular treatment are possible: endoleak and migration of the prosthesis. Endoleak occurs when a flow of blood persists inside the aneurysm with, for example, blood circulating between the artery and the prosthesis. Migration takes place when the prosthesis moves. Late aneurysm ruptures can also occur, most of the time in patients who have experienced an endoleak or migration. These complications can be observed after several months or several years and sometimes require reoperation. Therefore, it is very important that the surgeon continues to provide clinical follow-up of patients treated with this approach with regular radiological examinations.

[47]Elkouri S, Gloviczki P, McKusick MA et al. "Perioperative complications and early outcome after endovascular and open surgical repair of abdominal aortic aneurysms" *J Vasc Surg* 2004; 39 (3): 497-505.

Endovascular treatment (EVAR)



Source: Mayo Clinic

Initially, the endovascular technique was mainly reserved for patients suffering from other pathologies, which significantly increased the risks of open surgery. Surgeons have tended to broaden gradually the criteria for recommending endovascular treatment to the point of this becoming the dominant technique in certain countries such as the United States[48].

In 2010, a study called EVAR-1[49] was published with comparative data on the medium- and long-term evolution of patients operated on for AAA by open surgery and by the endovascular technique. These data showed that the number of reinterventions required after an EVAR procedure is relatively worrying with 28% of reinterventions at 8 years compared with only 10% after a traditional surgery. The initial survival benefit for patients treated with stents is lost in the long term with an equivalent mortality of 28% at four years. Open surgery is therefore preferred for younger patients with few concomitant diseases since it is a definitive treatment that requires little or no lifelong monitoring.

Comparison of the two approaches to AAA treatment[50]

	Open surgery	EVAR
Mortality at 30 days	4.3%	1.8%
Mortality at 4 years	28%	28%
Complications after 4 years	9%	41%
Costs after 4 years	Lower	Higher
Reoperation need after 8 years	10%	28%

	Open surgery	EVAR
Advantages	• Final treatment • Little or no lifelong follow-up	• Less invasive method • Shorter hospital stay (2 days) • Lower short-term morbidity and mortality
Drawbacks	• Contraindication for some people (age, related pathologies, etc.) • More invasive method • Longer hospital stay (5/7 days) • Long-term complications of laparotomy (adhesions, incisional hernias)	• Need for lifetime follow-up and serial imaging exams • Increase in the number of reoperations • Persistent risk of rupture

[48] Infoholic Research – 2017: Global Aortic Aneurysm Market – Drivers, Opportunities, Trends and Forecasts 2017-2023
[49] Greenhalgh RM, Brown LC, Powell JT et coll. Endovascular versus open repair of abdominal aortic aneurysm. The United Kingdom EVAR Trial Investigators. *N Engl J Med* 2010; 362 (20): 1863-71.
[50] Greenhalgh RM, Brown LC, Powell JT et coll. Endovascular versus open repair of abdominal aortic aneurysm. The United Kingdom EVAR Trial Investigators. *N Engl J Med* 2010; 362 (20): 1863-71.
Greenhalgh RM, Brown LC, Epstein D and EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR-1 trial 1): randomised controlled trial. Lancet 2005; 365 (9478): 2179-86.

Complications of the EVAR procedure, which therefore require more frequent reoperations, come from type II endoleaks (reflux of collateral arteries causing reinjection of the aneurysm sac). Improvement of implants should make it possible to avoid or reduce these complications and reoperations. It is clearly in this context that Kardiozis is positioning itself with an endovascular technology designed with thrombogenic fibres to reduce the size of the aneurysm and prevent the risk of endoleaks.

The incidence of endoleaks is high from 9.9% to 47% depending on the series analysed in the meta-analysis carried out on the EVAR[51]. The most frequent type II endoleaks (representing 52.7% to 67% of endoleaks according to these same meta-analyses) are the result of non-thrombosis of the collateral arteries covered by the prosthesis. Embolisation is the standard treatment for type II endoleaks. This is a technique whose purpose is to inject into an artery, a substance and/or a material that will make it possible to completely obstruct this artery. The embolising agents can be metal spirals (coils), or glues (Onyx®, Glubran®, Tissucol®). Embolisation can be performed during the implantation of an EVAR in a prophylactic or post-operative setting after detecting type II endoleaks. Embolisation is not perfect, and cases of endoleaks may still persist. Post-operative open surgery treatment remains the ultimate solution as this remains a onerous procedure and can cause an infection risk.

The purpose of monitoring stents is therefore to identify in time and prevent any endoleaks or migrations, in order to treat them before a possible rupture. Thus, the various imaging means for identifying any endoleak, and notably those causing a significant increase in the aneurysm sac (greater than 6 millimetres in 6 months or more than 1 centimetre in 1 year relative to the preoperative diametre), intra or post prosthetic stenosis or possible migration of one of the prosthetic components. 40% of patients treated with the EVAR stents currently available on the market may experience post-operative endoleaks[52], which is why there is a need to monitor any new increase in the size of the aneurysm sac post implantation.

The Kardiozis technology, developed by Affluent Medical, addresses the need to avoid type II endoleaks and the non-absorption of the aneurysm by the inclusion of thrombogenic fibres (see section 5.2.4.2 below).

► The abdominal aortic aneurysm market

Minimally invasive stents currently on the market to treat AAA (sales of which represented a global market of $1.7 billion in 2016[53]).

Unlike the other markets in which Affluent Medical is positioned where few or no medical devices are marketed, there are a significant number of products marketed for the minimally invasive treatment of the abdominal aortic aneurysm. This market is mainly dominated by three players, in order of size: Medtronic, WL Gore & Associates (Gore) and Cook Medical. These players hold more than 85% of the market worldwide; other players exist such as Endologix, Terumo, Jotec, Lombard Medical, Boston Scientific and Cordis.

[51] Powell JT. Et al (Br. J. Surg. 2017 Feb)

[52] Source: AORN Journal, September 2014, Vol 100, No. 3 – Treatment of Abdominal Aortic Aneurysms: The role of Endovascular repair, Phyllis A. Gordon and Boulos Toursarkissian

[53] Infoholic Research – 2017: Global Aortic Aneurysm Market – Drivers, Opportunities, Trends and Forecasts 2017-2023

	NDURANT II MEDTRONIC	EXCLUDER GORE	ZENITH COOK MEDICAL
PRODUCTS			
COMPARISON	Not designed to prevent endoleaks type II.	Not designed to prevent endoleaks type II.	Not designed to prevent endoleaks type II.
ADVANTAGE	Gold standard used in 1 out of 2 EVAR cases. Treats both straightforward and challenging anatomy	Repositionable delivery system with active infrarenal fixation	Maximises seal Endoleaks reduced compared to average.
STATUS	FDA approval CE marking	FDA approval CE marking	FDA approval CE marking

The stents sector for aortic aneurysms is active in mergers and acquisitions or equity raising transactions[54]:

- Medtronic invested in the capital of Arsenal AAA in 2015 and benefited from an option to acquire the remaining share capital (polymeric elastomeric material with in situ curing that fills and seals the aneurysm sac around a stent-graft to reduce type I, II and III endoleaks while preventing graft migration);
- The same year, Medtronic acquired Aptus Endosystems for $110 million (EVAR and TEVAR);
- Endologix and Trivascular Technologies merged in 2015 on the basis of an enterprise value of $221 million (Stent-graft for AAA);
- Terumo acquired Bolton Medical in 2017 for $174 million (Stent graft for AAA and AAT*)

5.2.4.2. Kardiozis: endovascular technology designed with thrombogenic fibres to reduce the size of the aneurysm and prevent the risk of endoleaks

► Kardiozis technology

On the strength of the observation that stents implanted in a minimally invasive manner for the treatment of AAA are a real answer to the problems of open surgery but only provide a marginal advantage over time due to the frequent endoleaks that maintain blood circulation within the aneurysm, Affluent Medical has developed, through its subsidiary Kardiozis, a technology for stents exploiting the properties of thrombosis with thrombogenic fibres that induce the coagulation of the aneurysm and prevent any internal circulation within the aneurysm, i.e. type II endoleaks.

The Kardiozis technology provides a major solution to the problems of type II endoleaks caused by existing stents and their consequences for patients: risks of reoperation and anxiety generated by the increasing possibility of aneurysm potentially leading to rupture and the death of the patient.

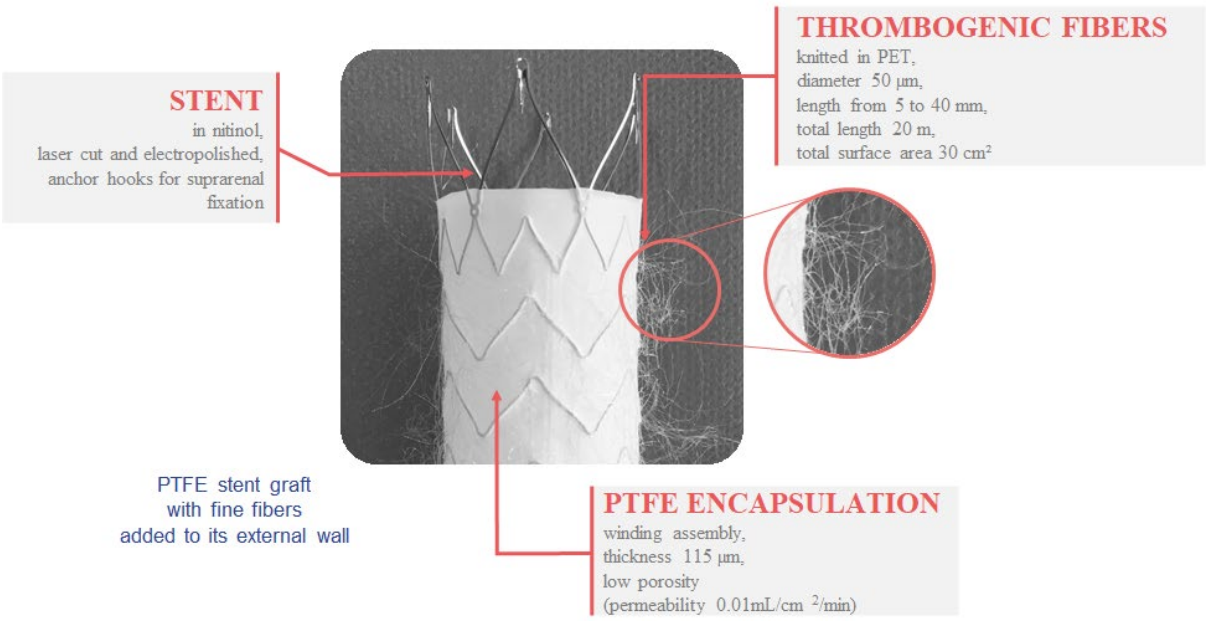
This technology could thus significantly increase the market for endoprostheses, which is limited by the risk of endoleaks, through more systematic treatment, simple monitoring of the evolution of AAA and thus interventions carried out earlier.

[54]Merger Market - Operations carried out since 2015 in the field of stents for the treatment of aortic aneurysms

The Kardiozis technology was designed for endovascular prostheses (a stent graft with a bifurcated structure and legs made of self-expanding metal material in nitinol (shape memory metal), covered with a thin layer of synthetic biomaterial). The Kardiozis technology was designed with thrombogenic fibres integrated into the biocompatible external wall of the prosthesis. These fibres have a length and distribution that allows them to fill the aneurysm evenly after implantation, similar to the thrombogenic "coils" that can be used today, implanted separately in the aneurysm sac after the implantation of a conventional endovascular prosthesis.

These fibres have a thrombogenic effect so as to reduce the aneurysm and prevent endoleaks after implantation.

Kardiozis technology



Source: Affluent Medical - Kardiozis

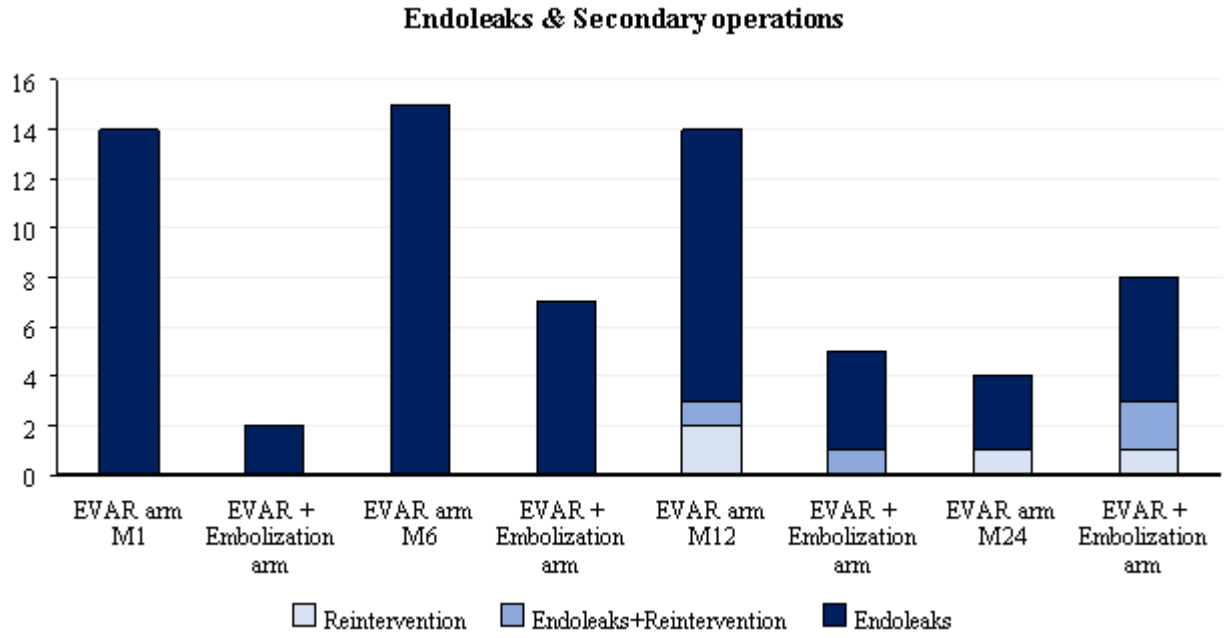
► Results of the Scope studies and the in vitro study

The Scope 1 clinical trial began in 2015 under the supervision of Professor Dominique Fabre, thoracic and vascular surgeon at the Marie Lannelongue - Le Plessis-Robinson hospital, in collaboration with Université Paris-Sud Saclay and with the participation of Professor Frédéric Cochennec, vascular surgeon at the Hôpital Henri Mondor - Créteil, in collaboration with the Université Paris-Est.

Scope 1 is a prospective, multi-centre, controlled, randomised clinical study evaluating the efficacy and clinical outcomes of aneurysm sac embolisation during conventional endovascular aneurysm repair (*EndoVascular Aneurysm Repair, EVAR*).

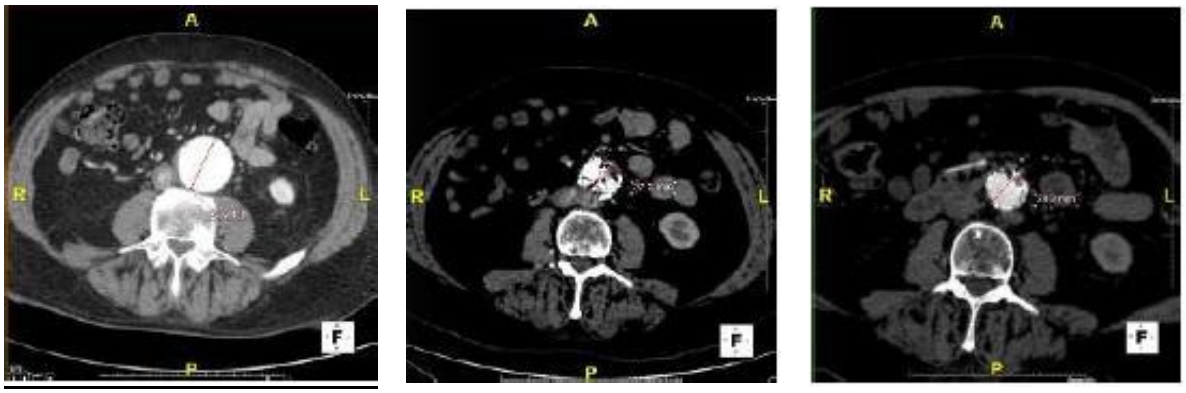
102 patients were included in two arms, 91 were analysed:

- 45 patients in the control arm: patients implanted using the EVAR procedure alone;
- 46 patients in the experimental arm: patients implanted according to the EVAR procedure accompanied by aneurysm sac embolisation.



Source: Scope 1 Study

Evolution of aneurysm size



Before EVAR
53.2 mm

After one year
37.5 mm

After two years
28.2 mm

Source: Scope 1 Study

At the end of a follow-up period of 24 months after implantation, the experimental group of patients showed a considerable improvement in terms of absence of endoleaks and secondary interventions as well as reduction in volume and diameter of the aneurysm:

- no embolisation complications were observed;
- significant reduction in revision surgery and endoleaks in the group treated by embolisation from 78% to 47% ($p = 0.003$); and
- substantial reduction in the aneurysm size of approximately 55% at 24 months ($p = 0.001$) observed in the embolisation group compared to the control group

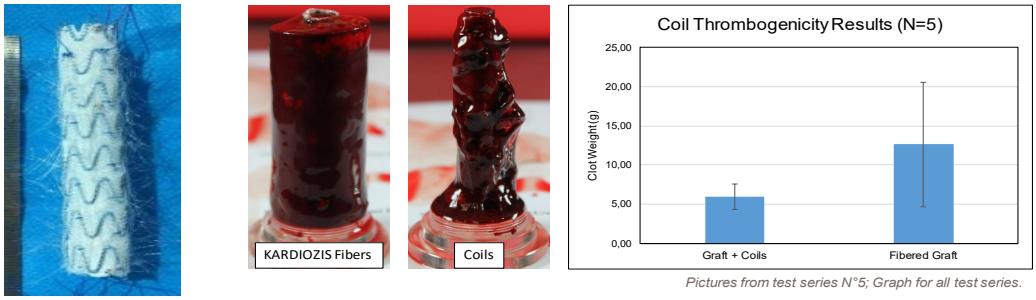
The results were presented on Saturday, 9 February 2019 at the CACVS congress (*Controversies And Updates in Vascular Surgery*) in Paris.

This Scope 1 study followed a first study, called Scope 0, also conducted under the direction of Professor Dominique Fabre at the Marie Lannelongue hospital between 2009 and 2013. This proof-of-

concept study successfully demonstrated the value of embolisation in preventing the risk of endoleaks and secondary reoperation of AAA treatment by EVAR.

Affluent Medical supplemented the Scope clinical studies with an in vitro study carried out in 2019 to compare the thrombogenic properties of Kardiozis fibres on the external wall of the implant and those of the coils. The study was conducted by Thrombodyne Inc in Salt Lake City.

The parameters of the study were the quality and volume distribution of the clot formed around the implant.



Source: In Vitro study - Kardiozis

The results of the in vitro study showed that Kardiozis fibres are at least as effective as coils:

- the thrombogenic properties of the coils and the Kardiozis fibres are equivalent;
- the clot formed around the implant with the Kardiozis fibres is homogeneous with complete embolisation around the implant, which is not observed with the use of coils;
    - the weight of the clot is greater with Kardiozis fibres than with coils; and
    - the fibres can improve the stability and expansion of the clot with uniform distribution.

All these studies show the clinical value of thrombogenic Kardiozis fibres. They make it possible to provide a response to the limits of EVAR with a reduction in type II endoleaks and secondary reoperations thanks to homogeneous embolisation around the implant while noting a significant reduction in the volume and diameter of the aortic aneurysm over time.

► Strategy and objective for the marketing of the Kardiozis technology

Kardiozis technology improves the benefits of traditional EVAR treatment for all players in the healthcare system:

For surgeons:	For patients:	For third-party payers:
– No change of procedure compared to a conventional EVAR implant – Reduction in complications from type II endoleaks – Avoids the need for open surgery – No additional embolisation procedure with coils	– Treatment can take place earlier and reduce the anxiety of living with the fear of rupture of an AAA – Reduced risk of secondary reoperations and open surgery – Reduction in post-operation radiation doses (less monitoring, fewer CT-scans, etc.) – Reduction in length of hospital stays	– Reduction of re-intervention costs – Reduction in length of patient hospital stays – Limitations of additional costs included by the use of coils – Significant reduction in patient monitoring costs
Better results	**Improved benefits**	**Lower costs**

Kardiozis technology aims to position itself as a *game changer* in the world of EVAR treatment with proven safety and improved efficacy, without modifying the procedure, thus ensuring rapid adoption of the technology by practitioners.

Given these factors, the protection of the Kardiozis technology until 2041 and a market for the treatment of the abdominal aortic aneurysm focused mainly on three major players in medical devices, active in licensing or mergers and acquisitions in this sector, Affluent Medical is aiming to sign a partnership agreement with one of the main players in the treatment of AAA with a view to the marketing of stents incorporating Kardiozis thrombogenic technology. Preliminary discussions have been initiated by Affluent Medical with several players with a view to signing such a partnership agreement, which could enable them to have an offensive strategy to gain market share and improve average selling prices or a strategy of "life cycle management" by integrating Kardiozis fibres into their own medical devices.

5.3. An agile and robust organisation from clinical development to industrial and commercial strategy

5.3.1. Experienced and complementary management

Affluent Medical benefits from an experienced and complementary management team with in-depth knowledge of the medical devices sector, from the conduct of preclinical and clinical trials, to product registration, to industrialisation, marketing and business development issues in an international context.

The entire management team brings experience acquired both within large groups such as Aventis, Sanofi, Medtronic, Bard and Philips, as well as companies specialising in the cardiology sector (Carmat, Sorin, LeMaitre Vascular, Stentys) or in successfully marketed innovative medical devices (Vexim, Theradiag).

Michel Finance - Chairman and Chief Executive Officer of Affluent Medical

Michel Finance has a parallel experience as both a corporate executive and financier. He began his career as a financial auditor at PricewaterhouseCoopers and has held various positions as Chief Executive Officer or Chief Financial Officer in the pharmaceutical, biotechnology and in vitro diagnostics industries for over 30 years. Before joining Affluent Medical, Michel Finance held various financial positions within the Pasteur Mérieux Group (from 1986 to 2000) then at the Aventis Group as Group Senior Vice-President (from 2000 to 2005) before becoming Deputy Chief Executive Officer of Flamel Technologies (from 2005 to 2008), then Chief Executive Officer of Carmat between 2008 and 2009 and successively leading the IPOs of Neovacs and Theradiag as Deputy Chief Executive Officer between 2009 and 2010 and Chief Executive Officer between 2010 and 2019. Michel Finance is a graduate of EM Lyon, a chartered accountant and also a director of France Biotech (the French association of life science entrepreneurs).

Olivier Pierron - Chief Operating Officer

Olivier Pierron has nearly 25 years' experience in team management and the sale and marketing of medical devices, particularly in the cardiovascular field in France and internationally. In particular, Olivier Pierron was Sales Director (Europe) and then Deputy CEO of Stentys (between 2017 and 2019), General Manager, France, Belgium & Luxembourg, of LeMaitre Vascular (2010-2013) and Director (France) of the Vascular and EVH division of Datascope Maquet Cardiovascular (2000-2009).

Jérôme Geoffroy - Chief Financial Officer of Affluent Medical

Jérôme Geoffroy has 17 years' experience in various financial and strategic positions acquired within the Sanofi Group in France and abroad (Japan, China, United Kingdom, Poland). In particular, Jérôme Geoffroy was Chief Financial Officer of the Polish subsidiary of Sanofi and Head of Finance for the Sanofi R&D department in the Asia-Pacific region. Jérôme Geoffroy's academic career covered in parallel finance (Neoma) and biology (degree in cell biology and microbial physiology).

Prof. François Laborde - Medical Director of Affluent Medical

François Laborde is a trained physician. He is a university professor (Paris V). For more than 30 years, he was a cardiac surgeon at the Institut Mutualiste Monsouris (IMM) where he was head of the medical-surgical department for cardiac pathology. At the same time, he was Chief Executive Officer of IMMR between 1999 and 2019, a CRO* affiliated with IMM in charge of preclinical studies in various surgical fields including cardiothoracic and vascular surgery.

Wenzel Hurtak - VP Operations Epygon

Wenzel Hurtak is an experienced medical device professional having worked at companies such as Cordis, Johnson & Johnson, where he held various management positions in production and process engineering, as well as in advanced R&D. In 2004, he joined Integra LifeSciences Corporation, a world leader in neurosurgery and orthopedics, where he became Vice-President of European operations and where he was responsible for five production sites in Europe and contributed to the development of more than ten products. Wenzel Hurtak was Director of the New Products Division at Contract Medical International GmbH, a leader in product development for minimally invasive devices in cardiology before joining Carmat in 2017 as Industrial Director. Wenzel Hurtak is a graduate engineer in physics and materials sciences from the University of Groningen.

Pascale Lagrange - Director of Quality Assurance

Pascale Lagrange has 16 years of experience in quality management for companies in the medical devices sector. Before joining Affluent Medical, Pascale Lagrange was quality manager at Vexim, a company specialised in the minimally invasive treatment of spinal fractures between 2012 and 2019 and the Hemodia Group, manufacturer of sterile single-use medical devices, between 2005 and 2012.

Eric Jague - Director of Regulatory Affairs

Eric Jague has 17 years of experience in regulatory affairs applied to medical devices, in various types of product portfolios, mainly class III implantable devices and class IIb active devices in Europe. Eric Jague was notably Manager and then Regulatory Affairs Director at Medtronic (from 2007 to 2017), then Regulatory Affairs Director of the Application Devices Business Unit at Fresenius Kabi (from 2017 to 2020), where he deployed the registration strategies across all international markets.

5.3.2. A leading Scientific Council

Affluent Medical is also supported by a leading international scientific council with personalities recognised worldwide for their scientific medical expertise and the development of surgical techniques and innovative medical devices.

Alain Carpentier
- Professor of cardiac surgery
- Co-founder of Carmat
- Inventor of biological valves to avoid immunological rejection

Alain Berrebi
- Cardiologist
- Specialist in interventional echocardiography
- Head of the Echo-Lab Department of the Cardiovascular Surgery Department of the Georges Pompidou European Hospital

Theodor Fischlein
- Professor of cardiac surgery in Nuremberg

Christian Latremouille
- Director of Surgical Affairs at Carmat
- Professor of cardiac surgery

Gunther Laufer
- Professor of cardiac surgery
- Head of the Cardiac Surgery Department at Vienna University Hospital

Martin Misfeld
- Professor of Cardiothoracic Surgery in Leipzig

Piergiorgio Tozzi
- Professor of Cardiology and Cardiothoracic Surgery in Lausanne

Daniel Hayoz
- Professor and Head of the Department of General Internal Medicine and Angiology at the Cantonal Hospital of Friborg (HFR)

Nicolas Barry DelongChamps
- Professor of urology at Cochin hospital

Roger Dmochowski
Professor of Urological Surgery at Vanderbilt University Medical Center in Nashville

Dominique Fabre
- Professor of thoracic and vascular surgery and cardiopulmonary transplantation at the Marie Lannelongue hospital

Stephan Haulon
- Professor of vascular surgery at the Marie Lannelongue surgical centre
- President of the European Society for Vascular Surgery

5.3.3. An intellectual property policy at the heart of Affluent Medical's development strategy

5.3.3.1. Group intellectual property protection policy

The Group protects the processes, products or new applications that result from its research work and expertise. As a result, it has filed and obtained patents on its medical devices, the methods for implanting them, kits adapted to the marketing of these technologies, and processes for the manufacture of these devices.

The Group also makes the necessary registrations of the brands it uses or intends to use, as well as the domain names for its various websites.

The Group has always placed industrial property at the heart of its development and value creation strategy. Thus, each new technological advance is the subject of an initial patent filing, generally in Europe or the United States, in order to ensure a priority date in the major regions. During the priority year, the invention is consolidated, and the first filing is generally followed by a world extension, essentially through the Patent Cooperation Treaty ("PCT") system to[55] ensure appropriate territorial

[55] PCT (Patent Cooperation Treaty): the PCT is a centralised filing system that covers, simply and for conservation, a large number of territories. The Administration responsible for the International Search selected by the applicant conducts a search for priorities and transmits the corresponding international search report along with a preliminary opinion on the patentable nature of the invention. At the end of the international phase of a PCT application (which lasts 30 months from the date of

coverage. These international, PCT filings can designate countries (United States, China, Japan, etc.) or larger geographic areas, such as the member countries of the European patent system managed by the European Patent Office ("EPO").[56]

The Group also analyses competing patents to verify the positioning of its technologies and their freedom of use or the possible risks of dependence.

The portfolio of patents constructed by the Group is enhanced over time with new applications, in order to strengthen protection on the technologies and protect the new results obtained. As at the date of approval of the Registration Document, the Group's portfolio of patents comprises 31 patent families and patent applications in force (filed, under examination or granted) (29 are the full and entire property of the Group, 2 are under exclusive license to the Group).

5.3.3.2. Patents and patent applications

The current distribution of the portfolio is summarised in the table below.

Object	Registered holder	Date of priority filing	Regular term (1)	Status	Reference
Ring with changeable element (2)	Kephalios	October 2013	October 2034	**Issued in Europe, USA, Japan and the following countries: AU, CN, JP, RU** Examination in progress in Brazil, Canada, China (divisional).	1
Cage	Kephalios	February 2014	January 2035	**Issued in Europe, USA, Japan and the following countries: AU, CN** Examination in progress in Brazil, Canada	2
Flow sensor	Kephalios	April 2015	April 2036	Examination in progress in Europe and the US	3
Transcatheter Annuloplasty ring	Kephalios	July 2017	July 2037	**Issued in Russia** Examination in progress in Europe, the USA, and in the following countries: AU, BR, CA, CN, JP	4
Artificial contractile sphincter	MyoPowers Medical Technologies	July 2007	July 2028	**Issued in the US and Europe**	5
Medical device with artificial contractile structure	MyoPowers Medical Technologies	July 2010	July 2031	**Issued in the US and Europe and in Canada**	6
Medical device with artificial contractile structure	MyoPowers Medical Technologies	July 2010	July 2031	**Issued in the USA, Europe and Canada**	7
Medical device with artificial	MyoPowers Medical	December 2011	December 2032	**Issued in the US, Europe, Japan and China** Examination in progress in the US (div) and Canada	8

priority), the process moves into the national/regional phases, i.e. choosing the countries/regions in which investigation of the patent demand must effectively be initiated (within 30 or 31 months from the date of priority, depending on the countries/regions selected).

[56] The EPO centrally manages the procedure of filing the invention in 38 European member States, including Turkey. Once delivered, the European patent filing results in several national rights in each of the countries in which the applicant decides to keep the patents in force.

Object	Registered holder	Date of priority filing	Regular term (1)	Status	Reference
contractile structure	Technologies				
Medical device with artificial contractile structure	MyoPowers Medical Technologies	February 2014	February 2034	**Issued in the USA, Europe, Japan,** Examination in progress in the USA (div) and in Japan (div)	9
Artificial contractile structure and medical device	MyoPowers Medical Technologies	November 2017	November 2037	Examination in progress in Europe, the USA, and in the following countries: TW, BR, CA, CN, IL, JP	10
Artificial contractile structure	MyoPowers Medical Technologies	November 2017	November 2037	Examination in progress in Europe, the USA, and in the following countries: TW, BR, CA, CN, IL, JP	11
Actuator with modular structure	MyoPowers Medical Technologies	November 2017	November 2037	Examination in progress in Europe, the USA, and in the following countries: TW, BR, CA, CN, IL, JP	12
Endoprosthesis and delivery device	Kardiozis	June 2012	June 2033	**Issued in Europe, the US, China and Australia and in the following countries: CA, ID, JP, KR, MX, MY, RU, SG; UA, ZA,** Examination in progress in the following countries: BR, JP (div) VN	13
Delivery device, delivery system and stent graft	Kardiozis	December 2018	December 2038	Examination in progress in Europe, USA and in the following countries: AU, BR, CA, CN, ID, JP, JP, KR, MX, MY, RU, SG, UA, VN, ZA	14
Endoprosthesis with Fibres	Kardiozis	September 2019	September 2039	PCT filing made – not published	15
Sandwiched fibres	Kardiozis	September 2020	September 2040	PCT filing made – not published	16
Graft modification for fibre attachment	Kardiozis	January 2021	January 2041	PCT filing made – not published	17
Stent modification for fibre attachment	Kardiozis	January 2021	January 2041	PCT filing made – not published	18
Fibre in Suture	Kardiozis	January 2021	January 2041	PCT filing made – not published	19
Heart valve prosthesis	Epygon	April 2012	April 2033	**Issued in China, Australia, Russia, Ukraine, Singapore, Canada, Japan, USA and South Korea and in the following countries: ID, IL, MX, MY and ZA** Examination in progress in Europe, and in the following countries: BR, IN, VN	20
Stent with enhanced grip	Epygon	April 2013	April 2034	**Issued in Europe and in the** US	21
Elastic chain	Epygon	March 2014	March 2035	**Issued in China, Japan, USA and Europe** Examination in progress in the following countries: BR, CA, IN	22

Object	Registered holder	Date of priority filing	Regular term [(1)]	Status	Reference
Inclined Leaflet	Epygon	March 2014	March 2 035	**Issued in Japan, USA and Europe** Examination in progress in the following countries: BR, CA, CN, IN	23
Percutaneous triangular resection	Epygon	January 2015	January 2036	**Issued in the USA and China** Examination in progress in Europe and in the following countries: BR, CA, IN, JP	24
AMLL Paddle	Epygon	June 2015	June 20 36	**Issued in the USA, Europe [(3)] and in the following countries: AU, CN, JP, MX, RU, SG** Examination in progress in the following countries: BR, CA, HK, ID, IL, IN, KR, MY, UA, VN and ZA	25
Delivery system	Epygon	March 2017	March 2 037	Examination in progress in Europe and the USA and in the following countries: AU, BR, CA, CN, HK, IL, IN, JP, KR, RU, SG,	26
Valve leaflet with variable thickness	Epygon	February 2017	Februar y 2038	Examination in progress in Europe and the US	27
Pericardial tissue treatment	Epygon	February 2017	Februar y 2038	Examination in progress in Europe and the USA and in the following countries: AU, BR, CA, CN, HK, IL, IN, JP, KR, RU, SG,	28
Crimping device for heart valve	Epygon	December 2018	Decemb er 2038	Examination in progress in Europe and the US and in the following countries: CA, CN, HK, IN, JP,	29

(1) The regular term of a patent is generally 20 years from the filing date in the country in question. In some cases, this term can be extended (for example, the Supplementary Protection Certificate in Europe, the Patent Term Extension (PTE), and the Patent Term Adjustment (PTA) in the United States) or reduced (for example, by Terminal disclaimer in the United States).

(2) The Group also benefits from a license granted by the Centre Hospitalier Universitaire Vaudois (CHUV) on two patent families covering an annuloplasty ring and an activator for annuloplasty ring. None of the patents in these two families is currently used by the Group. This exclusive license provides for the payment of staggered royalties based on the achievement of regulatory milestones and royalties (low single-digit percentage) based on the net sales of products using the licensed patents until the expiry of the latter.

(3) Ongoing opposition proceedings by a third party. This type of proceedings is nonetheless common in the Company's business sector and the Company does not anticipate any adverse consequences that could result from this procedure**.**

The Company's patent demands have an international scope, generally via the PCT procedure. The territories ultimately selected depend on the strategic importance of the patent and circumstances specific to the invention. The protected territories include in particular Europe and the United States, sometimes also Japan, China and/or Canada. In Europe, the countries selected for validation after the issuance of the European right are generally at least France, Germany, the United Kingdom, Spain and Italy.

► **Protection of the Artus implant:**

The Artus implant and its components are described or claimed, in whole or in part, by patent families and patent applications (No. 7 to 10 in the table above).

No. 7 (WO 2012/000681) relates to a specific actuation mechanism having advantageous operating parameters for the opening and closing of a contractile element.

No. 8 (WO 2013/093074) is directed to a device with means of reducing corrosion. A sealed chamber contains an electric motor and a reducer. The parts that are less sensitive to humidity are placed in a second non-sealed chamber.

No. 9 (WO 2015/117664) refers to an advantageous contractile element structure. The contractile element is a flexible element for applying occlusion pressure with a plurality of transverse reinforcing elements. A tensioning device bends the flexible band into a U-shape, the bottom of the U being positioned so as to apply an occlusive pressure to the body organ.

No. 10 (WO 2019/106403) is directed to a specific connector and transmission for clamping the contractile element formed in a closed loop around a hollow body member when a tensile force is applied to the end of a tension element by an actuator.

Patents corresponding to Nos. 5 to 9 of the table above have been issued in Europe and the United States, confirming the innovative nature of this technology.

Subject to their continued validity, these patents are due to expire in July 2028 (No. 5), in July 2031 (Nos. 6 and 7), December 2032 (No. 8) and February 2034 (No. 9).

► **Protection of the Kalios implant:**

The Kalios implant and its components are described and claimed, in whole or in part, by the patent families and patent applications Nos. 1 and 2 in the table above. These families cover the device. They were filed for the following territories: Europe, the United States, Japan, Brazil, Canada, Australia, China and Russia (for the application corresponding to No. 1 only).

In particular, No. 1 corresponding to patent application WO2015/058808 relates to an adjustable annuloplasty ring comprised of a support ring, an adjustable ring embedded at least partially in the support ring, and a number of pressure elements at different positions around an interface between the support ring and the adjustable ring; each pressure element can be deployed to deform the adjustable ring toward the inside by using the support ring for support, in order to adjust the shape of the adjustable ring.

No. 2 corresponding to patent application WO2015/121075 relates to an adjustable annuloplasty device comprising a tube having a substantially annular shape or designed to be brought to an annular shape, at least a portion of an outer wall or the entire outer wall of the tube being more rigid than the opposite parts of an inner wall or the entire inner wall so that the inner wall can be moved inward while the outer wall remains substantially constant.

Patents for Nos. 1 and 2 have been issued in Europe and the United States, confirming the innovative nature of this technology.

Subject to their continued validity, the patents No. 1 will expire in October 2034 and patents No. 2 will expire in January 2035.

► **Protection of the Epygon implant:**

The Epygon implant and its components are described and claimed, in whole or in part, in patent families and patent applications Nos. 20, 23, 25, 26 and 28 in the table above. The family of patents and patent applications No. 20 relates in particular to a cardiac valve prosthesis comprising an annular support structure to be anchored to the valve ring, and a valve of flexible material supported in a floating manner by said support structure, characterised in that said support structure comprises a portion of support wall to which a radicular end of the valve is connected, and a complementary wall portion opposite said support wall portion, which supports a static or quasi-static coaptation surface. The free end of the valve is connected to the supporting wall portion or to the complementary wall portion by means of at least one traction element made of flexible material.

Certain aspects of the implant are stipulated in the other families of patents, such as the inclined mode (No. 23), the asymmetric tubular shape with a special anchoring system (No. 25) and the tissue treatment process (No. 28) as well as a device for implanting Epygon (No. 26).

The family of No. 20 covers patents granted in the United States, China, Australia, Russia, Ukraine, Singapore, Canada, Japan and South Korea, as well as pending patent applications, particularly in Europe.

The family of No. 23 covers patents granted in particular in Europe and the United States and pending patent applications in other countries.

The family of No. 25 covers patents granted in Europe and the United States and pending patent applications in other countries.

Provided they are issued and/or maintained in force, the patents within these families are due to expire between 2033 and 2038.

- **Protection of Kardiozis technology:**

The Kardiozis technology and its components are described and claimed, in whole or in part, in the family of patents and patent applications Nos. 13, 14 and 16. Patent No. 13 discloses and claims the implant, in particular a vascular or cardiac stent comprising at least one body part of which at least one zone of an external surface is provided with thrombogenic elements which are distributed in a substantially uniform manner. The implant is provided with at least one retaining means that can be selectively deactivated to retain the thrombogenic elements near the surface of the body portion of the implant.

Patent No. 13 has already been issued in certain major territories, including the United States and Europe, confirming its innovative nature.

Provided they are issued and maintained in force, the No. 13 patents are due to expire in June 2033.

- **Other patent families:**

The other families of patents and patent demands cover devices or methods of production that represent advances in implants currently developed or complementary innovative projects.

- **Exclusive license agreements granted:**

On 28 October 2017, Kephalios, Epygon and MyoPowers entered into joint-venture agreements with Shanghai Zuquan Investment Management Company Limited under the terms of which the parties agreed to form Shanghai Epygon Medical Technology Co., Ltd and Shanghai MyoPowers Medical Technology Co., Ltd (the "**Joint Ventures**"), the purpose of which is research and development and the manufacturing and marketing in China (including mainland China, Hong Kong, Macao and Taiwan) of

medical devices developed or being developed by the subsidiaries Epygon and MyoPowers respectively, which will be selected jointly by the parties.

In accordance with the agreements entered into as part of these Joint Ventures, in April 2018, Epygon and MyoPowers respectively granted exclusive rights to use their patents and their know-how to develop, manufacture and market the Epygon and Artus implants to Shanghai Epygon Medical Technology Co. Ltd and Shanghai MyoPowers Medical Technology Co., Ltd in China (including mainland China, Hong Kong, Macao and Taiwan). The license agreements expire on 26 April 2033 for the patent rights for the Epygon implant and on 21 December 2032 for the patent rights for the MyoPowers implant (see section 20.1 of the Registration Document).

In addition, some of the Subsidiaries have entered into license option agreements with the companies Meningose and Corazan, shareholders of the Company whose main activity is the research, development and marketing of innovative products in the field of life sciences and healthcare, and, for this purpose, in particular, the licensing of any patent. The license agreements will have the following terms in the event of exercise of the options.

The Company has entered into licensing option contracts to allow it to distribute its products in certain secondary, non-priority territories in which it is not planning direct marketing at this stage (South Africa and Australia).

The licensing option agreements were entered into between:

(i) Epygon and Meningose, a French simplified joint stock company (*société par actions simplifiée*) with capital of €1,158,096, and registered office at 5 rue de la Baume — 75008 Paris, registered in the Paris Trade and Companies Register under number 819 788 878, on 16 March 2018;

(ii) Kardiozis and Corazan, a French simplified joint stock company (*société par actions simplifiée*) with capital of €767,447 and registered office at 5 rue de la Baume, 75008 Paris, registered in the Paris Trade and Companies Register under number 811 421 817, on 16 March 2018; and

(iii) MyoPowers and Bionicos, on 27 March 2018, Bionicos has since been absorbed by Corazan, presented above.

Pursuant to the provisions of these agreements, the option may be exercised by each of the co-contracting parties at any time from the date of the conclusion of the license option agreement for a period of 42 months. In the event that the option is exercised, the license agreement to be entered into between the Subsidiary concerned and its co-contractor will cover (i) patents and patent applications filed in the Subsidiary's name (or on its behalf) or owned by the Subsidiary as of the date of the license option agreement, and (ii) the territories of Australia and South Africa. The license agreement shall be concluded for the shorter of (i) 15 years and (ii) the term of the licensed patents. The Company will receive *royalties* in the event that the option is exercised and the products are marketed based on the licensed patents. Pursuant to the terms of each of the license option agreements, the Subsidiaries may cancel the license option agreement (and consequently any license agreement that would be entered into when the option is exercised).

5.3.3.3. Other intellectual property items

► **Trademarks:**

The Group uses the verbal or figurative trademarks "AFFLUENT MEDICAL", "ARTUS", "MYOPOWERS", "EPYGON", "KALIOS", "4EVAR", "KARDIOZIS", "KEPHALIOS" and "MITRAFLEX" described in the table below, which lists the trademarks in force (both those that have already been registered and those that are still being examined by the relevant office) that belong to the Group. These trademarks are registered to designate certain products and services, i.e. in Classes 5

(pharmaceutical products) and 44 (particularly for services among the following: medical services; alternative medicine services; medicine, pharmaceutical, drugs, medical devices, health services; medical assistance, health consulting; medical equipment leasing; medical material leasing; therapeutic services), or in Class 10 (notably for products among the following: surgical and medical devices and instruments; artificial heart valves; stents; artificial implants), or in Classes 10 and 42 (notably for research and development services for medical products), or in Classes 10, 35 (retail and wholesale or supply for third parties of medical products and devices), 42 and 44, or finally in Classes 5, 10 and 42 of the Nice Classification.

Subject to regular renewal and in the absence of a challenge to their validity or forfeiture, the trademarks can be protected indefinitely in the country in which they are registered and for the products and services for which they are registered.

Name	Holder	Territory	Filing date	Renewal date
AFFLUENT MEDICAL	AFFLUENT MEDICAL	France	5 February 2018	5 February 2028
ARTUS	MYOPOWERS	International: Turkey, Russia, EU, Norway, Singapore, ~~Switzerland~~, Australia	24 January 2013	24 January 2023
ARTUS	MYOPOWERS	Switzerland	22 January 2013	22 January 2023
ARTUS	MYOPOWERS	Great Britain	24 January 2013	24 January 2023
EPYGON	EPYGON	European Union	15 July 2016	15 July 2026
EPYGON	EPYGON	Switzerland	1 July 2016	1 July 2026
EPYGON	EPYGON	Great Britain	15 July 2016	15 July 2026
EPYGON	EPYGON	China	22 November 2017	28 October 2028
EPYGON	EPYGON	United States	28 July 2016	20 March 2028 (DoU 20 March 2024)
KALIOS	KEPHALIOS	Brazil	26 July 2018	2 July 2029
KALIOS	KEPHALIOS	Canada	6 July 2018	Application pending
KALIOS	KEPHALIOS	European Union	3 April 2018	3 April 2028
KALIOS	KEPHALIOS	Great Britain	3 April 2018	3 April 2028

Name	Holder	Territory	Filing date	Renewal date
KALIOS	KEPHALIOS	International: Switzerland, India, Japan, United States	6 April 2018	6 April 2028
KALIOS	KEPHALIOS	United States	6 April 2018	28 May 2025 (DoU, Declaration of Use)
KALIOS	KEPHALIOS	Hong Kong	9 July 2018	8 July 2028
KALIOS	KEPHALIOS	Macao	10 July 2018	21 December 2025
KALIOS	KEPHALIOS	Taiwan	10 July 2018	15 February 2029
KARDIOZIS	KARDIOZIS	France	10 May 2011	10 May 2021
KEPHALIOS	KEPHALIOS	European Union	6 December 2017	6 December 2027
KEPHALIOS	KEPHALIOS	Great Britain	6 December 2017	6 December 2027
KEPHALIOS	KEPHALIOS	International: China, Switzerland, India, Japan, United States	6 December 2017 (China) and 9 April 2018 (other territories)	6 December 2027
KEPHALIOS	KEPHALIOS	United States	9 April 2018	21 May 2025 (DoU, Declaration of Use)
KEPHALIOS	KEPHALIOS	Canada	15 May 2018	Application pending
KEPHALIOS	KEPHALIOS	Hong Kong	14 December 2017	13 December 2027
KEPHALIOS	KEPHALIOS	Macao	18 December 2017	26 July 2025
KEPHALIOS	KEPHALIOS	Taiwan	19 January 2018	15 August 2028
4EVAR	KEPHALIOS	France	6 June 2018	6 June 2028
MITRALFLEX	KEPHALIOS	European Union	7 September 2012	7 September 2022
MITRALFLEX	KEPHALIOS	Great Britain	7 September 2012	7 September 2022
MITRALFLEX	KEPHALIOS	International: Switzerland	14 March 2013	14 March 2023

Name	Holder	Territory	Filing date	Renewal date
MYOPOWERS	MYOPOWERS	France	4 December 2017	4 December 2027
MYOPOWERS	MYOPOWERS	China	1 December 2017	14 November 2028
MYOPOWERS	MYOPOWERS	Great Britain	23 May 2018	23 May 2028
MYOPOWERS	MYOPOWERS	International: European Union, Switzerland, Israel, United States	23 May 2018	23 May 2028
MYOPOWERS	MYOPOWERS	United States	23 May 2018	23 July 2025 (DoU, Declaration of Use)
MYOPOWERS	MYOPOWERS	Hong Kong	25 May 2018	24 May 2028
MYOPOWERS	MYOPOWERS	Macao	25 May 2018	21 December 2025
MYOPOWERS	MYOPOWERS	Taiwan	25 May 2018	15 May 2029
MYOPOWERS	MYOPOWERS	South Africa	29 May 2018	4 December 2027
	MYOPOWERS	France	4 December 2017	4 December 2027
	MYOPOWERS	Great Britain	23 May 2018	23 May 2028
	MYOPOWERS	International: Switzerland, China, European Union, Israel, United States	23 May 2018	23 May 2028
	MYOPOWERS	United States	23 May 2018	23 July 2025 (DoU, Declaration of Use)

Name	Holder	Territory	Filing date	Renewal date
	MYOPOWERS	Hong Kong	25 May 2018	24 May 2028
	MYOPOWERS	Macao	25 May 2018	21 December 2025
	MYOPOWERS	Taiwan	25 May 2018	15 May 2029
	MYOPOWERS	South Africa	29 May 2018	4 December 2027

► **Domain names:**

In addition, the Group uses the domain names affluentmedical.com, myopowers.eu and myopowers.com, as well as the domain names epygon.com and kephalios.eu.

The Group also holds the domain names listed below, which are inactive as of the date hereof:
Affluentmedical.care
Affluentmedical.am
Affluentmedical.de
Affluentmedical.eu
Affluentmedical.fr
Affluentmedical.healthcare
Affluentmedical.it
Affluentmedical.org
Affluentmedical.uk
Kephalios.ch
Kephalios.com
Kephalios.de
Kephalios.fr
Kephalios.it
Kephalios.net
Kephalios.org
Kardiozis.fr
Kardiozis.com
Epygon.it

Subject to regular renewal and in the absence of a challenge by third parties, particularly on the basis of prior rights, the domain names can be retained indefinitely.

5.3.4. ISO 13485: 2016 certifications already obtained validating the quality system of the Group's various subsidiaries

Among the regulatory aspects to which the Group must respond, which are presented in Chapter 9 of the Registration Document, the management of the quality system is essential for a company developing medical devices.

The quality management system covers all the activities, from conception to distribution of medical devices. It applies equally to all products and is audited by an independent body. It aims to ensure that the device remains effective and safe in accordance with the applicable requirements throughout its lifetime.

ISO 13485:2016 certification is essential quality management system certification for manufacturers and other stakeholders involved in the design, production, storage or distribution of medical devices to meet a number of quality requirements imposed by the applicable European regulations. ISO 13485: 2016 was therefore drafted to help manufacturers and other industry stakeholders design a quality management system that establishes and maintains the efficiency of their processes. It covers the design, development, production, installation and delivery of medical devices.

The quality management system and technical documentation of certified medical devices are audited by a notified body in accordance with the requirements of European regulations. These audits and quality control will be strengthened with the entry into force of Regulation (EU) 2017/745 on 26 May 2021, to the extent that it provides for an annual audit of the proper application of the quality management system and the post-marketing surveillance plan, an unannounced on-site audit of the manufacturer and, where applicable, its suppliers and/or subcontractors, carried out by the notified bodies at least once every five years, as well as the preparation, by the manufacturer of class III medical devices, of a periodic safety report updated annually and communicated to the notified body involved in the product certification procedure.

Similarly, for the United States, manufacturers must apply the provisions set out in Sections 820.1 et seq. of Title 21 of the Code of Federal Regulations (CFR). In particular, the regulation provides for the verification of the proper application of these provisions by the FDA every two years, for Class III medical device manufacturers, during an inspection of the manufacturer's site.

Medical devices are also subject to monitoring of incidents or risks of incidents resulting from their use after being placed on the market. This surveillance is commonly called medical device vigilance. It is a system permitting preventing or correcting defects and malfunctions observed in the medical devices concerned. When an incident or risk of incident occurs and is attributed or is likely to be attributed to a medical device, a medical device vigilance sheet is completed by the user, the manufacturer or any other person concerned. This information is forwarded to the various parties involved and in particular to the competent national authority of the country in which the manufacturer is based, as well as the competent authority of the country in which the incident occurred.

The Kephalios, Epygon and MyoPowers subsidiaries each have their own quality system with a dedicated quality manager at the entity, and apply quality standards harmonised by Quality Department of Affluent Medical.

All the quality processes of each entity are mapped and are based on documented procedures.

The quality procedures make it possible to:

- standardise quality practices to meet the requirements of ISO 13485:2016 and the applicable regulations more generally;

- detect internal or external areas of non-compliance and to record all investigations and analyses related to the analysis of the causes of these areas of non-compliance and the related risks;
- trigger corrective or preventive action and measure the effectiveness of actions taken to eliminate non-compliance;
- regularly assess the effectiveness of the quality system.

Each Group entity holds ISO 13485:2016 - Quality Management system certification and is the subject of a specific audit cycle, including an annual audit carried out by the certification body of each entity. Potential cases of non-compliance detected on one entity therefore do not affect the other entities.

ISO 13485:2016 certification has now already been obtained, thus validating the quality system of the various subsidiaries of the Group. Indeed, the notified body BSI granted ISO 13845:2016 certification to the subsidiaries Kephalios and Epygon and the notified body Dekra granted ISO 13485:2016 certification to MyoPowers.

Kephalios
ISO 13485:2016 certificate


bsi.
Certificate of Registration
QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

Epygon
ISO 13485:2016 certificate


bsi.
Certificate of Registration
QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

MyoPowers
ISO 13485:2016 certificate


CERTIFICATE
DEKRA
MyoPowers Medical Technologies France SAS
EN ISO 13485:2016

Each subsidiary is audited annually by the certification body according to the requirements of the ISO standard 13485 (main chapters: Quality System, Management Responsibilities, Resource Management, Design & Development, Production/Control/Traceability, Improvement).

ISO 13485:2016 certificate is valid for a period of three years (expiry +three years from the date of the first (re) certification):
- First year: (re) certification audit;
- Second two: surveillance audit 1;
- Third year: surveillance audit 2.

All Group suppliers are selected, qualified and evaluated according to the tasks entrusted to them and their impact on the production of medical devices:
- qualification according to quality standards applicable to the supplier's area of expertise (ISO certifications 13485:2016 for suppliers assembling the products of the Group , ISO 9001:2015 for material suppliers, ISO 11135:2014 for ethylene oxide sterilisers or ISO 17025:2017 for laboratories);
- annual evaluation by Group technical teams on product compliance aspects (number of non-compliances and results of supplier audits), capacity of the supplier to meet the requirements of the Group, product delivery times; and

- regular audits by the quality department to verify the maintenance of compliance with standards and the compliance of products delivered.

The products are checked via representative sampling throughout the manufacturing cycle by suppliers, by qualified laboratories and by the subsidiaries concerned (Kephalios, Epygon or MyoPowers):

- checks on raw materials by suppliers on the basis of compliance certificates and technical data sheets and inspection on receipt of critical raw materials by the subsidiary concerned;
- checks on manufacturing operations by suppliers through size checks on parts;
- checks on the packaging and integrity of blisters by suppliers via sealing integrity tests;
- checks on the traceability labels affixed to finished products, including instructions for use, by the relevant subsidiary, through a 100% check;
- checks on sterilisation by the entity for verification of the sterilisation cycle applied and by laboratories for sterility checks on products; and
- final checks of the finished product by functional tests.

All results of these checks are verified by the Production Department and validated by the Quality Department of the subsidiary concerned. A final release of the batch is carried out by the Quality Manager of the subsidiary concerned to authorise the release of medical devices on the market (for clinical investigations at this stage of the Group's development and eventually for marketing).

In the context of the clinical study, a declaration of compliance with the applicable regulatory requirements is issued by the Regulatory Affairs Director for each shipment of medical devices to the healthcare centre.

The manufacturing equipments for the Group's products are qualified by suppliers and the qualification reports approved by the relevant subsidiary. Manufacturing processes (moulding, etc.) and special processes (sterilisation, packaging, transport, etc.) are validated and maintained by the subsidiary concerned.

On each significant process change, the procedures must be revalidated to confirm the compliance of the equipment and manufacturing processes.

5.3.5. A dual model for the industrialisation of the Group's various innovative implants

The production of the Kalios implant is currently subcontracted to a set of subcontractors, experts in their respective fields, for the needs of the Optimise II clinical trial. The production of this medical device will continue to be outsourced once Affluent Medical has obtained the relevant marketing authorisations.

Medical device	Industrialisation / Subcontracting
Kalios	- Outsourcing of the production of this device
Artus	- Assembly of this device by MyoPowers at its premises in Besançon - Subcontracting of the production of sub-assemblies
Epygon	- Assembly of the Epygon valves (stitching of the bovine pericardium structure) and treatment of the bovine pericardium at the Epygon Italy premises - Subcontracting the supply of system components

In addition, Affluent Medical has two production sites, equipped with clean rooms, for the manufacture of Artus and Epygon implants and located at:

- Besançon, in the premises of MyoPowers, for the production of the Artus artificial sphincter;

- Colleretto Giacosa, approximately 50 km north of Turin, in the premises of Epygon Italie, for the production of the Epygon mitral valve.

At this stage of the Group's development, these two sites are intended to produce the medical devices that will be used in the Dry and Minerva clinical trials. As soon as the regulatory authorisations have been obtained for the marketing of Artus (CE marking expected in the 4th quarter of 2023) and Epygon (CE marking expected in the 2nd half of 2025), these sites are then expected to produce significantly higher volumes which could be further increased following optimisation of the production tool through the implementation of lean manufacturing tools.

MyoPowers has its own clean room* (ISO 8 & ISO 7) within its premises to carry out the production of the Artus devices at the Technopôle Microtechnique et Scientifique (TEMIS) in Besançon, a centre of excellence bringing together innovative companies, particularly in the Medtech-Biotech industries. Offices, a space containing equipment and R&D test benches, a quality control room, as well as a clean room are set up over a total area of 255 m^2. The current capacity allows the manufacture of all of the devices required for the Dry clinical study. An annual capacity of 5,200 Artus implants is possible from this surface area by the time CE marking is obtained and could be almost doubled to reach 10,000 implants/year by an extension of production to a two-shift structure (2 x 8).

MyoPowers site in Besançon

The premises of Epygon Italie are part of the Bioindustry Park, bringing together innovative companies in the health sector. The premises include in particular a laboratory and a clean room. Current production capacity is around twenty valves per month, for the needs of the Minerva study.


Colleretto Giacosa laboratory and cleanroom

The Group's products contain raw materials (bovine pericardium used for the Epygon implant) and specific components (in particular the stents used for the Epygon and Kalios implants) necessary for the production of these innovative implantable devices. Affluent Medical therefore uses specialised and

certified suppliers or subcontractors for its supply. Given the highly innovative nature of its medical devices, the high level of specialisation of the suppliers and subcontractors, and the regulatory requirements, the number of qualified suppliers or subcontractors is restricted.

At this stage of development, the Group's production activity is limited to the production of a small number of implants for the purposes of clinical studies. When the various Group products enter the marketing phase, Affluent Medical will first put in place a policy of sourcing raw materials and components based on the establishment of long-term contracts with these specialised suppliers in order to ensure the quality and availability of these raw materials and eliminate all supply risks. The Group will systematically seek out a second source of supply for its raw materials and sub-assemblies. Although its number of suppliers is limited at this stage, Affluent Medical has already identified several suppliers able to provide the raw materials necessary for the production of each of these products in order to always have a backup solution should one of its suppliers default.

5.3.6. A clear marketing strategy combining direct and indirect sales

Affluent Medical wants to implement a commercial strategy based on a hybrid model combining its own sales force in strategic European countries with local distributors and partners.

► **Direct distribution:**

Affluent Medical intends to set up experienced sales teams for the sale of its medical devices in strategic Western European countries, in particular Germany, France, Italy and the United Kingdom, which will require the mobilisation of a portion of the funds that will be raised as part of the proposed listing of the Company on the regulated Euronext Paris market.

This direct distribution will allow Affluent Medical to maintain direct contact with hospitals, prescribing surgeons and other KOL and thus remain at all times responsive to their needs and adapt to their changes.

Another advantage of direct distribution is that it generates a higher gross margin than indirect distribution.

Two sales forces need to be set up:

- a sales force dedicated to the cardiovascular market for the sale of the Kalios and Epygon implants;
- a second sales force dedicated to the urology market for the marketing of Artus.

The Group believes that with a sales force of around thirty people, it should be able to cover all the strategic European areas being targeted.

► **Indirect distribution: local distributors and strategic partners**

In addition to its sales network, Affluent Medical intends to set up distribution agreements with local specialised players in the urology and cardiovascular markets, such as the distribution agreement set up with Palex Medical to cover Spain and Portugal.

Sales to distributors will allow relying on the skills of a service provider who knows the specific features of each country. This strategy will also have the benefit of limiting storage costs, as the distributor will buy stocks of implants and implantation systems from Affluent Medical and make them available to hospitals. Distributors will thus be able to market the Group’s various implants in certain non-priority countries in Europe, such as the Nordic countries, and cover certain countries in Asia and America.

These stocking distributors, local intermediaries employing salaried medical representatives and/or sub-distributors/agents, are in direct contact with practitioners. These distributors will be selected for their proven ability to distribute a complete range of innovative products in the structural heart and urology sectors.

In addition to entering into agreements with local distributors, the Group also intends to enter into strategic partnerships to ensure the distribution of its implants:

- In China, the Group has already signed agreements leading to the creation of joint ventures with Shanghai Zuquan Investment Management Company Limited (see section 20.1 of the Registration Document):
    - Shanghai Zuquan Investment Management Company Limited is owned by the Gaoze group which is originally a real estate group in the construction industry generating several billion dollars in annual revenue, designing urban development projects, mainly in the Ningbo region near Shanghai. Gaoze decided to use part of its investment capacity in the Chinese high-tech medical devices sector, taking up an investment opportunity with the Artus and Epygon devices;
    - Affluent Medical, with its unique portfolio of Class III medical devices under development and validation, as well as its expertise in medical innovation, is an ideal partner for Gaoze for establishing high-added-value products on the Chinese market. The convergence of interests of the two parties with complementary capabilities and common objectives allows Affluent Medical, via the joint ventures presented in Section 20.1 of the Registration Document, to position itself in a high-growth segment that is the Chinese market for high-end medical devices.

- Concerning the Kardiozis technology, as indicated in section 5.2.4.2 of the Registration Document, the Group intends to enter into a license agreement with one of the major players in the treatment of abdominal aortic aneurysm by stent.

- For the United States, Affluent Medical plans to enter into distribution or license agreements for its products with major players in the urology and structural heart markets for the commercial and even clinical development of Artus, Kalios and Epygon.

► **A multidisciplinary training strategy for practitioners**

Affluent Medical intends to target primarily doctors practising in leading medical establishments specialising in cardiovascular and urinary surgeries. The Group will also have to be referenced by the purchasing departments and/or central purchasing division of medical establishments.

Practitioner training aims to ensure the adoption of the technology, best practices and expected clinical performance and is part of the regulatory monitoring requirements.

These practitioners are the prescribers of the Group's products, while the equipment is purchased by the medical establishment in which they practise. It is the practitioner who ultimately chooses the material used during surgery. This being the case, the decision-making power of the practitioner may vary depending on their status (salaried or not) at the medical establishment and the country. Therefore, the medical establishment may also be considered an influential decision-maker. In addition, an intermediary may intervene between the Group and the practitioner. These intermediaries are agents responsible for pre- and post-surgery logistics and, when permitted by law, are present in the operating

room in order to provide knowledge of the equipment used and answer the practitioner's questions. This is often the case in the United States in particular.

To optimise the clinical benefit, patients must also be trained in the proper use of the Artus product.

In addition to the internal vendor training program, Affluent Medical plans to collaborate with several KOLs and medical centres as training centres to offer its future customers comprehensive training programs so that they can better understand the benefits of the innovations of the Group and become the best ambassadors of the products sold.

► **A strategy of cross-functional industrial and commercial partnerships aimed at accelerating the use of the Group's various medical devices**

In order to speed up the marketing of the various Artus, Kalios and Epygon devices, the Group intends to develop a strategy of cross-functional industrial and commercial partnerships aimed at improving, facilitating and monitoring the implementation of these products and patient monitoring.

The Group intends to create a favourable ecosystem through partnerships involving players in medical imaging, robotics and data management to increase the benefits provided to patients with secure pre-, peri and post-operative implantation procedures. These projects will consist of:

- the implementation of a complete operating program using the most advanced imaging tools:
    - Pre-operative analyses:
        - Anatomical analysis of the patient to validate the chosen size of the device and/or its positioning through image fusion;
        - Virtual pre-installation to optimise the planning of the installation (choice of access route to final positioning of the device)
    - Confirmation of the proper implantation of the device during the operation and post-operation
- the use of robotics to carry out the implantations;
- the collection of anonymised data on operations and devices to improve the tools used to program implantations and the devices themselves.

► **Pricing and reimbursement policy:**

Affluent Medical's pricing policy will depend on the distribution method and the country.

The pricing policy is different for distribution via distributors or directly to enable distributors to invest more significantly from a marketing perspective in the implants marketed by the Group.

In Europe, each country is independent in the pricing policy. In the United States, prices are higher (sometimes 3 to 4 times more expensive than in Europe depending on the medical device) and unrestricted but are increasingly imposed on suppliers by hospitals that group together into purchasing groups.

Affluent Medical envisages average selling prices to end customers which could range from €8,000 to €10,000 for Artus (see section 5.2.2.25.2.2.2 of the Registration Document), around €4,000 for Kalios (see section 5.2.3.2 of the Registration Document) and between €35,000 and €50,000 for Epygon (see section 5.2.3.3 of the Registration Document).

In order to benefit from the best possible reimbursements given the advantages provided by the Group's various medical devices, Affluent Medical plans to:

- conduct medico-economic studies highlighting a favourable cost-effectiveness ratio for treatments performed with the Group's implants;
- accumulate positive data on the safety and efficacy and superiority of the Group's implants;
- forge relationships with private insurers, particularly in the United States, for the reimbursement of the Group's implants.

This should make it possible to obtain premium reimbursements for the Group's devices where there are already reimbursement codes for more or less similar devices or procedures with favourable conditions.

5.4. Investments

5.4.1. Principal investments made since 2018

The investments made over the last three financial years are as follows:

(In thousands of euros)	Financial year 2018	Financial year 2019	Financial year 2020
Intangible assets	14	3	0
Property, plant and equipment	181	196	304
Financial assets	1,869	0	0
Total acquisitions	**2,064**	**199**	**304**

The main investments made by the Group correspond to investments in laboratory and IT equipment. Financial assets in 2018 mainly correspond to the interests held indirectly by Affluent Medical in the two joint ventures in China accounted for using the equity method.

5.4.2. Main investments in progress and future investments

Affluent Medical plans to invest around €180,000 in the acquisition of new machines to perform mechanical and fatigue tests for its Epygon bioprosthesis, as well as new machines for producing these implants.

5.4.3. Information concerning joint ventures and companies in which Affluent Medical holds a significant interest

Affluent Medical directly owns 100% of the share capital and voting rights of its four subsidiaries: Kephalios, Epygon, Kardiozis and MyoPowers, and indirectly, 100% of the share capital and voting rights of Epygon Italie SRL, a wholly-owned subsidiary of Epygon, and of Medev Europa SRL, a wholly-owned subsidiary of MyoPowers (see section 6.2 of the Registration Document).

In addition, Affluent Medical indirectly holds a 40% stake in the capital of Shanghai Epygon Medical Technology Co. Ltd and Shanghai MyoPowers Medical Technology Co. Ltd through its subsidiaries Epygon and MyoPowers in the context of joint ventures established with Shanghai Zuquan Investment Management Company Limited (see section 20.1 of the Registration Document).

5.4.4. Environmental issues

The nature of the Group's activities does not entail any significant risk for the environment.

The Group's activities in the context of the manufacture of certain of its implants may involve the controlled handling, use and processing of biological and chemical agents, in particular for the treatment of bovine pericardium and the washing and sterilisation of medical devices.

In this context, the Group subsidiaries MyoPowers and Epygon Italie use clean rooms for the production of the Artus and Epygon implants, and to carry out the processing mentioned above. These clean rooms are controlled and qualified by experts in compliance with the standards and regulations in force, so that the concentration of airborne particules is controlled and volatile organic compounds from the chemical materials used are filtered by extractors to avoid any external contamination. Waste from the raw materials used in the context of the production of the Group's medical devices is also collected and reprocessed by professionals.

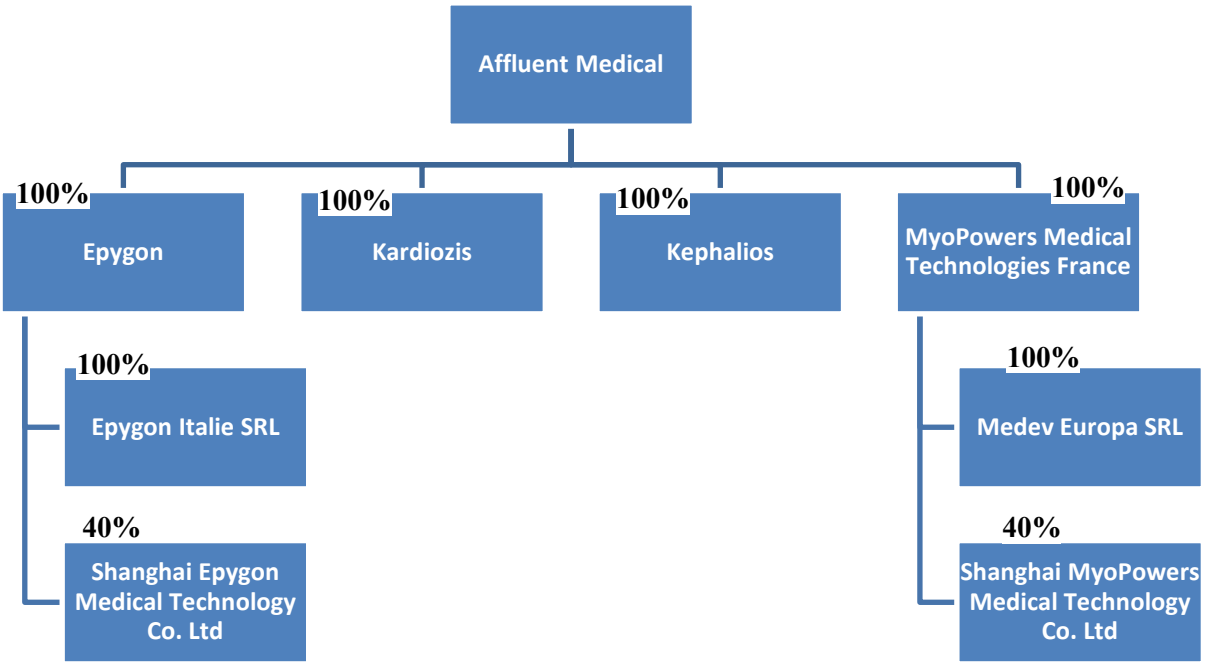
6. ORGANISATIONAL STRUCTURE

6.1. Legal organisational structure

As at the date of approval of the Registration Document, the Company does not have any branch or secondary establishment.

The Company directly holds 100% of the share capital and voting rights of the four subsidiaries: Kephalios, Epygon, Kardiozis and MyoPowers. The Company also indirectly holds 100% of the share capital and voting rights of Epygon Italie SRL, a wholly-owned subsidiary of Epygon, and of Medev Europa SRL, a wholly-owned subsidiary of MyoPowers Medical Technologies France. Lastly, the Company indirectly holds 40% of the share capital and voting rights of the two Chinese companies Shanghai Epygon Medical Technology Co. Ltd and Shanghai MyoPowers Medical Technology Co. Ltd as part of the joint ventures entered into with Shanghai Zuquan Investment Management Company Limited (see section 20.1 of the Registration Document).

Affluent Medical is the Group's parent company, which sets the strategy and oversees all support functions for the various operational entities.



6.2. Companies in the Group

Epygon, a French simplified joint stock company (*société par actions simplifiée*) with a share capital of €540,119 at 31 December 2020, whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, registered with the Aix-en-Provence Trade and Companies Registry, under number 539 455 238 ("**Epygon**"), was established in 2012 to develop medical devices and techniques for transcatheter implantation for the replacement of deficient mitral valves.

Epygon Italie SRL, an Italian limited liability company (*Società a Responsabilita Limitata*) with a share capital of €10,000, whose registered office is located at via Ribes 5 – 10010 Colleretto Giacosa (TO), Italy, registered with the Turin Trade and Companies Registry under number 11311520016 (**"Epygon Italie**"), is a wholly-owned subsidiary of Epygon, bringing together its research and development division and its production division.

Kephalios, a French simplified joint stock company (*société par actions simplifiée*) with a share capital of €508,395 at 31 December 2020, whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, registered with the Aix-en-Provence Trade and Companies Registry, under number 531 557 650 ("**Kephalios**"), was established in 2011 and is developing a mitral ring that can be adjusted over time, called Kalios, for the minimally invasive correction of mitral regurgitation.

Kardiozis, a French simplified joint stock company (*société par actions simplifiée*) with a share capital of €293,997 at 31 December 2020, whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, and registered with the Aix-en-Provence Trade and Companies Registry under number 532 628 336 ("**Kardiozis**"), was established in 2011. It specialises in medical equipment and is developing a prosthesis to treat the abdominal aortic aneurysm using the EVAR technique.

MyoPowers Medical Technologies France, a French simplified joint stock company (*société par actions simplifiée*) with a share capital of €3,633,091 at 31 December 2020, whose registered office is located at 18, rue Alain Savary – 25000 Besançon, France, registered with the Besançon Trade and Companies Registry under number 799 927 355 ("**MyoPowers**"), was established in 2014 and specialises in the development of an artificial urinary sphincter to treat severe urinary incontinence.

Medev Europa SRL, a Romanian limited liability company (*Societate cu Raspundere Limitata*) with a share capital of 2,000 lei, whose registered office is located at Bucureşti Sectorul 4, Bulevardul Regina Maria, Nr. 32, Parter Biroul NR. 3, Modul, Romania, registered with the Romanian National Office of the Trade Register under number J40/524/2020 and the unique identification code 42124756 ("**Medev Europa**"), was established in 2020 and has no operational activity as at the date of approval of the Registration Document.

Shanghai Epygon Medical Technology Co., a Chinese limited liability company registered under number 91310115MA1H9W000X, whose registered office is located at 301 & 401, No. 12-13, 100 Nong, Banxia Road, Pudong New Area, Shanghai, China, was established in 2018 as part of a joint-venture contract to develop Epygon products in China, Macau, Taiwan and Hong Kong.

Shanghai MyoPowers Medical Technology Co., a Chinese limited liability company registered under number 9130115MA1H9W027M, whose registered office is located at 402, No. 12-13, 100 Nong, Banxia Road, Pudong New Area, Shanghai, China, was established in 2018 as part of a joint-venture contract to develop MyoPowers products in China, Macau, Taiwan and Hong Kong.

6.3. Description of the Group's cash flow

Please refer to section 17.2 of the Registration Document.

7. REVIEW OF THE FINANCIAL POSITION AND RESULTS

Readers are invited to read this analysis of the Group's financial position and results in conjunction with the Group's consolidated financial statements prepared in accordance with IFRS, as adopted by the European Union, for the financial years ended 31 December 2019 and 2020, as well as the consolidated financial statements of the Group prepared in accordance with French accounting principles (CRC 99-02) presented in Chapter 18 "Financial information concerning the Group's assets, financial position and results" of the Registration Document and any other financial information included in the Registration Document.

It should be noted that the Company published consolidated financial statements according to the CRC 99-02 standard until 31 December 2018. Subsequently, the Company decided to adopt the IFRS framework for the preparation of its consolidated financial statements from 1 January 2019. In accordance with the provisions of point 18.1.4 of Commission Delegated Regulation (EU) 2019/980 of 14 March 2019, the Company publishes a complete set of financial statements prepared in accordance with IFRS as at 31 December 2020, including comparative information.

7.1. Financial position

7.1.1. General presentation

The Group is developing next-generation minimally invasive medical devices, at a clinical stage, with the aim of saving the lives and improving the quality of life of millions of patients around the world affected by severe pathologies in the fields of urology and structural heart.

Affluent Medical has a portfolio of products or technologies to regulate urethral, cardiac or aortic flows by restoring the natural physiology of patients, while simplifying the surgical procedure (optimal precision, speed and safety) and reducing the total cost of short-term and long-term care:

- three best-in-class innovative implantable prostheses at the clinical development stage:
    - Artus: artificial sphincter for the treatment of severe urinary incontinence restoring the complete control of the bladder, by closing or opening the urinary flow at the will of the patient using a simple remote control and designed both for men and women;
    - Kalios: the only ring designed for mitral valve repair optimised for minimally invasive cardiac surgery and allowing multiple post-operative readjustments via the transcatheter route-without invasive reoperation. It is therefore a unique hybrid technology; and
    - Epygon: the only physiological mitral valve bioprosthesis implanted via a transcatheter route capable of mimicking the native mitral valve.
- A Kardiozis technology based on thrombogenic fibres that fits on an endoprosthesis (stent-graft) for the treatment of abdominal aortic aneurysm, ensuring a natural embolisation to reduce the risk of endoleaks generating a risk of the aneurysm rupturing.

The company was incorporated on 23 February 2018 as a holding company to hold stakes in four operating companies. Affluent Medical directly holds 100% of the share capital and voting rights of Epygon, Kardiozis, Kephalios and MyoPowers, and indirectly 100% of Epygon Italie SRL and Medev Europa SRL. The Company indirectly holds 40% of the share capital and voting rights of the two Chinese companies Shanghai Epygon Medical Technology Co Ltd and Shanghai MyoPowers Medical Technology Co. Ltd as part of the joint ventures entered into with Shanghai Zuquan Investment Management Company Limited (refer to section 6.1 of the Registration Document).

The Group's research and development (R&D), preclinical and clinical activities have mobilised most of its resources, enabling significant progress in the validation of the medical devices and technologies

presented in more detail in Chapter 5 “Overview of business activities” in the Registration Document. It should be noted that all R&D, pre-clinical and clinical costs are recognised as operating expenses in the year in which they are incurred. The Company also devotes a sizeable percentage of its resources to protecting its intellectual property by filing international patent applications at an early stage.

Since the creation of Affluent Medical, the Group’s cumulative consolidated losses have amounted to nearly €43 million, mainly related to R&D expenses and preclinical and clinical studies as well as overheads and operating expenses. Operating expenses dedicated to R&D, preclinical and clinical activities, regulatory affairs and quality, and excluding general administrative expenses, represent approximately 85% of the Company’s total expenses.

As R&D, preclinical and clinical expenses are recognised as operating expenses for the year in which they are incurred, the developed projects require growing financial needs and generate operating losses. Affluent Medical's first operating revenues will be generated when the developed projects reach the commercialisation or license agreement stage, which could generate revenues in the form of lump sums or royalties (refer to section 5.1.1 of the Registration Document).

Since its creation, the Group has been financed by:

- capital increases;
- convertible and non-convertible bond issuances;
- repayable advances, subsidies and an innovation loan granted by Bpifrance;
- State-guaranteed loans from BNP Paribas, Société Générale and CIC; and
- the research tax credit as well as its pre-financing from the specialised organisation Neftys (see section 8.1.5 of the Registration Document).

7.1.2. Main factors affecting the consolidated financial statements of Affluent Medical prepared in accordance with IFRS

Given the development stage of the Group, the main factors affecting its activity, financial position, results, development and outlook are:

- the scope of research and development programmes, clinical and preclinical studies, compliance with their progress schedule as well as the scientific uncertainties and possible delays caused by the Covid-19 pandemic (refer to Chapter 3 of the Registration Document);
- changes in the Group’s structure, particularly in terms of recruitment;
- the existence of tax incentives for companies conducting technical and scientific research activities (CIR);
- obtaining subsidies and repayable advances;
- the signature or continuation of collaboration agreements with its partners or new partners, particularly for the marketing phase of its products; and
- obtaining financing, in particular, without being exhaustive, in the form of convertible and non-convertible bonds, loans guaranteed by the State or the pre-financing of research tax receivables.

7.1.3. Presentation and analysis of the items from Affluent Medical's consolidated balance sheets prepared in accordance with IFRS as at 31 December 2020, 31 December 2019 and 1 January 2019

SIMPLIFIED STATEMENT OF FINANCIAL POSITION (Amounts in €000)	31/12/2020 IFRS	31/12/2019 IFRS	01/01/2019 IFRS
Non-current assets	56,915	59,136	61,710
Current assets	7,911	6,116	7,133
Total assets	**64,826**	**65,252**	**68,843**
Equity	35,289	30,964	47,058
Non-current liabilities	19,772	24,780	14,779
Current liabilities	9,765	9,508	7,006
Total liabilities	**64,826**	**65,252**	**68,843**

7.1.3.1. Non-current assets

NON-CURRENT ASSETS (Amounts in €000)	31/12/2020 IFRS	31/12/2019 IFRS	01/01/2019 IFRS
Goodwill	32,203	32,203	32,203
Intangible assets	22,566	24,442	26,318
Property, plant and equipment	1,781	1,746	1,468
Shareholdingsin equity-accounted companies	14	414	1,580
Non-current financial assets	351	331	140
Total non-current assets	**56,915**	**59,136**	**61,710**

On 27 March 2018, the Company benefited from the contribution of shares in Epygon SAS, Kardiozis SAS, Kephalios SAS and MyoPowers Medical Technologies France. The Company has decided not to apply IFRS 3 retrospectively to business combinations occurring before the IFRS transition date.

Thus, the allocation of the purchase price made in accordance with French accounting principles in 2018 (CRC 99-02) was maintained in the opening balance sheet as at 1 January 2019.

The difference between the acquisition cost of the shares and the total valuation of the assets and liabilities identified at the acquisition date constitutes goodwill, which amounts to €32,203 thousands.

In particular, technologies developed in-house and recorded as intangible assets are amortised over a period of 15 years, which mainly explains the decrease in intangible assets compared to the amount as at 1 January 2019 (see note 4.1 to the consolidated financial statements under IFRS for the financial years ended 31 December 2019 and 2020).

Property, plant and equipment mainly comprise:

- use rights recognised in accordance with IFRS 16 *Leases*
- laboratory equipment and tools; and
- IT equipment.

The decrease in the carrying amount of companies accounted for under the equity method reflects the development expenses incurred by the joint ventures (refer to section 7.1.3 of the Registration Document).

Non-current financial assets consist mainly of guarantee deposits (advance payment of the last monthly repayment of tranches A and B) set up when tranches A and B of the non-convertible bond with Kreos Capital were issued. They amounted to €128 thousand as at 1 January 2019 and €256 thousand as at 31 December 2019 and 2020.

7.1.3.2. Current assets

CURRENT ASSETS (Amounts in €000)	31/12/2020 IFRS	31/12/2019 IFRS	01/01/2019 IFRS
Other receivables	2,261	3,989	3,795
Cash and cash equivalents	5,650	2,126	3,339
Total current assets	**7,911**	**6,116**	**7,133**

Other receivables include:

- receivables in respect of the research tax credit (abbreviated CIR in French) amounting to €509 thousand as at 31 December 2020, €2,109 thousand as at 31 December 2019 and €1,951 thousand as at 31 December 2018;
- VAT credit amounting to €1,038 thousand as at 31 December 2020, €1,324 thousand as at 31 December 2019 and €1,157 thousand as at 31 December 2018. The Company's French subsidiaries are structurally in VAT credit in the absence of revenue.

The decrease in the value of the RTC for 2020 compared to previous years is explained by the fact that in 2020 the Group received a part of the Bpifrance repayable advances and subsidies which are deducted from the calculation base of the RTC.

Cash and cash equivalents consist of bank accounts and investments with an original maturity of less than three months (see Chapter 8 concerning the source and changes in cash and cash equivalents).

7.1.3.3. Equity

EQUITY (Amounts in €000)	31/12/2020 IFRS	31/12/2019 IFRS	01/01/2019 IFRS
Share capital	15,257	11,900	11,900
Share premiums	62,683	47,701	47,646
Currency translation	21	24	0
Other items in comprehensive income	(22)	(20)	-
Reserves and net income attributable to shareholders of the parent company	(42,649)	(28,641)	(12,489)
Equity, Group share	**35,289**	**30,964**	**47,058**
Non-controlling interests	-	-	-
Total equity	**35,289**	**30,964**	**47,058**

The share capital as at 31 December 2020 is set at €15,256,824.00 and is divided into 4,049,423 ordinary shares and 11,207,401 A preferred shares with a nominal value of €1.00.

A preferred shares will be automatically converted into ordinary shares subject to admission of the Company's shares to trading on the Euronext Paris market (refer to section 19.1.1 of the Registration Document).

The change in equity during financial year 2020 mainly corresponds to:

- capital increases for a total amount of €7,456 thousand that took place in June, October and December 2020;
- the impact of the conversion of certain bonds in June 2020 for an amount of €10,224 thousand (refer to section 7.1.3.4 of the Registration Document);
- the impact of share-based payment (IFRS 2) in the amount of €959 thousand; and
- the loss of -€14,319 thousand for financial year 2020.

Please refer to the statement of changes in consolidated equity presented in the financial statements prepared under IFRS for the financial years ended 31 December 2020 and 31 December 2019 in section 18.1.1.1 of the Registration Document.

7.1.3.4. Financial liabilities

The table below shows non-current and current financial liabilities:

CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amounts in €000)	**31/12/2020**	**31/12/2019**	**01/01/2019**
Repayable advances	9,489	6,052	2,021
Loans guaranteed by the State	2,155	-	-
Bond loan	4,593	13,782	7,862
Other loans and liabilities	9	48	118
Non-current financial liabilities	**16,248**	**19,882**	**10,001**
Non-current lease liabilities	731	811	597
Non-current derivative liabilities	-	995	713
Total non-current financial liabilities	**16,978**	**21,687**	**11,311**
Pre-financing of Research Tax Credit receivables	-	669	354
Bond loan	3,573	2,621	815
Other loans and liabilities	-	-	17
Bank overdrafts	2	1	2
Current financial liabilities	**3,575**	**3,290**	**1,188**
Current lease liabilities	226	202	119
Current derivative liabilities	1,351	270	141
Total current financial liabilities	**5,152**	**3,762**	**1,448**
Total financial liabilities	**22,131**	**25,449**	**12,759**

Repayable advances (presented in non-current financial liabilities) increased by €7,468 thousand between 1 January 2019 and 31 December 2020 following the receipt of a repayable advance in the

amount of €3,659 thousand as part of the PIAVE Artus project in 2019 and the receipt of repayable advances in 2020 amounting to €2,755 thousand (innovation loan with Bpifrance for €1 million and Mivana project for €1.8 million).

The Company set up four loans guaranteed by the State in 2020 for a total amount of €2.1 million (refer to section 18.1.1.1 note 11 of the Registration Document and section 8.1.4 of the Registration Document).

Bonds amounted to €8,677 thousand as at 1 January 2019 of which €7,862 thousand in non-current financial liabilities and €815 thousand in current financial liabilities. They consist of tranche A of the non-convertible bonds issued in October 2018 to the benefit of Kreos Capital in the amount of €3,704 thousand (of which €815 thousand in current financial liabilities), and the convertible bonds issued in March 2018 ("CB 2018" with a nominal value of €2.85 million) for €2,524 thousand and the convertible bonds issued in April 2018 ("Financing CB", with a nominal value of €3 million) for €2,488 thousand.

In the 2019 financial year, bond issuances increased overall by €7,726 thousand to reach €16,403 thousand (of which €13,782 thousand in non-current financial liabilities and €2,621 thousand in current financial liabilities). The portion at less than one year of the bond issued to the benefit of Kreos (tranches A and B) is recorded under current financial liabilities in the amount of €2,621 thousand. Other bonds are presented as non-current financial liabilities.

In June 2019, the Company issued tranche B of the non -convertible bonds to the benefit ofKreos Capital in the amount of €4 million. The Company repaid €516 thousand of Tranche A in 2019. As as at 31 December 2019, the debt to Kreos Capital in respect of tranches A and B amounted to €7,262 thousand of which €2,621 thousand under current financial liabilities.

In December 2019, the Company issued convertible bonds to the benefit of Truffle Innov FRR France and Truffle Biomedtech Crossover Fund for €4 million (first tranche of the "**2019 CB**"), the value of which as at 31 December 2019 was €3,614 thousand in accordance with IFRS 9.

In financial year 2020, bond issues decreased overall by €8,236 thousand to reach €8,167 thousand (of which €4,593 thousand in non-current financial liabilities and €3,573 thousand in current financial liabilities).

In June 2020, the convertible bonds of the 2018 CB, Financing CB and the first tranche of the 2019 CB were converted, which explains a decrease in bonds of €9,141 thousand compared to 31 December 2019.

In October 2020, the Company issued a bond for the benefit of Head Leader (second tranche of the 2019 CB) for €4 million, the value of which as at 31 December 2020 was €2,684 thousand in accordance with IFRS 9.

In addition, the Company repaid €1,952 thousand of bonds issued to Kreos Capital (tranches A and B). As at 31 December 2020, non-convertible bonds issued to Kreos Capital totalled €5,483 thousand (of which €3,573 thousand in current financial liabilities).

Liabilities related to lease obligations relate to the premises occupied by the Company in Paris, Aix-en-Provence, Besançon and Colleretto Giacosa (Italy), laboratory equipment, IT equipment and vehicles. They amounted to €716 thousand (of which €119 thousand due in less than one year) at 1 January 2019. In financial year 2019, the Company entered into a new lease for its premises in Aix-en-Provence and leased laboratory equipment and transport vehicles generating an additional debt of €480 thousand. In addition, the Company repaid €184 thousand of liabilities related to lease obligations in 2019.

In financial year 2020, the Company renewed the lease for its premises in Besançon and set up new vehicle leases generating an additional debt of €167 thousand. The Company repaid €222 thousand in 2020.

In accordance with IFRS 9, the conversion options on the convertible bonds (Financing CB, 2019 CB) have been separated, recognised in derivative liabilities based on a variable conversion rate and measured at fair value, with changes in this fair value recorded in the income statement in accordance with IFRS 9.

The warrants attached to Tranche A of the non-convertible bond issued to Kreos Capital were recognised as derivative liabilities and measured at fair value with changes in this fair value recorded in the income statement in accordance with IFRS 9.

At the time of the conversion of the Financing CB bonds and the first tranche of the 2019 CB in June 2019, the derivative liabilities relating to the conversion options were recorded in equity on the conversion date.

Please refer to section 8.1 of the Registration Document for more information on the Group's financing sources.

7.1.3.5. Non-current liabilities

NON-CURRENT LIABILITIES (Amounts in €000)	**31/12/2020 IFRS**	**31/12/2019 IFRS**	**01/01/2019 IFRS**
Non-current financial liabilities	16,248	19,882	10,001
Non-current lease liabilities	731	811	597
Employee benefits commitments	117	86	45
Non-current provisions	228	103	-
Deferred tax liabilities	2,440	2,669	2,899
Derivative liabilities	-	995	713
Other non-current liabilities	9	234	525
Total non-current liabilities	**19,772**	**24,780**	**14,779**

Non-current financial liabilities and their evolution are presented in Sections 7.1.3.4 and 8.1 of the Registration Document.

Liabilities related to non-current lease obligations, recorded in accordance with IFRS 16 *Leases* consist mainly of commitments relating to the property leases for the premises occupied by the Group in Paris, Aix-en-Provence, Besançon and Colleretto Giacosa (Italy).

Employee benefit obligations consist of the commitment relating to defined benefits under the Italian TFR scheme ("End of Report Salary") and the provision for retirement benefits for employees covered by the French scheme.

Non-current provisions consist of provisions for industrial tribunal disputes.

Other non-current liabilities consist mainly of deferred income relating to the deferment of subsidies received under the Mivana and PIAVE Artus projects.

The Company noted:

- deferred tax liabilities on the technology developed in-house and resulting from the business combination in 2018; and
- deferred tax assets in the amount of deferred tax liabilities after application of the capping mechanism for tax loss carryforwards (refer to section 7.2.1.4 of the Registration Document).

7.1.3.6. Current liabilities

CURRENT LIABILITIES (Amounts in €000)	31/12/2020 IFRS	31/12/2019 IFRS	01/01/2019 IFRS
Current financial liabilities	3,575	3,290	1,188
Non-current lease liabilities	226	202	119
Trade payables and related accounts	2,352	3,704	3,703
Other current liabilities	2,261	2,043	1,854
Derivative liabilities	1,351	270	141
Total current liabilities	**9,765**	**9,508**	**7,006**

Other current liabilities consist mainly of tax and social security payables, deferred income and a current account with the FCPI Truffle Innocroissance 2016 in the amount of €300 thousand.

In accordance with IFRS 9 *Financial instruments*, the Company recognised derivative liabilities in respect of the conversion options of the Financing CBs and the 2019 CBs, and in respect of the Kreos Capital warrants in the absence of a fixed parity (refer to section 18.1.1.1 note 11 of the Registration Document).

Current financial liabilities increased during financial year 2019, following the issuance of tranche B of the Kreos Capital non-convertible bonds in the amount of €4 million. Current financial liabilities decreased in financial year 2020 due to the following:

- repayment of pre-financing of Research Tax Credit ("CIR") receivables in the amount of €0.7 million;
- repayment of instalments for the Kreos non-convertible bonds in the amount of €1,952 thousand;
- offset by the receipt of the second tranche of the 2019 CB bond issue for €4.0 million; and
- recognition of the liability derivative on the second tranche of the 2019 CB bond issue for €1.4 million.

Trade payables and related accounts relate to expenses incurred in connection with the development of medical devices and general expenses. The decrease in payables to suppliers in 2020 is mainly due to the shortening of the supplier payment period.

7.1.3.7. Opening balance sheet as at 1 January 2019: transition from French standards CRC 99-02 to IFRS standards

Affluent Medical SA Statement of financial position	Consolidated financial statements CRC 99-02 31 December 2018	Consolidation of the EPYGON SRL subsidiary Note A	IAS 20 repayable advances Note B	IFRS 16 leases Note C	Loans IFRS 9 Note D	Deferred taxes IAS 12 Note E	Equity-accounted companies Note F	IAS 19R Pension commitment Note G	Reclassifications Other	Consolidated financial statements IFRS 1 January 2019
ASSETS										
Goodwill	32,203									32,203
Other intangible assets	26,209	110								26,318
Property, plant and equipment (including right-of-use assets)	362	407		699						1,468
Shareholdings in equity-accounted companies	1,829						(249)			1,580
Other non-current financial assets	10	(10)			128				12	140
Other non-current assets	12								(12)	-
Deferred tax assets	-									-
Total non-current assets	**60,626**	**506**	**-**	**699**	**128**	**-**	**(249)**		**-**	**61,710**
Clients	4	18							(21)	-
Other current receivables	8,041	271				(4,436)			(80)	3,795
Current tax asset	-									-
Cash and cash equivalents	3,224	115								3,339
Total current assets	**11,268**	**403**	**-**	**-**	**-**	**(4,436)**	**-**		**(101)**	**7133**
Total assets	**71,894**	**910**	**-**	**699**	**128**	**(4,436)**	**(249)**		**(101)**	**68,843**
Share Capital	11,900									11,900
Share Premiums	47,646									47,646
Currency translation	(40)						40			-
Other items in comprehensive income	-									-
Reserves and net income attributable to owners of the Group	(10,998)	404	(1,407)	(17)	575	(880)	(289)	(5)	128	(12,489)
Total equity attributable to owners of the parent company	**48,509**	**404**	**(1,506)**	**(17)**	**575**	**(880)**	**(249)**	**(5)**	**128**	**47,058**
Other equity	1,451								(1,451)	-
Non-current financial liabilities	9,722		570		(1,045)				755	10,001
Non-current lease liabilities	-			597						597
Employee benefits commitments	-							45		45
Non-current provisions	26							(26)		0
Deferred tax liabilities	6,454					(3,556)				2,899
Derivative liabilities	-				713					713
Other non-current liabilities	-		525							525
Non-current liabilities	**17,653**	**-**	**1,095**	**597**	**(332)**	**(3,556)**	**-**	**19**	**(696)**	**14,779**
Current financial liabilities	392				(255)				1,050	1,188
Current lease liabilities				119						119
Trade payables	3,573	239							(108)	3,703
Other current liabilities	1,766	266	312					(14)	(475)	1,854
Derivative liabilities					141					141
Current liabilities	**5,732**	**505**	**312**	**119**	**(114)**	**-**	**-**	**(14)**	**466**	**7,006**

Total liabilities and equity	**71,894**	**910**	**-**	**699**	**128**	**(4,436)**	**(249)**	**-**	**(101)**	**68,843**

Note A: Epygon SRL is fully consolidated in the consolidated financial statements under IFRS, although it is considered a non-significant subsidiary according to the French standard (CRC 99-02).

Note B: According to IAS 20 *Accounting for government subsidies and disclosure of government assistance,* the fact that a repayable advance or a loan does not include the payment of an annual interest or the payment of a reduced interest means that the Company benefited from a rate which is more favourable than the market conditions. The difference between the amount of the advance or loan at historical cost and that of the advance discounted at a marginal debt ratio is considered as a subsidy received from the State.
Subsidies received as part of development projects are spread over the duration of the expenses incurred in the context of the said project, using deferred income.
Repayable advances are recognised in "other equity" in accordance with French standards (CRC 99-02).

Note C: According to IFRS 16 *Leases*, all leases (finance leases, operating leases, real estate leases) are restated and lead the company to recognise a right of use and a liability relating to lease obligations. Only finance leases are restated according to French accounting standards (CRC 99-02).

Note D: According to IFRS 9 *Financial instruments* and IAS 32 *Financial instruments: presentation* (i) debt components are recognised at amortised cost. (ii) conversion options and warrants attached to financial debts are recognised as derivatives in the absence of a fixed exchange rate or as equity instruments (refer to section 8.1.3 of the Registration Document).

Note E: Capitalised deferred tax assets in the amount of deferred tax liabilities are presented in the statement of financial position in net position.

Note F: In the IFRS opening balance sheet as at 1 January 2019, the company took into account the share of expenses incurred by joint ventures as part of the equity method.

Note G: The pension obligations under IAS 19 R include the commitment relating to the defined benefits of the Italian TFR scheme ("End of Report Processing") not included in the consolidated financial statements prepared according to the French standard (CRC 99-02) as at 31 December 2018.

7.2. Operational results

7.2.1. Presentation and analysis of the consolidated income statements of Affluent Medical prepared in accordance with IFRS for the financial years ended 31 December 2020 and 2019 as well as in accordance with French accounting principles (CRC 99-02) as at 31 December 2018.

INCOME STATEMENT (Amounts in €000)	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months	31/12/2018 CRC 99-02 10 months
Revenue	-	-	1,902
Other operating income	824	1,429	127
OPERATING EXPENSES			
Purchases consumed	(3,108)	(5,483)	-
External expenses	(3,563)	(3,899)	(11,213)
Personnel expenses	(4,694)	(3,607)	(1,795)
Taxes and duties	(67)	(34)	(28)
Other current operating income and expenses	46	14	(217)
Provisions	(125)	-	-
Depreciation	(1,907)	(2,260)	(1,988)
OPERATING INCOME	**(12,594)**	**(13,841)**	**(13,212)**
Share of net income of equity-accounted companies	(398)	(1,190)	-
OPERATING INCOME after share of net income of equity-accounted companies	**(12,992)**	**(15,031)**	**(13,212)**
Financial income (loss)	(1536)	(1,769)	(424)
Exceptional income and expenses			91
Income taxes	209	210	2,297
Net income (loss)	**(14,319)**	**(16,589)**	**(11,248)**

7.2.1.1. Revenue and other operating income

OPERATING INCOME (Amounts in €000)	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months	31/12/2018 CRC 99-02 10 months
Revenue	-	-	1,902
Other operating income	824	1,429	127

Under the joint venture agreements entered into in 2017 with Shanghai Zuquan Investment Management Company Limited (refer to section 20.1 of the Registration Document), the companies Epygon and MyoPowers granted exclusive licenses to the joint ventures in 2018 for the development, registration, manufacture and marketing of the companies' medical devices in Mainland China during the remaining term of patent protection. Revenue recognised under these licensing agreements amounted to €1,895 thousand in 2018.

Other operating income consists mainly of:

- research tax credits amounting to €380 thousand in 2020 and €1,087 thousand in 2019. the research tax credits for 2018 are recorded as income tax income according to French accounting principles (CRC 99-02) (refer to section 7.2.1.4 of the Registration Document); and
- of subsidies spread over the duration of the expenses incurred as part of the Mivana and PIAVE Artus development projects in the amount of €408 thousand in 2020 (of which €375 thousand

for the Mivana project, €33 thousand for the PIAVE Artus project), €330 thousand in 2019 and €65 thousand in 2018.

7.2.1.2. Operating income

The presentation in the income statement of purchases consumed and external expenses differs between the income statements prepared in accordance with IFRS in 2019 and 2020 and the income statement prepared in accordance with CRC 99-02.

The table below allows their comparison through the use of specific sub-totals:

PURCHASES CONSUMED, OTHER PURCHASES AND EXTERNAL EXPENSES (Amounts in €000)	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months	31/12/2018 CRC 99-02 10 months
Purchases consumed	(3,108)	(5,483)	
Other purchases			(7,336)
Subtotal purchases consumed and other purchases	***(3,108)***	***(5,483)***	***(7,336)***
Other external charges			(3,540)
Fees	(2,969)	(3,117)	
Missions and receptions	(128)	(414)	
Sub-total other external expenses	***(3,098)***	***(3,531)***	***(3,540)***
Other external services			(337)
Maintenance and repairs	(152)	(86)	
Advertising, publications, public relations	(21)	(38)	
Rentals and rental expenses	(58)	(39)	
Insurance premiums	(48)	(42)	
Studies, research, documentation and seminars	(9)	(22)	
Miscellaneous	(178)	(142)	
Sub-total other external services	***(465)***	***(368)***	***(337)***
Total purchases consumed and external expenses	**(6,671)**	**(9,382)**	**(11,213)**

Purchases consumed and other purchases consist of:

- subcontracting purchases which mainly include expenses related to external studies, subcontracting and scientific consulting;
- subcontracting for the manufacture of prototypes; and
- costs related to administrative supplies, electricity and equipment, particularly laboratory supplies;

The level of the Group's expenses depends on the stage of completion of clinical and pre-clinical trials.

Between 2018 and 2019, purchases consumed and other purchases decreased by nearly €1.9 million in conjunction with the level of activity in the pre-clinical phase for Epygon (-€1.4 million compared to 2018) and for MyoPowers (-€1.6 million compared to 2018). These reductions were offset in the amount of €0.9 million by the launch in 2019 of the Optimise II study for the Kalios product.

Between 2019 and 2020, purchases consumed and other purchases were decreased mainly due to the Covid-19 pandemic, the postponement of certain studies:

- decrease in the volume of general activity on Kardiozis (-€0.5 million compared to 2019);
- decrease in pre-clinical activity for Epygon (-€0.7 million compared to 2019);
- decrease in clinical activity as well as material purchases for Kalios (-€0.6 million compared to 2019); and

- decrease in R&D activity for Artus (-€0.6 million compared to 2019).

Other external expenses mainly break down as follows:

- Fees for legal assistance and administrative service providers;
- Service agreements with the consultants and scientific experts who assist the Company in the preparation and supervision of the research and development programmes;
- "Missions and travel" primarily performed in the context of the various pre-clinical studies initiated;

In line with the travel restrictions linked to the Covid-19 pandemic, travel and missions expenses were significantly reduced in 2020.

Other external services consist of:

- the rents paid in 2018 (leases are restated under IFRS from 2019 with recognition of a right-of-use and a liability for lease obligations, the rents are restated via the repayment of the liability and the recognition of a financial expense, then the right-of-use is amortised), maintenance costs, rental expenses and servicing expenses of the various premises occupied by the Group in Paris, Aix-en-Provence, Besançon and Colleretto Giacosa (Italy) to carry out its administrative and research activities;
- documentation, technology watch and seminars;
- patent fees; and
- general expenses such as those associated with insurance, transport of materials and samples, telecommunications or banking.

PERSONNEL EXPENSES **(Amounts in €000)**	**31/12/2020 IFRS 12 months**	**31/12/2019 IFRS 12 months**	**31/12/2018 CRC 99-02 10 months**
Personnel expenses	(4,694)	(3,607)	(1,795)
Of which share-based payments (IFRS 2)	*(959)*	*(437)*	*N/A*

The Group had an average workforce of 42 employees for the year ended 31 December 2020 compared to 40 employees for the year ended 31 December 2019 and 34 employees for the year ended 31 December 2018. Most of the staff is assigned to research and development activities, divided between its research laboratories in Paris, Aix-en-Provence, Besançon and Colleretto Giacosa in Italy.

Personnel expenses presented under IFRS include the expense relating to share-based payments (IFRS 2) in respect of equity instruments granted to employees or corporate officers in the amount of €959 thousand as at 31 December 2020 and €437 thousand as at 31 December 2019. The increase in personnel expenses between 2018 and 2020 (excluding the effect of IFRS 2) is due to the gradual reinforcement of the Group's workforce involved in research and development activities and management functions.

French accounting principles (CRC 99-02) do not provide for the recording of a similar expense in the consolidated financial statements as at 31 December 2018.

AMORTISATION, DEPRECIATION AND PROVISIONS **(Amounts in €000)**	**31/12/2020 IFRS 12 months**	**31/12/2019 IFRS 12 months**	**31/12/2018 CRC 99-02 10 months**
Depreciation	(1,907)	(2,260)	(1,584)
Provisions	(125)	-	(404)
Amortisation, depreciation and provisions	**(2,032)**	**(2,260)**	**(1,988)**

Depreciation charges are mainly related to:

- internally developed technologies amortised over 15 years and recovered during the business combination in 2018. The depreciation amounted to €1,847 thousand in 2020, €1,847 thousand in 2019 and €1,505 thousand in 2018;
- property, plant and equipment (excluding right-of-use assets) for €204 thousand in 2020, €185 thousand in 2019 and €79 thousand in 2018; and
- right-of-use accounts recognised in accordance with IFRS 16 *Leases* for €231 thousand in 2020 and €197 thousand in 2019. The provisions of French accounting principles (CRC 99-02) do not provide for the recognition of rights-of-use in 2018 for leases that do not qualify as finance leases (operating leases, property leases). In 2018, no finance lease expense was recognised.

A provisions of €404 thousand was recognised in 2018 for the impairment of subsidies receivable recognised in previous years for the Mivana project (refer to section 18.1.1.2 of the Registration Document).

SHARE OF INCOME OF EQUITY-ACCOUNTED COMPANIES **(Amounts in €000)**	**31/12/2020** **IFRS** **12 months**	**31/12/2019** **IFRS** **12 months**	**31/12/2018** **CRC 99-02** **10 months**
Share of income of equity-accounted companies	(398)	(1,190)	-

The Group's 40% interest as at 31 December 2020 in Shanghai Epygon Medical Technology Co., Ltd. and Shanghai MyoPowers Medical Technology Co., Ltd., are accounted for using the equity method which provides for an initial recognition at the acquisition cost, then a subsequent adjustment of the Group's share in the income.

The purpose of the two joint ventures is the research and development, manufacturing and marketing in Mainland China of medical devices developed or under development, respectively by the subsidiaries Epygon and MyoPowers.

Given the stage of development of the products, the Joint Ventures did not generate revenue during the financial years presented. Accordingly, the share of losses of companies accounted for under the equity method reflects the development expenses incurred by the Joint Ventures. The Company did not have the financial information to update the equity value as at 31 December 2018.

7.2.1.3. Financial income (loss)

Financial income (loss) **(Amounts in €000)**	**31/12/2020** **IFRS** **12 months**	**31/12/2019** **IFRS** **12 months**	**31/12/2018** **CRC 99-02** **10 months**
Other financial income	-	-	61
Interest expenses	(2,129)	(1,884)	(424)
Foreign exchange income	1	(3)	(61)
Change in fair value of financial instruments	597	132	
Effect of accretion	(36)	(17)	
Other	30	3	-
Financial income (loss)	**(1,536)**	**(1,769)**	**(424)**

The financial income for the years presented is strongly negative given the financing set up in 2018, 2019 and 2020, and the increase in interest paid as a result. It is partially offset in 2019 and in 2020 by the change in the fair value under IFRS of derivative liabilities.

In particular, the financial result in 2020 includes:

- the amortised cost and accrued interest on bonds amounting to €623 thousand ;
- accrued interest of €758 thousand on repayable advances (Mivana and PIAVE Artus)

- interest paid in the amount of €715 thousand in 2020;
- accretion of repayable advances in accordance with IAS 20"*Accounting for government subsidies and disclosure of government assistance";* and
- changes in the fair value of derivative liabilities in accordance with IFRS 9 *"Financial instruments"*.

Foreign exchange gains and losses, which are not material, are also recognised in financial income.

7.2.1.4. Income taxes

INCOME TAXES (Amounts in €000)	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months	31/12/2018 CRC 99-02 10 months
Income taxes	209	210	2,297
Of which income tax	*20*	*19*	-
Of which deferred taxes	*188*	*192*	*347*
Of which research tax credits			*1,951*

The research tax credits for 2018 are recorded as income tax income according to French accounting principles (CRC 99-02). Under IFRS, they are recorded in other operating income (refer to section 7.2.1.1 of the Registration Document).

The Group recognised income tax at the level of its Italian subsidiary in 2020 and in 2019. The other entities have been making losses since the creation of the Group.

Affluent Medical has tax losses that can be carried forward indefinitely in France amounting to €68,487 thousand as at 31 December 2020.

The deduction of tax losses in France is capped at 50% of the taxable profit for the financial year, this limitation being applicable to the portion of profits that exceeds €1 million. The unused balance of the deficit can be carried forward over the following years, and can be charged under the same conditions without a limit over time. The income tax rate applicable to Affluent Medical is the rate currently in force in France, i.e. 28%. This rate will gradually decrease to 25% from 2022.

Deferred tax assets are recognised for tax losses carried forward when it is more likely than not that Affluent Medical will have future taxable profits against which these unused tax losses can be offset.

In accordance with the principles described above and the mechanism for capping tax losses carried forward, no deferred tax assets have been recognised in addition to deferred tax liabilities in the Group's consolidated financial statements as at 31 December 2020.

The main temporary differences are related to tax losses carried forward and technologies developed internally and recognised in the context of business combinations prior to the date of transition to IFRS (refer to section 18.1.1.1 note 4.1 of the Registration Document).

The change in deferred taxes is mainly due to:
- the impact of the decrease in deferred tax liabilities related to the amortisation of technologies developed in house; and
- the resulting adjustment of capitalised tax loss carryforwards.

7.2.1.5. Net income (loss)

EARNINGS PER SHARE (Amounts in €)	31/12/2020 IFRS	31/12/2019 IFRS	31/12/2018 CRC 99-02

	12 months	12 months	10 months
Number of shares at the end of the periods presented	**15,256,824**	**11,899,967**	**11,899,967**
Weighted average number of shares outstanding	**13,360,416**	**11,899,967**	**11,635,506**
Net income for the period - attributable to shareholders of the parent company (in €000)	(14,319)	(16,589)	(11,248)
Basic earnings per share (€/share)	**(1.07)**	**(1.39)**	
Diluted earnings per share (€/share)	**(1.07)**	**(1.39)**	
Earnings per share (€/share)			**(0.95)**

With the exception of the Italian subsidiary, the Group has not recorded any income tax expense.

The Group's loss-making situation during the financial years presented is not unusual given the stage of development of its medical devices.

8. LIQUIDITY AND CAPITAL RESOURCES

This section is devoted to the presentation of information concerning the Group's equity, liquidity and sources of financing.

The comments on equity, liquidity, sources of financing and cash flows presented in this section of the Registration Document are made on the basis of the Group's consolidated financial information prepared in accordance with IFRS and should be read jointly with IFRS, together with the consolidated financial information presented in chapter 18 "Financial information concerning the Group's assets, financial position and results" of the Registration Document.

8.1. Information on the Group's capital, liquidity and sources of financing

The Group has financed the development of its medical devices (research and development, clinical trials) through capital increases, issues of convertible and non-convertible bonds, obtaining subsidies and repayable advances from Bpifrance, bank loans and via the pre-financing of research tax credit receivables.
Overall, over the period 2018/2020 and previously, the Group was able to raise more than €65 million in dilutive and non-dilutive financing of which:

- Capital increases of €7.5 million in 2020;
- €7.9 million of repayable advances received (BPI Innovation loan for €1 million; Piave project: €3.7 million; Mivana project €3.2 million, of which €1.4 million before 31 December 2017);
- €2.1 million in loans guaranteed by the State;
- €13.85 million in convertible bond issuances (€2.85 million in CBs in 2018; €3 million in Financing CB); €8 million in the 2019 CB);
- €8 million in non-convertible bonds issued to Kreos Capital;
- €3.4 million in research tax credit for financial years 2018, 2019 and 2020;
- €23.4 million in capital increases at subsidiary level before 31 December 2017.

8.1.1. Group net financial debt

The Group's net financial debt can be summarised as follows:

NET FINANCIAL DEBT (Amounts in €000)	**31/12/2020 IFRS**	**31/12/2019 IFRS**	**31/12/2019 IFRS**
Non-current financial liabilities	16,248	19,882	10,001
Non-current lease liabilities	731	811	597
Non-current derivative liabilities		995	713
Current financial liabilities	3,575	3,290	1,188
Current lease liabilities	226	202	119
Current derivative liabilities	1,351	270	141
Total financial liabilities	**22,131**	**25,449**	**12,759**
Cash and cash equivalents	**5,650**	**2,126**	**3,339**
Net debt	**16,481**	**23,323**	**9,420**

The change in financial liabilities is presented in detail in Section 7.1.3.4 of the Registration Document.

The €13,902 thousand increase in net debt in 2019 compared to 2018 is mainly due to:

- an increase in current and non-current financial liabilities related to:
    - the issue of the first tranche of the 2019 CBs for €4 million;
    - the issue of tranche B of the non-convertible bonds issued to Kreos Capital for €4 million;
    - the collection of repayable advances relating to the PIAVE Artus project for an amount of €3,659 thousand ; and
- the recognition of new liabilities related to lease obligations in the amount of €480 thousand , offset by repayments of €184 thousand ;
- the recognition of a derivative liability in respect of the conversion option of the first tranche of the 2019 CBs;
- the decrease in the level of cash and cash equivalents between 1 January 2019 and 31 December 2019 in the amount of €1,213 thousand.

The €6,928 thousand decrease in net debt in 2020 compared to 2019 is mainly due to:

- the net decrease in non-current and current financial liabilities related to:
    - the repayments made in 2020 on the non-convertible bonds issued to Kreos Capital for an amount of €1,952 thousand ;
    - conversions of convertible bonds (2018 CB, Financing CB and the first tranche of the 2019 CBs) having an impact of €9,141 thousand compared to 31 December 2019;
    - the issue of the second tranche of the 2019 CBs to Head Leader in October 2020 for €4 million.
- the recognition of new liabilities related to lease obligations amounting to €167 thousand , offset by repayments of €222 thousand ;
- the recognition of a derivative liability in respect of the conversion option of the second tranche of the 2019 CBs (valued at €1 million as at 31 December 2020).
- the decrease in derivative liabilities relating to the conversion options of the Financing CB and the first tranche of the 2019 CBs, which were recorded in equity at the conversion date (€680 thousand);
- the increase in cash and cash equivalents between 31 December 2019 and 31 December 2020 for €3524 thousand.

8.1.2. Financing by capital

The table below summarises the main capital increases relating to Affluent Medical up to the date of this Registration Document:

Periods	Contribution value In €000	Gross amounts raised and conversions In €000	Total In €000	Transaction
2018	**59,500**	-	**59,500**	Creation of the company for €1 and capital increase as part of the contributions of securities of the companies KEPHALIOS, EPYGON, MYOPOWERS, KARDIOZIS paid in the amount of €59,500 thousand.
2020	**-**	**7,611**	**7,611**	Capital increase in May, September and December 2020.
2020	**-**	**10,224**	**10,224**	Conversion of convertible bonds (Financing CB, 2018 CB and the first tranche of the 2019 CBs).
Total	**59,500**	**18,035**	**77,535**	

Affluent Medical subsidiaries benefited from capital increases of €23.4 million before 31 December 2017.

In 2018, the Company made an unsuccessful attempt to increase its share capital in parallel with the

listing of its shares on the Euronext Growth market in Paris.

8.1.3. Financing by convertible and non-convertible bonds

The table below shows changes in convertible and non-convertible bonds in the consolidated financial statements prepared in accordance with IFRS as at 31 December 2020 and 31 December 2019:

CHANGE IN BONDS (Amounts in €000)	Kreos bonds	Financing CB*	2018 CB**	2019 CB***	Total
As at 1 January 2019	**3,704**	**2,448**	**2,524**	**-**	**8,677**
(+) Collection	3,872			4,000	7,872
(+) Security deposit	128				128
(-) Derivative liabilities	(144)			(399)	(543)
(+) Impact of amortised cost	217	102	102	4	424
(-) Reimbursement	(516)				(516)
(+/-) Accrued interest		180	171	9	360
As at 31 December 2019	**7,262**	**2,730**	**2,797**	**3,614**	**16,403**
(+) Collection				4,000	4,000
(-) Derivative liabilities				(1,364)	(1,364)
(+) Impact of amortised cost	174	63	62	39	338
(-) Reimbursement	(1,952)				(1,952)
(+/-) Accrued interest		88	84	113	285
(+/-) Conversion		(2,882)	(2,943)	(3,718)	(9,543)
As at 31 December 2020	**5,483**	**-**	**-**	**2,684**	**8,167**

* held by funds managed by Truffle Capital
** held by funds managed or companies advised by Truffle Capital
*** held by funds managed by Truffle Capital and Head Leader

MATURITIES OF BOND LOANS, IN REDEMPTION VALUE (Amounts in €000)	Kreos Capital bonds loan	Financing CBs*	2018 CBs**	2019 CBs*	Total
At 31 December 2020	**5,532**	**-**	**-**	**4,034**	**9,566**
Share at less than one year	3,378			4,034	**7,411**
Share between one and five years	2,154				**2,154**
Share at more than five years					**-**

* Held by Head Leader

2018 CB Convertible bonds

On 27 March 2018, the Company signed an agreement enabling the issue of convertible bonds (2018 CBs) representing a fundraising of €2.85 million in consideration for the contributions of convertible bonds issued by the Company's subsidiaries as part of the constitution of Affluent Medical.

At the end of this contract, the Company issued 2,850,000 convertible bonds with a par value of €1 (i.e. a total of €2.85 million) each maturing in May 2021 and bearing interest at an annual interest rate of 6%.

On 19 June 2020, all of these convertible bonds were converted into new shares, resulting in the issuance of 604,834 shares.

Due to the presence of a fixed exchange rate, the 2018 CBs were classified as compound instruments with a debt component of €2,331 thousand and an equity component of €519 thousand.

FINANCING CB convertible bonds

On 23 April 2018, the Company signed a bond issuance agreement (FINANCING CB) with funds managed by Truffle Capital representing a fundraising of €3 million and convertibility into new Company shares over a period of 60 months from the date of issue.

At the end of this agreement, the Company issued 3 million convertible bonds with a par value of €1 (i.e. a total of €3.0 million) each maturing in April 2023 and bearing interest at an annual interest rate of 6%.

On 19 June 2020, all of the convertible bonds were converted into new shares, resulting in the issue of 599,218 shares.

In accordance with IFRS 9, the debt component was measured using the amortised cost method. The convertible bonds option has been separated, recognised in derivative liabilities due to an exchange rate of variable conversion and measured at fair value, and changes in this fair value were recorded in the income statement in accordance with IFRS 9.

Kreos Capital non-convertible bonds

On 26 October 2018, the Company entered into a *"Venture loan agreement"* With Kreos Capital in place of a framework agreement organising the issuance of a bond loan for an amount of up to €12 million through the issue of three tranches of €4 million each and the issue of a maximum of 196,722 share subscription warrants depending on the tranches actually issued (BSA 2018-Kreos) (see section 19.1.4.1 of the Registration Document).

The "Venture loan agreement" provides for the pledge of certain assets of the Company and its Subsidiaries (bank account balances, goodwill, receivables, financial securities accounts, intellectual property rights outside of Kalios covering China) for the benefit of Kreos Capital (see section 20.4 of the Registration Document) until the entire non-convertible bond loan is repaid.

Each tranche bears interest at 10% per year. All tranches of non-convertible bonds issued are repayable in 36 monthly instalments with a repayment period of six months.

Under the terms of the agreement, the Company has the option to redeem or buy back non-convertible bonds at any time, provided that it notifies Kreos Capital at least 30 days in advance. The repayment will be equal to (i) the amount of the outstanding principal, plus (ii) the sum of the interest that the Company would have had to pay over the remaining term of the tranche in question, discounted at the rate of 4% per year (refer to section 18.1.1.1 note 11 of the Registration Document).

Tranche A was issued upon signature of the framework agreement on 29 October 2018, and tranche B on 1 June 2019. Tranche C has not been drawn down by the deadline of 30 September 2019, on the Company's decision.

A guarantee deposit of €256 thousand (€128 thousand per tranche) was retained by Kreos Capital on the payments made. It will be deducted from the last monthly payment. It is recognised in "Other non-current financial assets".

In accordance with IFRS 9, these non-convertible bonds were recognised using the amortised cost method. After analysis, the warrants attached to Tranche A and Tranche B (BSA 2018-Kreos) were

recognised as derivative liabilities and measured at fair value with changes in this fair value recorded in profit or loss in accordance with IFRS 9.

As at 31 December 2020, the amount of the Kreos Capital bonds to be repaid stood at €5,532 thousand and the number of Affluent Medical shares that may be issued upon exercise of the 131,148 BSA2018 – Kreos warrants amounted to 169,779 new Company shares.

Truffle Capital and Head Leader 2019 CB Convertible bond

On 10 December 2019, the Company signed a bond issuance agreement (2019 CB) with Head Leader Limited and the Truffle Biomedtech Crossover Fund and Truffle Innov FRR France Fund, representing a fundraising of €8 million over a period of 60 months from the date of issue.

At the end of this agreement, the Company issued 8 million convertible bonds with a par value of €1 each maturing in 2024 with:

- an annual interest rate of 4%;
- a bond conversion price equal to the subscription value of the share at the time of the most recent capital increase on the date of the conversion request.

- *Truffle Capital 2019 CB*

The Company issued 2.3 million 2019 CB to the benefit of Truffle Biomedtech Crossover Fund, 1,700,000 2019 CB to the benefit of Truffle Innov FRR France.

The Company was paid €4 million by the funds managed by Truffle Capital in December 2019.

On 19 June 2020, all of the 2019 CB held by the funds managed by Truffle Capital were converted into new shares, generating the issue of 679,116 Affluent Medical shares.

- *Head Leader 2019 CBs*

The Company issued 4 million 2019 convertible bonds for the benefit of Head Leader Limited. The payment of the €4 million from the Head Leader fund took place on 16 October 2020 (refer to section 19.1.4.3 of the Registration Document).

The 2019 CB, which amounted to €4.0 million in redemption value as at 31 December 2020 are guaranteed by the pledge in favour of their holder:

- Kalios patents covering China;
- the 40% stake held by Epygon in the capital of Shanghai Epygon Medical Technology Co Ltd (joint venture created with Shanghai Zuquan Investment Management Company Limited) and
- the 40% stake held by MyoPowers in the capital of Shanghai MyoPowers Medical Technology Co Ltd (joint venture created with Shanghai Zuquan Investment Management Company Limited).

On 25 February 2021, Head Leader Limited notified the Company of its request for the redemption of convertible bonds in the event of the listing of the Company's shares for trading on the regulated Euronext Paris market. This reimbursement totalling approximately €4.1 million will be made within 60 business days of the completion of the admission of the Company's shares to trading on the regulated Euronext Paris market.

In accordance with IFRS 9, the debt component of convertible bond loans was measured using the amortised cost method. The convertible bonds option has been separated, recognised in derivative liabilities due to an exchange rate of variable conversion and measured at fair value, and changes in this fair value were recorded in the income statement in accordance with IFRS 9.

8.1.4. Financing by repayable advances and loans guaranteed by the State

The tables below show the change in repayable advances and loans guaranteed by the State as shown in the consolidated financial statements prepared in accordance with IFRS as at 31 December 2020 and 31 December 2019:

CHANGE IN REPAYABLE ADVANCES - IFRS STANDARDS (Amounts in €000)	BPI innovation	Mivana project Epygon	Mivana project Kephalios	PIAVE Artus project	Total
As at 1 January 2019	**-**	**1,541**	**480**	**-**	**2,021**
(+) Collection				3,659	3,659
(-) Reimbursement					-
(+) Accrued interest		216	74	81	372
Financial expenses					-
As at 31 December 2019	**-**	**1,757**	**555**	**3,740**	**6,052**
(+) Collection	996	1,200	559		2,755
(-) Reimbursement					
(+) Accrued interest		360	145	254	758
Grant	(90)				(90)
Financial expenses	13				13
As at 31 December 2020	**919**	**3,317**	**1,259**	**3,944**	**9,489**

Maturities of repayable advances, in redemption value (Amounts in €000)	BPI Innovation	Project Mivana Epygon	Project Mivana Kephalios	PIAVE Artus project	Total
As at 31 December 2020	**1,000**	**3,288**	**1,259**	**3,985**	**9,532**
Share at less than one year	-	-	-	-	-
Share between one and five years	900	2,319	892	3,659	7,770
Share at more than five years	100	969	367	326	1,762

CHANGE IN LOANS GUARANTEED BY THE STATE (Amounts in €000)	BNP Paribas EMP	Société Générale EMP	Société Générale EMP	Société Générale EMP	Total
As at 31 December 2019	**-**	**-**	**-**	**-**	**-**
(+) Collection	1,000	90	160	890	2,140
(-) Reimbursement					-
(+/-) Accrued interest	8	1	1	6	15
As at 31 December 2020	**1,008**	**91**	**161**	**896**	**2,155**

Maturities of repayable advances, in redemption value (Amounts in €000)	BNP Paribas EMP	Société Générale EMP	Société Générale EMP	Société Générale EMP	Total
As at 31 December 2020	**1,000**	**90**	**160**	**890**	**2,140**
Share at less than one year	-	-	-	-	**-**
Share between one and five years	915	79	48	870	**1,911**
Share at more than five years	85	11	112	20	**229**

Bpifrance innovation loan

On 8 April 2020, the Company entered into an agreement with Bpifrance for an innovation loan of €1 million with a single payment and bearing interest at 1.14% for the "development of a disruptive medical device (adjustable mitral ring) to combat recurrent mitral insufficiency".

The Company received a total of €1 million in connection with this contract and met the conditions for the success of this project. Following the success of the project, the repayment schedule is as follows: €50 thousand per quarter from 30 September 2022 to 30 June 2027 (20 payments).

Loans guaranteed by the State

During 2020, the Group contracted four PGE to strengthen its cash position in the current context of the Covid-19 pandemic:

- loan guaranteed by the French State taken out by Affluent Medical with optional amortisation over five years, with BNP Paribas on 6 April 2020 for an amount of €1 million, over a period of 12 months, not bearing interest and repayable, in arrears, after a deferral period of 12 months. This loan benefits from a State guarantee under the "FDG State Coronavirus" guarantee fund of up to 90.00%;
- loan guaranteed by the State taken out by Epygon with optional amortisation over five years, with Société Générale on 5 June 2020 for an amount of €90 thousand , over a period of 12 months, bearing interest at the annual rate of 0.25%, repayable in arrears, after a deferral period of 12 months. This loan benefits from a State guarantee under the "FDG State Coronavirus" guarantee fund of up to 90.00%;
- loan guaranteed by the State taken out by Kardiozis with optional amortisation over five years, with Société Générale on 5 June 2020 for an amount of €160 thousand , over a period of 12 months, bearing interest at the annual rate of 0.25%, repayable in arrears, after a deferral period of 12 months. This loan benefits from a State guarantee under the "FDG State Coronavirus" guarantee fund of up to 90.00%; and
- loan guaranteed by the State taken out by Kephalios with optional amortisation over five years, with Société Générale on 5 June 2020 for an amount of €890 thousand , over a period of 12 months, bearing interest at the annual rate of 0.25%, repayable in arrears, after a deferral period of 12 months. This loan benefits from a State guarantee under the "FDG State Coronavirus" guarantee fund of up to 90.00%.

The Company requested the amortisation of these loans over four years after an addition one-year delay, in accordance with the legislation.

In February 2021, the Group took out a new loan guaranteed by the French State, in the amount of €395 thousand with CIC, bearing no interest and repayable in arrears, after a deferral period of 12 months. This loan benefits from a State guarantee under the "FDG State Coronavirus" guarantee fund of up to 90.00%.

Repayable Mivana Project advance

On 28 September 2015, as part of the Mivana project, the companies Kephalios and Epygon, in partnership with the entities MDB Texinov and IFTH (French Institute of Textile and Clothing) signed a financing agreement with Bpifrance.

The support granted by Bpifrance is made up of grants and repayable advances:

- repayable advances of a maximum amount of €5,458 thousand (including €4,512 thousand for Group companies) with payments in several instalments depending on the achievement of "key milestones" (progress of developments, presentation of interim results, EC/FDA marking) and bearing an annual interest of 1.22%. These advances are intended to finance the development of innovative medical devices and techniques derived from the textile industry for the creation of a national cardiovascular sector;

- grants of a maximum amount of €3,122 thousand (of which €1,957 thousand for Group companies).

Epygon received a total of €3,152 thousand (of which €2,319 thousand in repayable advances and €834 thousand in grants) in connection with this contract and met the conditions for the success of key steps 1, 2 and 3, out of a total four key steps. Following the success of the key steps 1, 2 and 3, the repayment schedule is as follows:

- €500 thousand at 30 June 2022 (1 payment);
- €800 thousand at 30 June 2023 (1 payment);
- €1,100 thousand at 30 June 2024 (1 payment);
- €1,350 thousand at 30 June 2025 (1 payment).

Kephalios received a total of €1712 thousand (of which €892 thousand in repayable advances and €820 thousand in subsidies) in connection with this contract and met the conditions for the success of key steps 1, 2 and 3, out of a total of 4 key steps. Following the success of the key steps 1, 2 and 3, the repayment schedule is as follows:

- €100 thousand at 30 June 2022 (1 payment);
- €250 thousand at 30 June 2023 (1 payment);
- €350 thousand at 30 June 2024 (1 payment);
- €450 thousand at 30 June 2025 (1 payment).

These agreements provide for additional payments detailed in section 20.2.1 of the Registration Document.

As at 31 December 2020, based on projected revenue, the Company estimated the additional payments. The debt recognised in this respect amounted to €367 thousand for Kephalios and €969 thousand for Epygon as at 31 December 2020.

PIAVE Artus project repayable advance

On 21 July 2016, as part of the PIAVE Artus project, MyoPowers entered into an agreement with Bpifrance for a subsidy of €201 thousand and a repayable advance carrying an annual interest of 0.99%, for a maximum amount of €7,796 thousand. The latter may be paid in several instalments depending on the achievement of "key milestones" (results of clinical studies, certificate of filing of MA applications) for the "development of an artificial urinary sphincter for the treatment of severe stress urinary incontinence".

MyoPowers received a total of €3,659 thousand in repayable advances and €117 thousand in subsidies in connection with this agreement and met the conditions for the success of key step 1.
The repayment schedule is as follows: €2,055 thousand per year from 1 September 2023 to 1 September 2026 (4 payments).

This agreement provides for additional payments detailed in section 20.2.2 of the Registration Document.

As at 31 December 2020, based on projected revenue, the Company estimated the additional payments. The debt recognised in this respect amounted to €326 thousand as at 31 December 2020.

8.1.5. Financing by the research tax credit

The Group benefits from the research tax credit in France. The research tax credit ("**CIR**") amounts to €380 thousand in 2020, €1,087 thousand in 2019 and €1,412 thousand in 2018.

The decrease in the value of the RTC for 2020 compared to previous years is explained by the fact that

in 2020 the Group received a part of the Bpifrance repayable advances and subsidies which are deducted from the calculation base of the RTC.

8.1.6. Financing through the disposal of CIR receivables

As at 31 December 2019, a portion of the receivables related to the CIR 2018 and CIR 2019 were pre-financed by the Predirec Innovation 2020 securitisation mutual fund, with Neftys Conseil as the arranger. As a result, the Group recognised the following items:

- a debt, for the amount payable to Neftys upon receipt of the CIR;
- a financial asset, for the amount of deductions made by Neftys on the receivables sold (equivalent to a guarantee deposit); and
- a current asset, for the amount of the receivable due by the French State.

In accordance with IFRS 9, the amount of the debt due to Neftys was calculated using the amortised cost method for each year:

- CIR 2018: €164 thousand
- CIR 2019: €505 thousand

As at 31 December 2020, the Company no longer had any pre-financed CIR receivables in its accounts.

8.2. Cash flows

The following information is taken from the consolidated financial statements as at 31 December 2020 and 31 December 2019 prepared in accordance with IFRS, as well as the Group's consolidated financial statements prepared in accordance with French accounting principles (CRC 99-02) presented in Chapter 18 "Financial information concerning the Group's assets, financial position and results" of the Registration Document. As regards cash flows, there are no differences between CRC 99-02 and IFRS.

Affluent Medical SA Summarised consolidated cash flow statement	Financial year 2020 IFRS €000	Financial year 2019 IFRS €000	Financial year 2018 CRC 99-02 €000
Cash flows consumed by operating activities	**(8,936)**	**(11,412)**	**(9,335)**
Net cash flow from investing activities	**(304)**	**(185)**	**(2,061)**
Cash flows from financing activities	**12,762**	**10,386**	**9,743**
Increase (Decrease) in cash	**3,522**	**(1,211)**	**(1,653)**
Opening cash and cash equivalents	2,126	3,336	4,874
Closing cash and cash equivalents	5,648	2,126	3,221

8.2.1. Cash flows consumed by operating activities

Cash consumption related to operating activities amounted to €8,936 thousand for the year ended 31 December 2020, €11,412 thousand for the year ended 31 December 2019 and €9,335 thousand for the year ended on 31 December 2018. This cash consumption is mainly related to the Group's medical device development activities in line with the stage of completion of clinical and preclinical studies.

8.2.2. Net cash flow from investing activities

Cash consumption from investing activities amounted to €304 thousand in 2020, €185 thousand in 2019 and €2,061 thousand in 2018. These relate mainly to acquisitions of property, plant and equipment or intangible assets. In 2018, investment flows amounted to €1,829 thousand for the subscription of 40%

of the capital of the joint ventures Shanghai Epygon Medical Technology Co., Ltd, and Shanghai MyoPowers Medical Technology Co., Ltd.

8.2.3. Net cash flow from financing activities

Cash flows from financing activities	Financial year 2020 IFRS €000	Financial year 2019 IFRS €000	Financial year 2018 CRC 99-02 €000
Capital increase net of capital increase costs	7,456		3,243
Collection of repayable advances	2,755	3,659	
Bank borrowings	2,140		
Change in other equity			-500
Issue of convertible and non-convertible bonds, net of fees	4,000	7,872	7,000
Redemption of non-convertible Kreos bonds	(1,952)	(516)	
Gross financial interest paid	(715)	(775)	
Other movements related to the pre-financing of the Research Tax Credit	(711)	276	
Repayment of debt related to lease obligations	(222)	(184)	
BSA subscription	11	55	
Cash flows from financing activities	**12,762**	**10,386**	**9,743**

In particular, in 2020 the Group completed:

- capital increases in May, September and December 2020 for a total of €7,456 thousand net of fees;
- the collection of repayable advances of €2,755 thousand (refer to section 8.1.4 of the Registration Document);
- the collection of loans guaranteed by the State for an amount of €2,140 thousand ;
- the issue of convertible bonds (2019 CB) in the amount of €4000 thousand for the benefit of Head Leader Limited;
- the repayment of maturities for the Kreos Capital loan in the amount of €1,952 thousand.

In particular, in 2019, the Group completed:

- the collection of repayable advances of €3,659 thousand (refer to section 8.1.4 of the Registration Document).
- the issue of non-convertible bonds in the amount of €4000 thousand for the benefit of Kreos Capital, which generated an inflow of €3,872 thousand after deduction of the guarantee deposit of €128 thousand (which will be returned in the form of a deduction upon payment of the last monthly payment of the loan);
- the issuance of convertible bonds (2019 CB) in the amount of €4000 thousand for the benefit of funds managed by Truffle Capital; and

In particular, in 2018 the Group completed:

- the issue of non-convertible bonds in the amount of €4000 thousand for the benefit of Kreos Capital, which generated an inflow of €3,872 thousand after deduction of the guarantee deposit of €128 thousand (which will be returned in the form of a deduction upon payment of the last monthly payment of the loan); and
- the issue of convertible bonds (2018 CB) for €3 million.

8.3. The Group's financing requirements and financing structure

Information relating to the financing of the Group’s activities is provided in Section 8.1 “Information on the Group’s capital, liquidity and sources of financing” of the Registration Document.

8.4. Restrictions, if any, on the use of capital

None.

8.5. Sources of funding needed in the future to meet investment commitments

The Group has carried out a specific review of its liquidity risk and believes, at the date of approval of the Registration Document, that it would be able to finance its activities until the end of May 2021, in view of the cash balance at its disposal to date.

In order to finance its future development and investments, the Company plans to carry out a capital increase concurrently to the admission of the Company's shares to trading on the regulated market of Euronext Paris. The Group may then have access to other financing through capital and/or loans. In addition, to ensure its financing, the Group will also be able to count on the payment of the RTC as well as the repayable advances and subsidies still to be received as part of the Mivana and PIAVE Artus projects for a maximum amount of approximately €5.8 million (see section 3.4.3 of the Registration Document). The Group could also enter into partnerships for its Kardiozis technology and for its Artus, Epygon or Kalios medical devices on the American market that would be a source of revenue.

9. REGULATORY ENVIRONMENT

9.1. Regulations applicable to medical devices: clinical trials, market launch and marketing

As implantable medical devices, the Group's products must meet strict regulatory requirements and be regularly enhanced to ensure patient safety.

To adapt to changes in the various laws and regulations, the Group has put in place:
- quality control and regulatory affairs departments;
- procedures that ensure constant monitoring of regulatory changes and thus ensure the ongoing regulatory compliance of its activities;
- an internal audit system, by carrying out audits to check the proper application of regulatory and quality requirements within its various subsidiaries;
- a network of partners specialising in medical devices and regulatory affairs.

The regulations adopted in this regard by the various countries where the Group intends to market its products govern many aspects of medical devices, including:
- design, development and manufacture;
- product testing;
- storage;
- marketing;
- certification of products for marketing; and
- post-market launch monitoring (Materiovigilance).

9.1.1. Regulation of clinical trials, market launch and marketing of medical devices in Europe

The basis of the European regulations applicable to medical devices is currently set by Council Directive No. 93/42/EEC of 14 June 1993.

This directive enacts the general principles regarding the design and manufacture of medical devices. Itprovides for a classification of medical devices into four classes according to their characteristics and the risks involved in their use (in ascending order of risk, classes I, IIa, IIb and III). This classification determines the level of requirements that medical devices must meet in order to be legally marketed in the European Union.

Before any marketing, the compliance of medical devices with regulatory requirements must be certified. This certification is carried out by the manufacturer for the least risky devices, and otherwise requires the issuance of a CE certificate of conformity by a notified body.

This Directive requires the CE marking for marketing. For the most critical devices (classes IIa, IIb and III), this CE marking requires a third-party notified body which, after examination of the technical file, issues a CE certificate of conformity.

These requirements will not be modified by the entry into force of Regulation (EU) No. 2017/745 of 5 April 2017, on 26 May 2021. This new regulation, which will repeal Council Directive No. 93/42/EEC, aims to develop a unified and strengthened European regulation, under which:

- notified bodies are placed under European control for better harmonisation of practices;
- a coordination group of national authorities and new mechanisms for close cooperation, notably for coordinated market surveillance;
- post-marketing due diligence provisions are improved with the establishment of a European incident database and the obligation for manufacturers, under the control of notified bodies, to produce periodic safety reports (PSUR);
- the obligations in terms of clinical evaluation are reinforced in particular by the use of clinical investigations, which becomes a mandatory prerequisite for the marketing of class III devices;

- transparency and traceability are improved, in particular by the implementation of European databases accessible to the authorities and/or the public.

This regulation is a significant change and has an impact on all players in the medical device value chain (manufacturers, distributors, importers, notified bodies, etc.).

The products developed by the Group (Artus, Kalios and Epygon) are subject to this regulation in order to obtain the CE marking. Artus, Kalios and Epygon are class III implantable medical devices and must therefore bear the CE marking when they are placed on the European Union market. A certificate issued by a notified body for a maximum period of five years guarantees the compliance of the product with the applicable regulations. This certificate is renewable on request for a period of five years.

This regulation will also apply to the Group as a manufacturer of medical devices, *i.e.* as a legal entity responsible for the design, manufacture, packaging and labelling of a medical device before it is released on the market under its own name, regardless of whether these transactions are carried out by the Group or on its behalf by a third party.

Thus, the operators involved in its manufacture and marketing must register with the competent authorities, and may be subject to random checks by notified bodies and national health agencies. In the event of an infringement of the regulations, the notified body is authorised to suspend or withdraw the certificate of compliance that it has issued. Health agencies may also take any measure necessary to protect public health, including suspending the marketing of the device in question.

Regulations specific to certain medical devices:

- the use of animal tissues in the manufacture of medical devices (currently governed by Regulation (EU) No. 722/2012 of 8 August 2012), with regard to the Epygon product;
- the market launch of radio equipment, the treatment of waste from electrical and electronic equipment and the limitation of the use of certain hazardous substances in electrical and electronic equipment (currently governed respectively by Directives No. 2014/53/EU of 16 April 2014, 2012/19/EU of 4 July 2012 and 2011/65/EU of 8 June 2011), as regards the Artus device.

Although the Group does not currently hold personal data of identifiable persons (the individual data received as part of clinical trials are anonymised), it is nevertheless subject to the General Data Protection Regulation (EU) No. 2016/679 ("**GDPR**"), which is more broadly applicable to the collection, processing and use of personal data relating to individuals in the European Union, including employees and partners of the Company.

In particular, the GDPR offers numerous guarantees to people whose personal data is collected and processed (right of access, rectification, etc.). As such, persons subject to the GDPR must take all necessary measures to secure the personal data they hold and inform the competent authorities in the event of a breach thereof. In addition, the GDPR strictly regulates the transfer of personal data outside the European Union. Companies concerned by this must ensure, by using one of the means exhaustively listed by the regulation, that the guarantees offered by the person established outside the European Union allow data protection at least equivalent to that offered by the regulation.

9.1.2. Regulation of clinical trials, market launch and marketing of medical devices outside Europe: example of American regulations

The market launch of medical devices in countries outside the European Union may require specific procedures to obtain the necessary authorisations, approvals and certifications (particularly in the United States, China, Japan, etc.).

CE marking sometimes has equivalents and is recognised, in terms of certification, in certain countries (Switzerland, Turkey, Australia, New Zealand, Israel, etc.). These CE equivalents or recognition will

also be important elements in the decision-making process for marketing the Group's products in a new country.

In the United States, the marketing of medical devices is governed by the Food, Drug and Cosmetic Act (FDCA), transcribed in Title 21, Code of Federal Regulations (CFR).

As in Europe, U.S. regulations provide for a classification of medical devices according to their intended use and the degree of risks involved in their use (in ascending order of risks, classes I, II and III). The regulatory requirements applicable to a device depend on this classification. As implantable devices, the Group's products fall under class III.

The marketing of class III medical devices requires prior approval by the Food and Drug Administration (FDA), which is based in particular on the results of clinical studies aimed at demonstrating the safety and efficacy of these devices.

Before clinical studies in the United States can be conducted, an Investigational Device Exemption (IDE) must first be obtained. For devices considered to present a significant risk, such as implantable devices, the study must be approved by the FDA and by the Institutional Review Board on the basis of an application submitted by the study's sponsor and including the research proposal and a report containing the results of the investigations previously carried out on the device. These trials must also be conducted in accordance with applicable Good Clinical Practices.

In order to be marketed on the American market, Class III medical devices must, in principle, be subject to a Premarket Approval (PMA) issued by the FDA. The applicant for this PMA must submit to the FDA an application containing the results of non-clinical and clinical studies conducted on humans with the device in question. A precise description of the device and how it works, as well as the methods, facilities and controls used in the manufacturing, processing, packaging and storage of the device must also be included in the application, as well as a copy of the proposed labelling. A significant fee is paid for the application process. The FDA generally makes a decision within 180 days following the application's registration and it may be rejected if it is insufficient or if the FDA considers that the information communicated does not demonstrate the safety and effectiveness of the device. Failure to obtain a PMA is an obstacle to the market launch of the device in question.

As an exception, class III medical devices can benefit from a simplified procedure, known as the 510(k), if it is considered that the device in question already has an equivalent on the U.S. market. This procedure is faster and less costly than the PMA: it generally does not involve prior inspection of the facilities used for the manufacture of the device and is based on the submission of a technical application demonstrating that the device covered by the application is substantially equivalent to a product legally sold on the American market. To demonstrate substantial equivalence, the applicant must provide evidence that its device has the same intended use and is as safe and effective as the device previously marketed (referred to as the "Predicate Device"). In this case, the deadline for the FDA's review of an application is generally 90 days. However, the FDA may suspend the deadline as long as the answers provided do not seem sufficient. When the FDA considers that the applicant device is substantially equivalent to a product legally sold on the American market, it grants 510(k) clearance to the applicant, which allows the applicant to market the medical device.

U.S. regulations also require the FDA to register the operators involved in the manufacture and marketing of medical devices on the U.S. market, as well as a declaration of the medical devices that they are manufacturing or marketing. These declarations must be regularly updated and are accompanied by the payment of an annual fee. The establishments concerned are subject to regular inspections to verify their compliance with the applicable regulations. For example, manufacturers must establish and implement quality control systems, in accordance with Good Manufacturing Practices, aimed at ensuring that medical devices ready to be marketed comply with regulations. Foreign-based manufacturers must appoint a representative based in the United States.

In addition, any operator involved in the marketing of products must comply with post-marketing surveillance requirements, including in particular notifying the FDA in the event of incidents related to

marketed medical devices. Finally, additional post-marketing obligations, such as the production of periodic reports on the safety and efficacy of the product, may be imposed by the FDA and determine whether or not a PMA is maintained.

In view of their anticipated marketing in China, the Group's innovative medical devices will also have to be registered by the National Medical Products Administration (NMPA), which may occur after clinical trials have been carried out in China. Operators involved in the manufacture and marketing of products must comply with local regulations.

The Group may have to comply with similar obligations and restrictions in all countries where it intends to market its products.

It should also be noted that the issuance of authorisations, approvals and certifications necessary for the marketing of a medical device by a national authority does not in any way presume such authorisations, approvals and certifications for the marketing of products will be obtained for another territory.

9.2. Management of relations with professional prescribers and managers of public hospitals awarding public contracts

9.2.1. Management of relations with healthcare professionals in Europe

In an effort to improve relations between industry and healthcare professionals, many countries have adopted regulations aimed at restricting these relationships and making them more transparent.

In France, for example, the relationships of manufacturers and distributors of devices with healthcare professionals are governed by measures commonly known as "anti-gift" and "transparency" mechanisms.

The anti-gift law establishes the principle for the general ban on giving or offering benefits to any professional providing healthcare services by any person producing or marketing healthcare products, regardless of their reimbursement status, or providing services associated with these products. However, certain specifically listed exemptions are limited to this general ban principle, such as the remuneration, compensation and defrayal of research, the promotion of research, scientific assessments, consulting, the provision of services or marketing. The implementation of these exemptions is, depending on the anticipated amount, subject to prior declaration or authorisation and any interaction must strictly comply with the conditions set for each type of exclusion or exemption.

The aim is to ensure that healthcare professionals, in choosing a medical device, are guided solely by medical information. In the event of non-compliance with this regulation, in addition to a significant risk to their reputation, the companies and professionals concerned may be subject to significant criminal penalties and, for the latter, to disciplinary sanctions.

The transparency mechanism provides citizens with access to certain information so that they can more objectively assess the relationships between healthcare players and companies that produce or market healthcare products or provide services associated with these products. Under the terms of this regulation, the companies concerned must disclose the main information relating to their relationships with healthcare professionals, such as compensation or benefits paid, and agreements entered into. Companies that knowingly fail to disclose this information may be subject to criminal penalties.

9.2.2. Management of relations with healthcare professionals outside Europe: example of U.S. regulations

Transparency and conflict of interest mechanisms exist in other countries where the Group intends to conduct its clinical studies and market its products in the event it obtains the necessary authorisations, approvals and certifications.

In the United States, transparency obligations stem from the Physician Payment Sunshine Act (the "**Sunshine Act**"), adopted in March 2010 under the U.S. Patient Protection and Affordable Care Act and implemented through various regulations adopted by the U.S. Centers for Medicare & Medicaid Services (the body that sets the reimbursement procedures for healthcare in the United States (the "**CMS**")) in February 2013. In principle, the Sunshine Act mandates that manufacturers and distributors established in the United States or operating in the United States, and involved in the manufacture or marketing of at least one medical device covered by one of the three American health insurance programs (Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP)) communicate to the Center for Medicare & Medicaid Services (CMS) any payment or transfer of value, direct or indirect, to doctors or university hospitals (including, for example, hospitality, reimbursement of transport costs, payment of fees) and all related information. The information thus declared is made public *via* the website of the "Open Payment Program" managed by the CMS.
The Sunshine Act defines "payments or other transfers of value" as any transfer of any value such as meals, fees or reimbursement of travel expenses. However, certain payments are expressly excluded from this definition, such as educational materials and in-kind contributions for charities.

The information to be disclosed to the CMS for each payment or transfer of value must include: (i) the name and address of the recipient; (ii) the amount and date of the payment or transfer; (iii) the form of payment or transfer (monetary or in shares); (iv) the nature of the payment or transfer (fees, gifts or entertainment expenses).

Monetary penalties are imposed on anyone who fails to provide this information in a timely manner. Civil fines are also imposed on anyone with knowledge of a failure to communicate to the CMS. The disclosure of a payment or transfer of value, a holding or an investment, in the public information database, in accordance with the Sunshine Act, does not necessarily imply that the persons in question have been engaged in reprehensible or illegal conduct. However, disclosing a payment in accordance with the Sunshine Act does not protect them from any legal liability with regard to other laws, in particular the "Anti-Kickback Statute".

The equivalent in the United States to the French anti-gift regulation is the Anti-Kickback Statute. In principle, this criminal law prohibits the offering, payment or solicitation of a benefit aimed at encouraging a healthcare professional to write prescriptions.

Indeed, under the Anti-Kickback Statute, it is a crime to make an offer or payment, or solicit or receive a valuable asset in order to promote or reward the use, recommendation, order or purchase of medical equipment or services financed by a federal health insurance program. Violators of this law may be punished with a fine, administrative sanctions, a prison sentence or exclusion from participation in federal healthcare programs.

9.3. Regulation of advertising of medical devices

After obtaining the necessary authorisations, approvals and certifications for the marketing of its products, the Group could be subject to various regulations that could limit its sales prospects for its products, such as advertising regulations.

Within the European Union, the regulations applicable to the advertising of medical devices are enacted at the national level by each member state.

France, for example, has adopted a strict framework in this regard provided for in Articles L. 5213-1 *et seq.* and R. 5213-1 *et seq.* of the French Public Health Code.

All forms of information (including for cold calling/door-to-door sales), prospecting or incentives to promote the prescription, delivery, sale and use of medical devices are considered to be advertising, with the exception of:

- labelling and instructions;

- correspondence, accompanied, where appropriate, by any non-advertising document required to answer a specific question about a device;
- information on warnings, precautions for use and adverse effects noted in the context of Materiovigilance and in-vitro diagnostic monitoring of medical devices;
- sales catalogues and price lists, if there is no information on the device; and
- information relating to human health or human illnesses, provided that it does not contain a reference, even indirectly, to a medical device.

For medical devices that are reimbursed, even partially, by mandatory health insurance plans, advertising to the public is strictly prohibited for class III devices. For non-reimbursable medical devices, advertising to the public is possible. However, it is subject to a preliminary control by the French National Agency for the Safety of Medicines and Health Products (ANSM) if the medical devices are on the list of devices presenting a significant risk to human health, such as coronary stents and certain prostheses (approved for a renewable five-year period). Advertising for other non-refundable devices is subject to a postliminary control and do not require an ANSM deposit.

The authorisation system for advertising to healthcare professionals depends solely on the risk that the device poses to human health, and does not take into account the product's status regarding reimbursement. Thus, advertisements for a device on the list of devices presenting a significant risk to human health are subject to a preliminary ANSM control. Advertising for other medical devices is subject to a postliminary control.

In all cases where advertising is authorised, its form and content must strictly comply with the obligations and restrictions prescribed by the Public Health Code, and in particular Articles L. 5212-3 and R. 5213-1 to R. 5213-3. In particular, advertising must describe the device objectively, must not be misleading or present a risk to public health, and must contain a certain amount of information listed by French regulations.

Failure to comply with these constraints may result in a criminal sanction as well as a financial sanction imposed by the ANSM. The latter may prohibit the continuation or broadcasting of an advertisement in addition to issuing its daily official penalties.

10. TREND INFORMATION

10.1. Principal trends since the end of the last year

Since the end of the last financial year ended on 31 December 2020, the Group has continued its clinical development programmes, as detailed in Sections 5.2.2.2, 5.2.3.2 and 5.2.3.3 of the Registration Document.

10.2. Known trends, uncertainties, demands, commitments or events reasonably likely to materially affect the outlook of the Group

At the date of approval of the Registration Document, the Group is not yet generating revenue. Given the development cycle of its products, the Group plans to generate revenue in 2023 subject to obtaining the CE marking on its Kalios medical device at the end of 2022 or in the event of entering into a license agreement for its Kardiozis technology or a licensing agreement for one of its three products (Artus, Kalios or Epygon) before this deadline.

The Company's objectives do not constitute prospective data resulting from a budget process, but simple objectives resulting from the strategic directions of the Company.

These objectives are founded on data and assumptions that are considered, on the date of registration of the Registration Document, to be reasonable by the Company's management. These data and assumptions could change or be modified, particularly as a function of changes in the economic, financial, competitive, accounting or fiscal context, or as a function of other factors of which the Company is not aware on the date of registration of this Registration Document. Furthermore, the materialisation of certain risks described in Chapter 3 "*Risk factors*" of this Registration Document could have an impact on the Company, its activity, outlook, ability to achieve its objectives, its financial position and/or development.

The achievement of the objectives also assumes the success of the Company's strategy described in Chapter 5 "*Overview of business activities*" of this Registration Document, which can itself be affected by the occurrence of these same risks. The Company therefore makes no commitment, nor gives any guarantee as to the achievement of the objectives described in this Registration Document.

11. EARNINGS FORECASTS OR ESTIMATES

The Group does not communicate profit forecasts or estimates.

12. CORPORATE GOVERNANCE, MANAGEMENT AND SUPERVISORY BODIES AND EXECUTIVE MANAGEMENT

12.1. General information relating to executives, directors and observers

Unless otherwise specified, references to the bylaws and internal regulations in this chapter are understood as references to the Company's bylaws and internal regulations that will govern the Company and its corporate governance and management bodies as from when the Company's shares are admitted to trading on the Euronext Paris regulated market.

As at the date of this Registration Document, the Company is a French corporation (*société anonyme*) governed by prevailing laws and regulations and the Company's bylaws. The Company's Combined General Meeting of Shareholders of 6 April 2021 decided to adopt new bylaws subject to the condition precedent of the admission of the Company's shares to trading on the Euronext Paris regulated market. The Board of Directors' amended internal regulations were also adopted by the Board of Directors at its meeting of 18 February 2021, subject to the condition precedent of the admission of the Company's shares to trading on the Euronext Paris regulated market. A description of the main provisions of the bylaws and Board of Directors' internal regulations pertaining to the Board's committees and executive management can be found in Chapter 14 "*Operating procedures of corporate governance and management bodies*" and in section 19.2 of this Registration Document.

12.1.1. Composition of the Board of Directors and the Advisory Board

12.1.1.1. Composition of the Board of Directors

As at the date of approval of the Registration Document, the Board of Directors of the Company is composed of the following eight members:

First and last name, business address	Office	Independent	Date of appointment, renewal and term	Committee member
Michel Finance 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France	Chairman of the Board of Directors Chief Executive Officer	No	Co-optation (replacing Vincent Gardès): 14 May 2020 Appointment as Chairman of the Board of Directors: 14 May 2020 Expiry date: renewed by the General Meeting on 6 April 2021 and by the Board of Directors meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	No
Truffle Capital, represented by Philippe Pouletty 5, rue de la Baume, 75008 Paris, France	Director	No	Appointment: 27 March 2018 Expiry date: renewed by the General Meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	Member and Chairman of the Compensation and Governance Committee
Patrick Coulombier 5, rue de la Baume, 75008 Paris, France	Director	No	Appointment: 27 March 2018 Expiry date: renewed by the General Meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	Member of the Compensation and Governance Committee

First and last name, business address	Office	Independent	Date of appointment, renewal and term	Committee member
Daniel Hayoz Fort St Jacques 139 1752 Villars sur Glane, Switzerland	Director	No	Appointment: 27 March 2018 Expiry date: renewed by the General Meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	No
Dominique Carouge 124 rue de Villiers 92300 Levallois-Perret, France	Director	Yes	Co-optation (replacing Thierry Herbreteau): 8 July 2020 Expiry date: renewed by the General Meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	Member and Chairman of the Audit Committee
Claire Corot 5, rue de la Baume, 75008 Paris, France	Director	No	Co-optation: 18 February 2021 Expiry date: renewed by the General Meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	Member of the Audit Committee
Ellen Roche 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France	Director	Yes	Co-optation: 18 February 2021 Expiry date: renewed by the General Meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	No
Véronique Phé 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France	Director	Yes	Co-optation: 8 April 2021 Expiry date: until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023	No

At the meeting of the Board of Directors of 20 May 2020, the Board of Directors duly noted the resignation of Mr Vincent Gardès from his position as director and Chairman of the Board of Directors of the Company. The Board co-opted Mr Michel Finance as new director to replace Mr Vincent Gardès for the remainder of his term of office, *i.e.* until the end of the General Meeting held to approve the financial statements for the financial year ended 31 December 2020. The General Meeting of 6 April 2021 renewed the term of office of Mr Michel Finance as director, and the Board of Directors meeting of 6 April 2021 renewed his term of office as Chairman of the Board of Directors of the Company.

At the meeting of the Board of Directors of 18 February 2021, the Board of Directors acknowledged the resignation of Substainable Development Partner International, represented by Mr Jean-François Le Bigot, Mr Jean-Michel Malbrancq, and Fate, represented by Mr Benoit Adelus, from their positions as directors of the Company. The Board co-opted Ms Claire Corot as new director to replace Substainable Development Partner International, represented by Mr Jean-François Le Bigot, and Ms Ellen Roche to replace Mr Jean-Michel Malbrancq for the remainder of their terms of office, *i.e.* until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2020.

The General Meeting of 6 April 2021 renewed the term of office of each of the directors for a period of three financial years, *i.e.* until the close of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023.

At the meeting of the Board of Directors of 8 April 2021, the Board of Directors noted the resignation of Mr Christian Latrémouille from his position as director of the Company. The Board co-opted Ms Véronique Phé as new director, replacing Mr Christian Latrémouille, for the remainder of his term of office, *i.e.* until the end of the General Meeting held to approve the financial statements for the financial year ended on 31 December 2020.

The term of office of director is three years and expires at the end of the Ordinary General Meeting held to approve the financial statements for the previous financial year. Directors may be re-elected without limitation. They can be dismissed at any time.

The directors' management expertise and experience are the result of various salaried and management positions they have previously held (see section 12.1.5 of the Registration Document).

At the date of approval of the Registration Document, the Board of Directors had eight members, including three women. The Company complies with the provisions of Articles L. 22-10-2 and L. 22-10-10 2° of the French Commercial Code relating to the diversity policy applied to the members of the Board of Directors with regard to criteria such as the age, gender or professional qualifications and experience.

In accordance with Articles L. 225-18.1 of the French Commercial Code, the Company guarantees gender balance within its Board of Directors, composed of eight members, by ensuring that the difference between male and female Board members is never more than two.

The independence of the directors who are currently members of the Board of Directors is assessed using criteria from the Middlenext Code.

12.1.1.2. Composition of the Advisory Board

As at the date of approval of the Registration Document, the Company also had an Advisory Board of observers (whose appointment is specified in section 19.2.2.1 of the Registration Document) composed as follows:

First and last name, business address	Office	Date of appointment, renewal and term
Kreos Capital V (UK) Limited **Represented by Maurizio PetitBon**	Observer	Appointed: 26 October 2018 Expiry date: renewed by the General Meeting on 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023
Substainable Development Partner International represented by Jean-François Le Bigot	Observer	Appointment: the General Meeting of 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023
Fate represented by Benoit Adelus	Observer	Appointment: the General Meeting of 6 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023

First and last name, business address	Office	Date of appointment, renewal and term
Christian Latrémouille	Observer	Appointment: the Board of Directors meeting on 8 April 2021 until the end of the General Meeting held to approve the financial statements for the financial year ending 31 December 2023

At the General Meeting of 26 October 2018, Kreos Capital V (UK) Limited, a private limited company under English law, was appointed observer for a term of three (3) years. Its appointment was renewed for a period of three (3) years at the General Meeting of 6 April 2021.

At the General Meeting of 6 April 2021, Substainable Development Partner, represented by Mr Jean-François Le Bigot, and Fate represented by Mr Benoit Adelus were appointed observers for a period of three (3) years.

During the Board of Directors meeting on 8 April 2021, Mr Christian Latrémouille was appointed observer for a term of three (3) years.

Substainable Development Partner, represented by Jean-François Le Bigot, and Fate, represented by Benoit Adelus and Professor Christian Latrémouille, were appointed observers of Affluent Medical so that the Board of Directors could benefit from the significant professional experience of the first two in managing companies in the healthcare sector, as well as from the experience of Christian Latrémouille's heart surgery experience with innovative prosthesis implants.

It should be noted that:

- observers are not compensated in respect of their position. Moreover, all other compensation that they could receive would be for services performed.
- Sustainable Development Partner and Fate are shareholders of the Company respectively with a stake of 2.23% and 0.22% of the share capital and 1.80% and 0.12% of the voting rights of the Company at the date of approval of the Universal Registration Document and do not hold securities giving access to the Company's share capital;
- Kreos Capital V is not a shareholder of the Company and holds 131,148 share subsciption warrants (BSAs) (see Section 19.1.4.1);
- Mr. Christian Latrémouille is not a shareholder of the Company and holds 34,524 BSAs (see Section 19.1.4.1).

12.1.2. Executive Management

As at the date of approval of the Registration Document, Executive Management is ensured by:

Name	Office	Main positions in the Company	Main positions outside the Company	Date of appointment and term
Michel Finance	Chief Executive Officer	Chairman and Chief Executive Officer	-	Appointed Chief Executive Officer by the Board of Directors on 20 May 2019 for a period of three years expiring at the end of the General Meeting held to approve the financial statements for the financial year ended 31 December 2022

The Company's Executive Management has been ensured by a Chairman and Chief Executive Officer (Mr Michel Finance) since 20 May 2019; the separation of the positions of Chairman of the Board of

Directors and Chief Executive Officer is not being considered at the date of approval of the Registration Document.

The business address of the Chief Executive Officer is the Company's registered office at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France.

12.1.3. Statements relating to members of the Board of Directors and the Chief Executive Officer

There are no family ties between the persons listed in Sections 12.1.1.1 and 12.1.2.

To the knowledge of the Company and as at the date of approval of the Registration Document, none of the directors or executive corporate officers of the Company over the last five years:

- has been convicted of fraud;
- has been associated, in his capacity as an executive or director, in a bankruptcy, receivership, liquidation or placement of companies under judicial administration;
- has been deprived by a court of the right to hold a position as a member of an administrative, management or supervisory body of an issuer or to intervene in the management or conduct in the affairs of an issuer; or
- has been challenged and/or officially and publicly sanctioned by statutory or regulatory authorities (including designated professional bodies).

At the date of approval of the Registration Document, the Company had three independent directors: Mr Dominique Carouge, Ms Ellen Roche and Véronique Phé (please refer to section 14.4 of the Registration Document), with regard to the criteria from the Middlenext Code to which it refers listed below, they cannot:

- be, or have been within the past five years, an employee or executive corporate officer of the Company or a company of the Group;
- have been within the past two years and not be in a significant business relations with the Company or its Group (as a client, supplier, competitor, service provider, creditor, banker, etc.);
- be a reference shareholder of the Company or hold a significant percentage of its voting rights;
- have any close ties or family relationship with a corporate officer or reference shareholder;
- be – or have been within the past six years – a statutory auditor of the Company.

The Board of Directors also considers that the grant of share subscription warrants to some directors (see Section 19.1.4.1 of this Registration Document) in no way affects their qualification as independent directors within the meaning of the Corporate Governance Code for small- and mid-cap companies as published in December 2009 and amended in September 2016 by Middlenext, given: (i) the subscription price paid for said subscription warrants; and (ii) that the amounts at stake are insignificant for the directors concerned.

12.1.4. Other corporate offices and functions held

Directors' other current corporate offices and functions held

As at the date of approval of the Registration Document, the other current corporate offices and functions held by the directors are:

First name, last name, function or position	Current corporate offices held as at the date of approval of the Registration Document
Michel Finance Chairman and Chief Executive Officer and director	- Director of Holding Incubatrices Série I - Director of Holding Incubatrices Série II - Director of France Biotech - Director of Shanghai Epygon Medical Technology Co. Ltd (a company registered in China)
Truffle Capital, represented by Philippe Pouletty Director	*As permanent representative of Truffle Capital:* - Director of Carmat SA (listed company) - Director of Pharnext SAS (listed company) - Director of Biokinesis SAS - Director of Carbios SA (listed company) - Member of the Management Committee of Diaccurate SAS - Member of the Management Committee of Nanosive SASU - Director of Holistick Medical SASU - Director of Skinosive SASU - Director of Artedrone SASU *In a personal capacity:* - Chief Executive Officer and Director of Truffle Capital SAS - Director of Deinove SA (listed company) - Manager of Nakostech SARL - Chairman of the Board of Directors of Abivax SA (listed company) - Honorary Chairman of France Biotech (a non-profit association) *Outside France, Mr Philippe Pouletty holds the following offices as representative of Truffle Capital:* - Director of Immune Targeting Systems Ltd (United Kingdom) - Director of Shanghai MyoPowers Medical Technology Co. Ltd (a company registered in China) - Director of Shanghai Epygon Medical Technology Co. Ltd (a company registered in China)
Patrick Coulombier Director	- Director of Shanghai MyoPowers Medical Technology Co. Ltd (a company registered in China)
Daniel Hayoz Director	- Director of PKMed - Director of Bariatek
Dominique Carouge Independent director	- Chairman of Doreca Conseil SASU - Director of *Les Enfants de Sanofi* association
Claire Corot Director	- Director of Holistick Medical - Senior Partner at Truffle Capital
Ellen Roche Director	- Director of Helios Cardiovascular - Associate professor at the Massachusetts Institute of Technology
Véronique Phé	- Urology surgeon, University Professor-Hospital Practitioner

Director	

Other corporate offices and functions held by the directors during the last five financial years and which have ended to date

As at the date of approval of the Registration Document, the other corporate offices and functions held by the directors during the last five financial years and which have now ended are:

First name, last name, function or position	Corporate offices and functions held outside the Company during the last five years and which have now ended
Michel Finance Chairman and Chief Executive Officer and director	- Chief Executive Officer (until January 2019) and director (until May 2018) of Theradiag
Truffle Capital, represented by Philippe Pouletty Director	*As permanent representative of Truffle Capital:* - Director of Vexim SA (listed company) - Director of Plasmaprime SAS - Director of Altimmune, Inc. (United States) - Member of the Management Committee of Kephalios - Member of the Management Committee of MyoPowers - Member of the Management Committee of Deinobiotics *In a personal capacity:* - Member of the Supervisory Board of Innate Pharma SA (listed company) - Chairman and director of Splicos SAS - Member of the Supervisory Board of Cytomics SA - Chairman of the Board of Directors of Theradiag SA (listed company) - Director of the *Association Centre Chirurgical Marie Lannelongue* (a non-profit association) *Outside France, Mr Philippe Pouletty held the following offices as permanent representative of Truffle Capital:* - Director of Symetis (Switzerland) - Director of MyoPowers SA (Switzerland)
Patrick Coulombier Director	- Chairman of Iollas Consulting (until January 2019) - Chairman of MyoPowers (Group company) (until May 2018) - Deputy Chief Executive Officer of Carmat (listed company) (until March 2016)
Daniel Hayoz Director	- Chairman of the Board of Directors of Myopowers SA (Switzerland)
Dominique Carouge Independent director	- Director of APSA – Aventis Pharma SA - Director of Sanofi North America - Director of Sanofi Europe - Director of Aventis France - Director of Sanofi Pasteur Mérieux - Director of Sanofi Espoir - Director of SETC (Belgium)
Claire Corot Director	- Head of Research, Innovation and Business Development of Guerbet
Ellen Roche	- None

Director	
Véronique Phé Director	- None

12.1.5. Biographies of directors, the Chief Executive Officer and observers

- **Mr Michel Finance: Director, Chairman of the Board of Directors and Chief Executive Officer**

Please refer to section 5.3.1 of the Registration Document.

- **Dr Philippe Pouletty (representative of Truffle Capital), director**

Dr Philippe Pouletty, Truffle Capital's representative on the Board of Directors, is a Doctor of Medicine (University of Paris VI), an immunologist and former resident at Hôpitaux de Paris. He holds a Master's degree in immunology from the Pasteur Institute and was a postdoctoral research fellow at Stanford University. He is the inventor of 29 patents, including the second highest revenue-generating life science patent for Stanford University. Dr Philippe Pouletty is co-founder and Chief Executive Officer of Truffle Capital.

He is the former Chairman of France Biotech, the French biotech industry association, and former vice-chairman of Europabio, the European biotech industry association. He is also the founder of three biotechnology companies in Europe and the United States that have generated a market capitalisation of more than $800 million and is a member of the Board of Directors of several biotechnology and medical device companies in Europe and North America (Carmat, Abivax, Carbios, Deinove, Pharnext).

Dr Philippe Pouletty was behind a number of government initiatives in France, including the 1999 law on the simplification of company law (SAS), the 2002 Biotech Plan to launch and develop biotechnology, and the Young Innovative Company (*Jeune Entreprise Innovante* – JEI), which grants important tax exemptions to technology companies.

- **Mr Patrick Coulombier: director**

Mr Patrick Coulombier was Chairman of MyoPowers Medical Technologie France until May 2018. Until 2016 he was Deputy CEO of Carmat, a French company developing a bioprosthetic artificial heart. A graduate in electronic engineering, he began his career in 1978 in the aerospace industry at Thalès Avionics where he held various positions related to research and development projects (Airbus A130, A320, Rafale, Combat Aircraft, Super Puma Helicopter and the Hermès spacecraft). In 1990 he joined MBDA France as Vice-President of International Programs, in the defence sector where he spearheaded two key programs, one relating to a British air combat training system and the other to a Franco-German drone system.

- **Dr Daniel Hayoz: director**

Dr Daniel Hayoz is Head of the Department of Medicine and Head of the Medicine Department of the Cantonal Hospital of Fribourg, and a professor at the Universities of Lausanne (UNIL) and Fribourg (UFR) in the faculty of medicine. He specialises in hospital internal medicine and vascular medicine. Author of more than 300 articles, he is the former President of the Swiss Society of Angiology, former Vice-President of the European Society of Clinical Investigation (ESCI), and former president of the Cardiovascular Biology Working Group of Swiss Society of Cardiology. Holder of several patents and member of the management committee of several start-ups, Dr Daniel Hayoz is also an Operating Partner at Truffle Capital.

- **Mr Dominique Carouge: Independent director**

Mr Dominique Carouge began his career as an external auditor at Ernst & Young in France and in the United States in 1985. He joined Sanofi in 1991 where he held various financial and management positions for 29 years with increasing responsibilities in France and internationally, until he became Executive Vice-President – Business Transformation, and joined the Group's Executive Committee. He was Chief Financial Officer for Hoechst Marion Roussel in Australia, Head of Business Planning and Reporting at Aventis Pharma in Frankfurt and Operations Controller of the Aventis Group. In 2005, he became Chief Financial Officer of the Vaccines Division, then Vice-Chairman in charge of Strategy and Chief Financial Officer of Sanofi Pasteur. In 2011, he was appointed Vice-President, Administration and Management of Sanofi Global R&D, then in 2016, Deputy Chief Financial Officer responsible for the Group's financial operations and management control. Mr Dominique Carouge is a graduate of the *École Supérieure de Commerce de Reims* and holds a chartered accountancy diploma and a certificate as a director of companies from the French Institute of Directors (IFA).

- **Ms Claire Corot: director**

Over the last 30 years, Ms Claire Corot has developed a dual world-renowned expertise in research and business development in the fields of pharmaceuticals and interventional medical devices. A member of Guerbet's Executive Committee, Ms Claire Corot led the Group's innovation as Vice-President of Research Innovation & Business Development Licensing, through the clinical development of several products and external growth operations that enabled Guerbet to double in size and accelerate its transformation into interventional radiology. Ms Claire Corot coordinated the development of innovative MRI concepts for Guerbet (the Iseult project funded by Bpifrance) and was the intermediary for the world's first construction of a whole-body 11.7T MRI by the French Alternative Energies and Atomic Energy Commission (CEA) in its Neurospin research centre. A clinical biology pharmacist by training, a former intern at Lyon's public hospitals (*Hôpitaux de Lyon*) with a PhD in biotechnology, Ms Claire Corot helped launch the Medicen Paris region competitiveness cluster as a director.

- **Ms Ellen Roche: Independent director**

Ms Ellen Roche is a professor at the Institute for Medical Engineering and Science and at the Mechanical Engineering department at the Massachusetts Institute of Technology (MIT). She heads the laboratory for the design and development of therapeutic techniques. Ms Ellen Roche has a PhD in Engineering and Applied Sciences from Harvard. Her research focuses on the application of innovative technologies for the development of medical devices, in particular for the repair of the cardiac function, combining different approaches (robotics, cell therapy, etc.). Ms Ellen Roche worked for more than five years in the medical device industry as an R&D engineer. She is the inventor of several patents, has submitted several patent applications and has published around 40 articles in journals on medical devices or presented them at conferences. Ms Ellen Roche has received several awards including the Fulbright International Science and Technology Award, Wellcome Trust Seed Award in Science, American Heart Association Pre-Doctoral Award, and the NIH Trailblazer Award.

- **Véronique Phé: Independent Director**

Véronique Phé is a doctor of medicine, specialised in urological surgery. She teaches at La Sorbonne is the first woman to have been appointed University Professor of Urology. Her clinical practice focuses on functional urology and neuro-urology, and in particular on urinary incontinence for women and men. She has developed skills in reconstructive surgery and minimally invasive surgery with laparoscopic robot-assisted procedures applied to neuro-urological and incontinent patients. She holds various positions within learned societies in urology (the French Urology Association, the French Association of Urologists, etc.). In addition, she has published more than 140 articles in renowned scientific journals (European Urology, Nature Reviews Urology, BJU International, Journal or Urology, etc.) and has received various national and international awards for her work in urology, including the prestigious EAU Crystal Matula Award in 2021).

- **Mr Jean-François Le Bigot – representative of Substainable Development Partner International: Observer**

Mr Jean-François Le Bigot is currently Chief Executive Officer of Oncovita and Chairman of Ginko Invest. He was previously Chairman of Citoxlab Group (formerly CIT), which he joined in 1987. Over a period of more than 30 years, he developed Citoxlab which has become a leading international CRO with more than 1,500 employees. Under his leadership, Citoxlab acquired numerous CROs in North America and Europe. He successfully sold Citoxlab in 2019 to Charles River. He previously held management positions at Sandoz. Mr Jean-François Le Bigot holds a PhD in biomedical pharmacology.

- **Mr Benoit Adelus - representative of Fate: Observer**

Mr Benoit Adelus has more than 30 years of experience in the healthcare, MedTech, *in vitro* diagnostics, vaccines and animal health. He has led a number of successful companies that he has significantly developed through innovation, international expansion and acquisitions, particularly in the United States and China. He has extensive international experience, having held various positions, as Sales Director, in R&D and Managing Director in the United States and Latin America. He managed the IPO of BioMérieux on the Paris stock exchange in 2004 as Chief Executive Officer. He has extensive experience in LBOs, having successfully managed a total of four transactions, and has been Chairman or member of the Board of Directors of several health technology companies.

- **Mr Christian Latrémouille: Observer**

Mr Christian Latrémouille is a doctor of medicine, specialised in cardiac surgery, and is a university professor at the University of Paris. Mr Christian Latrémouille began his career in 1993 as clinical head-assistant in the cardiac surgery department of Professor Alain Carpentier at the Broussais Hospital. After completing a doctorate in xenotransplantations, he took responsibility for the heart transplant program in 1995. First a university hospital assistant in 1995, then a university lecturer in 2000, he was appointed associate professor at the University of Paris-Descartes in 2004, with a university degree in clinical anatomy and a hospital residency in adult cardiac surgery. He was entrusted with the preclinical development phase of the Carmat total bioprosthetic artificial heart, and he performed the world's first implantation of the Carmat heart in humans on 18 December 2013. He then became the lead investigator of the safety and feasibility study of the Carmat heart, and later, during the pivotal study, remained "Proctor Principal", providing training for all new teams joining the project. In 2017, Mr Christian Latrémouille became Head of the Cardiac Surgery Department at the Georges Pompidou European Hospital. In 2020, he joined Carmat as Vice-President of Surgical Affairs.

12.2. Conflicts of interest of administrative and executive bodies

Chapters 13 "*Compensation and benefits*" and 16 "*Major shareholders*" of this Registration Document refer to the members of Executive Management and/or the Board of Directors who are direct or indirect shareholders of the Company and/or holders of securities giving rights to the Company's capital as at the date of this Registration Document.

To the Company's knowledge, and subject to the agreements between related parties described in Chapter 17 "*Related-party transactions*" of this Registration Document, there are no current or potential conflicts of interest between Company-related duties and the private interests and/or other duties of the members of the administration and Executive Management bodies, set forth in section 12.1 "*General information relating to executives, directors and observers*" of this Registration Document.

The Company's internal regulations, applicable as from the admission of the Company's shares to trading on the Euronext Paris regulated market, provide for an information and prevention procedure for existing or potential conflicts of interest. Accordingly, as from that date, each director must (i) inform the Board of Directors, as soon as he becomes aware of any conflict of interest situation, even if only potential, and must refrain from participating in the debates and in the vote on the corresponding deliberation, and (ii) tender their resignation in the event of a permanent conflict of interest. Subject to changes in the legal and statutory provisions, the Board of Directors will review identified conflicts of interest at least once a year.

The shareholders' agreement in force between the shareholders of the Company and the Company, as at the date of approval of the Registration Document, will be automatically terminated on the day on which the Company's shares are admitted for trading on the Euronext Paris regulated market. Furthermore, to the Company's knowledge, beside the dilutive instruments referred to in section 19.1.4.4 of this Registration Document, there is no other agreement or understanding between shareholders, customers, suppliers or other partners under whose terms and conditions one of the Company's directors or executives referred to in section 12.1 of this Registration Document has been named and regarding a commitment to hold or sell their stake in the Company's capital.

12.3. Evaluation **procedure for current agreements concluded under normal conditions**

In accordance with the provisions of Article L. 22-10-12 of the French Commercial Code and subject to the admission of the Company's shares trading on the regulated market Euronext Paris, during its meeting of 18 February 2020, the Board set up a procedure for evaluating agreements relating to current transactions entered into under normal conditions.

This procedure provides for the identification of agreements that may be classified as regulated, their submission to the Board of Directors for analysis prior to signature, an assessment of the conditions for the establishment the agreements concerned, a review of the current nature and normal conditions of these agreements, and at least once a year the presentation by the Audit Committee of the procedure's implementation.

13. COMPENSATION AND BENEFITS

13.1. Compensation paid and benefits in kind for executives

13.1.1. Compensation policy for corporate officers

The compensation policy for executive and non-executive corporate officers is presented below, in accordance with Article L. 22-10-8 of the French Commercial Code, subject to the admission of the Company's shares to trading on the Euronext Paris regulated market, which was submitted to the shareholders for approval.

13.1.1.1. General principles regarding the compensation policy for corporate officers

The compensation policy for corporate officers defines the principles and criteria for determining, reviewing and implementing the components of compensation allocated to the Company's corporate officers for their service.

On the recommendation of the Compensation and Governance Committee and taking into account the recommendations of the Middlenext Code, the Board of Directors has established a compensation policy for each of the Company's corporate officers in line with its corporate interests, contributing to its long-term sustainability and part of its business strategy as described in the Registration Document.

Subject to the admission of the Company's shares to trading on the Euronext Paris regulated market, no element of compensation of any kind whatsoever may be determined, allocated or paid by the Company, nor any commitment made by the Company if it does not comply with the compensation policy approved by the General Meeting of 6 April 2021 or, if the meeting is not held, with the compensation or practices previously existing within the Company.

However, in exceptional circumstances, (which could consist in particular of circumstances that are unforeseeable or external to the Company, impossible to take into account or reflect in the definition of the compensation policy – and in particular (without limitation), any material event impacting the Company's markets and/or business sector or any unforeseen change to the competitive environment), the Board of Directors may exceptionally derogate from the application of the compensation policy if this derogation is temporary, in accordance with the Company's interest and necessary to guarantee the Company's sustainability or viability. In accordance with the order of 27 November 2019, the adaptation of the compensation policy to exceptional circumstances would be decided by the Board of Directors on the recommendation of the Compensation and Governance Committee.

The Board of Directors determines, revises and implements the compensation policy for each corporate officer on the recommendation of the Compensation and Governance Committee.

The compensation policy takes into account the following principles in accordance with the rules set out in the Middlenext Code, to which the Company has adhered, subject to the admission of the Company's shares to trading on the Euronext Paris regulated market:

- **the completeness of the compensation** presented: all compensation components are used in the overall assessment of compensation and are all clearly justified;
- **the principle of balance and consistency**: the Compensation and Governance Committee ensures the balance and consistency of compensation so that it complies with the Company's corporate interest;
- **the clarity of the rules**: the rules must be simple and transparent; the performance criteria used to determine the variable compensation, or, where applicable, for the allocation of stock options or performance shares must be in line with the Company's performance, correspond to its objectives and be stringent, understandable and, as much as possible, sustainable;
- **the measurement**: compensation must be balanced and take into account the general interest of the Company, market practices and the performance of executives;

- **transparency**: annual information to shareholders on all compensation and benefits received by executives must be provided transparently in accordance with applicable regulations;
- **principle of comparability** (benchmark) respected by the Board of Directors and the Compensation and Governance Committee. Compensation is assessed in the context of the reference market subject to the specific roles assigned, the responsibility assumed, the results obtained and the work carried out by the executive corporate officers.

As part of the decision-making process when determining and revising the compensation policy, the compensation and employment conditions of the Company's employees are taken into account by the Compensation and Governance Committee and the Board of Directors. To this end, the principles of the Company's employment policy are regularly presented by the Chief Executive Officer. The directors are thus able to verify the consistency between the compensation of the corporate officers and the compensation and employment conditions of the Company's employees.

For the 2020 financial year, the Company's management was as follows:

- Mr Vincent Gardès, Chairman of the Board of Directors until 14 May 2020;
- Mr Michel Finance, Chief Executive Officer and Chairman of the Board of Directors as from 14 May 2020.

13.1.1.2. Compensation policy for executive corporate officers

The structure of the compensation of executive corporate officers is reviewed each year by the Board of Directors, which sets the various components, on the recommendations of the Compensation and Governance Committee, it being noted that Mr Michel Finance receives compensation in respect of his office as Chief Executive Officer, and exercises his duties as Chairman of the Board of Directors without compensation.

On this basis, it was proposed to the Board of Directors on 18 February 2021 to decide on the stability of the fixed compensation and on the stability of the level of variable compensation of the Chief Executive Officer (35% of the fixed compensation), as this structure is connected to the Company's performance and the maintenance of the balance between short- and medium-term performance.

It is specified that, subject to the admission of the Company's shares to trading on the Euronext Paris regulated market, the payment of any variable and exceptional compensation of the executive corporate officers may only be made if approved by the shareholders, pursuant to Article L. 22-10-34 of the French Commercial Code.

Fixed annual compensation

Chairman and Chief Executive Officer – Michel Finance

On the recommendation of the Compensation and Governance Committee and after deliberation of the Board of Directors of 18 February 2021, the annual fixed compensation of Mr Michel Finance, in his capacity as Chief Executive Officer, in respect of the 2021 financial year, has been set at €250,000.

In addition, in the event of the appointment of one or several new Chief Executive Officers or Deputy Chief Executive Officers, the principles set out above would apply to the determination of their compensation policy, it being specified that the amount could be adapted depending on the profile, experience or level of responsibility of the new corporate executive officer.

No compensation is granted to the Chairman of the Board of Directors in his capacity. Where applicable, and in particular in the event of the separation of the position of Chairman of the Board of Directors and Chief Executive Officer, and the appointment of a new Chairman of the Board of Directors, the annual fixed compensation of the Chairman of the Board of Directors would be determined by the Board of Directors on the recommendations of the Compensation and Governance Committee, the principles set out above would apply to the determination of its compensation policy, it being specified that the

amount would be calculated depending on the profile, experience or level of responsibility of the new executive corporate officer.

Annual variable compensation

The variable compensation aims to link the executive corporate officers with the Company's short-term performance. The rules for setting this compensation are also consistent with the Company's strategy. The terms of the annual variable compensation are intelligible for the shareholders and will give rise to clear and exhaustive information each year in the annual report.

The indicators taken into account to determine the variable portion and the level of the objectives to be achieved are defined each year by the Board of Directors on the recommendations of the Compensation and Governance Committee at the beginning of the reference period in which they apply.

As part of the determination of the variable portion of the compensation for the executive corporate officers, it was proposed to the Board of Directors to set the financial performance indicators, their objectives and their weighting for 2021.

It is specified that, subject to the admission of the Company's shares to trading on the Euronext Paris regulated market, the payment of any variable compensation to the executive corporate officers may only be made if approved at the General Meeting held to approve the 2021 financial statements pursuant to Article L. 22-10-34 of the French Commercial Code.

Chairman and Chief Executive Officer – Michel Finance

There is no variable compensation for the Chairman of the Board of Directors as long as the positions of Chairman and Chief Executive Officer are not separated.

The target annual variable compensation of Mr Michel Finance, in respect of his office as Chief Executive Officer, is subject to performance criteria, the objective of which is set each year. It corresponds to a maximum percentage of the amount of his fixed compensation determined annually by the Board of Directors on the recommendations of the Compensation and Governance Committee (*i.e.* 35% of his fixed compensation for 2021; this percentage was proposed by the Compensation and Governance Committee on 17 February 2021 and approved by the Board of Directors on 18 February 2021).

The performance criteria used to determine the variable compensation are drawn up on the basis of specific personal and corporate objectives based on quantitative and qualitative criteria. These targets are based on operational objectives (including, for a 45% minority share of the variable compensation for the year 2021, the achievement of the admission of the Company's shares to trading on the Euronext Paris regulated market or the signature of strategic agreements) and clinical trials (relating to the progress of the clinical development of the Company's medical devices).

It is also proposed that the Board of Directors decide that in the event of the appointment of a new corporate executive officer, these same principles will apply, it being specified that in the event of an appointment occurring during the second half-year, performance is assessed on a discretionary basis by the Board of Directors.

Long-term and exceptional compensation

Long-term compensation

In respect of his office as Chairman of the Board of Directors, Mr Michel Finance will not receive any conditional compensation paid in the form of stock options, share subscriptions or warrants in respect of the 2021 financial year.

The allocation of securities giving access to the share capital may also be considered to the benefit of Mr Michel Finance for the 2021 financial year.

Exceptional compensation

The Board of Directors may, at its discretion, grant the executive corporate officers in office or appointed during the financial year, exceptional compensation in certain specific circumstances and in compliance with the principles set out in the Middlenext Code, it being specified that, subject to the

admission of the Company's shares to trading on Euronext Paris regulated market, the payment may only be made if approved by the shareholders, pursuant to Article L. 22-10-34 of the French Commercial Code.

Compensation as a director (formerly directors' fees)

Mr Michel Finance does not receive compensation as a director. Where appropriate, the Board of Directors may, at its discretion, grant compensation to executive corporate officers in office or appointed during the financial year in respect of their directorships.

Compensatory payments and benefits due as a result of termination of executive corporate officers

Mr Michel Finance does not receive any compensation in respect of his office related to a forced departure or to a non-compete clause.

Employment contract

Mr Michel Finance does not have an employment contract.

Benefits in kind

Mr Michel Finance has a company car.

Supplemental retirement plan

None.

Liability insurance for executive corporate officers

Civil liability insurance for corporate officers has been taken out by Affluent Medical with AIG for a total coverage amount of €7,500,000 per year.

13.1.1.3. Compensation policy for non-executive corporate officers

The compensation policy mentioned below is applicable to the members of the Board of Directors, it being noted that Mr Michel Finance, as Chairman of the Board of Directors, performs his duties without charge.

Directors' terms of office are set out in section 12.1.1 of the Registration Document.

The components of total compensation and benefits of any kind that may be granted to non-executive corporate officers are as follows:

Compensation allocated to members of the Board of Directors

The total amount of compensation allocated annually to the Company's directors (formerly called directors' fees) is allocated and paid in accordance with the Board of Directors' Internal Regulations. This breakdown takes into account participation in the work of the Board and its Committees.

With this in mind, it was proposed to the General Meeting of Shareholders to set the overall amount of compensation allocated annually to the Company's directors at €120,000, until decided otherwise.

Other benefits

Non-executive corporate officers may be reimbursed for expenses incurred while performing their duties.

They may also receive exceptional compensation for a one-off or special assignments.

13.1.1.4. Components of compensation paid or granted in respect of the 2020 financial year to executive corporate officers

In accordance with Article L. 22-10-34 of the French Commercial Code, the General Meeting will approve, as of the date of the General Meeting held to approve the financial statements for the financial year ending 31 December 2021, the fixed, variable and exceptional elements of the total compensation and benefits of any kind paid or granted in respect of the previous financial year by separate resolutions

for the Chairman of the Board of Directors and the Chief Executive Officer. The General Meeting must explicitly approve the payment of variable or exceptional compensation.

It will therefore be proposed, as from the Ordinary General Meeting held to approve the financial statements for the financial year ending 31 December 2021 and subject to the admission of the Company's shares to trading on the Euronext Paris regulated market, to approve the elements of compensation paid or granted in respect of the 2021 financial year to the Chief Executive Officer, as set out below, it being specified that the Chairman of the Board of Directors performs his duties free of charge.

In respect of the 2020 financial year, Mr Michel Finance, in his capacity as Chief Executive Officer, was paid a total fixed compensation of €250,000 and a total variable compensation of €43,750 for the completion of a portion of the specific personal and company objectives based on quantitative and qualitative criteria He also received benefits in kind totalling €11,435. He has not entered into an employment contract with the Company. He did not receive any compensation in respect of his office as Chairman of the Board of Directors.

Mr Vincent Gardès, Chairman of the Board of Directors until 14 May 2020, did not receive any fixed or variable compensation in respect of the 2020 financial year. He received, before social security contributions, €3,500 in attendance fees in respect of his office as a director of the Company.

The directors received compensation in respect of their office, which is detailed below in table 3 of section 13.1.2.

13.1.2. Compensation and benefits paid or allocated to corporate officers

The tables in this chapter are included in Appendix 2 of the French Financial Markets Authority's (*Autorité des Marchés Financiers* – AMF) Position-Recommendation No. 2021-02 "Guide for the preparation of universal registration documents – DOC 2021-02" published by the AMF on 8 January 2021.

The information is prepared by reference to the Middlenext Code.

Table 1: Summary table of compensation, stock options and shares granted to each executive corporate officer

In euros	Financial year 2019	Financial year 2020
Mr Michel Finance - Chairman and Chief Executive Officer*		
Compensation due in respect of the financial year *(for details see table 2)*	197,664	305,185
Value of multi-year variable compensation granted during the financial year *(for details see table 2)*	0	0
Value of founders' share warrants (BSPCEs) granted during the financial year *(for details see table 4)*	997,905**	180,978**
Value of bonus shares granted in respect of the financial year *(for details see table 6)*	0	0
Value of other long-term compensation plans	0	0
Total	1,195, 569	486,163

** Mr Michel Finance was appointed Chief Executive Officer of the Company on 20 May 2019 and Chairman of the Board of Directors of the Company on 14 May 2020.*

*** The difference in compensation is due to a lower allocation of BSPCEs in 2020, it being specified that 2019 was the year in which Michel Finance took office as Chief Executive Officer of the Group.*

In euros	Financial year 2019	Financial year 2020
Mr Vincent Gardès – Chairman of the Board of Directors*		
Compensation due in respect of the financial year *(for details see table 2)*	72,250	3,500
Value of multi-year variable compensation paid during the financial year *(for details see table 2)*	0	0
Value of stock options granted during the financial year *(for details see table 4)*	0	0
Value of bonus shares granted in respect of the financial year *(for details see table 6)*	0	0
Value of other long-term compensation plans	0	0
Total	**72,250**	**3,500**

** Mr Vincent Gardès was appointed Chairman of the Board of Directors of the Company on 18 April 2018 and resigned from his position on 14 May 2020.*

In euros	Financial year 2019	Financial year 2020
Mr Daniele Zanotti – Chief Executive Officer*		
Compensation due in respect of the financial year *(for details see table 2)*	63,206	0
Value of multi-year variable compensation paid during the financial year *(for details see table 2)*	0	0
Value of stock options granted during the financial year *(for details see table 4)*	0	0
Value of bonus shares granted in respect of the financial year *(for details see table 6)*	0	0
Value of other long-term compensation plans	0	0
Total	63,206	0

** Mr Daniele Zanotti was appointed Chief Executive Officer of the Company on 27 March 2018 and resigned from his position on 19 May 2019.*

Table 2: Summary of the compensation of each executive corporate officer

The following tables present the compensation payable to executive corporate officers in respect of the financial years ended 31 December 2019 and 2020 and the compensation received by the same people during the same financial years.

In euros	Financial year 2019		Financial year 2020	
	Amounts allocated(1)	Amounts paid(2)	Amounts allocated(1)	Amounts paid(2)
Mr Michel Finance – Chairman and Chief Executive Officer*				
Fixed compensation	154,891	154,891	250,000	250,000
Annual variable compensation	35,553	0	43,750	35,553**
Multi-year variable compensation	0	0	0	0
Exceptional compensation	0	0	0	0
Compensation paid for directorships	0	0	0	0
Benefits in kind***	7,220	7,220	11,435	11,435
Total	**197,664**	**162,111**	**305,185**	**296,988**

(1) In respect of the financial year. (2) During the financial year.

** Mr Michel Finance was appointed Chief Executive Officer of the Company on 20 May 2019 and Chairman of the Board of Directors of the Company on 14 May 2020.*

*** In addition to the fixed portion of his compensation, Mr Michel Finance also receives variable compensation. The maximum gross amount of this variable compensation in respect of the 2020 financial year was proposed by the Compensation and Governance Committee at its meeting on 17 February 2021 and validated by the Board of Directors on 18 February 2021 at 35% of his fixed compensation, subject to the achievement of personal and general objectives set by the Company's Board of Directors. These objectives in respect of the 2020 financial year were set by the Board of Directors on 19 February 2020. They included operational and clinical objectives. At its meeting on 17 February 2021 in view of the achievement of these objectives, the Compensation and Governance Committee estimated that the achievement rate for these objectives was 50%. On a proposal from the Compensation and Governance Committee, the Company's Board of Directors on 18 February 2021 proposed to Mr Michel Finance gross variable compensation of €43,750 for the 2020 financial year. A single payment was made for this variable compensation.*

**** Benefits in kind correspond to a company car.*

In euros	Financial year 2019		Financial year 2020	
	Amounts allocated(1)	Amounts paid(2)	Amounts allocated(1)	Amounts paid(2)
Mr Vincent Gardès – Chairman of the Board of Directors*				
Fixed compensation	60,000	60,000	0	0
Annual variable compensation	0	0	0	0
Multi-year variable compensation	0	0	0	0
Exceptional compensation	0	0	0	0
Compensation paid for directorships	12,250	12,250	3,500	3,500
Benefits in kind	0	0	0	0
Total	**72,250**	**72,250**	**3,500**	**3,500**

(1) In respect of the financial year. (2) During the financial year.

** Mr Vincent Gardès was appointed Chairman of the Board of Directors of the Company on 18 April 2018 and resigned from his position on 14 May 2020.*

In euros	Financial year 2019		Financial year 2020	
	Amounts allocated(1)	Amounts paid(2)	Amounts allocated(1)	Amounts paid(2)
Mr Daniele Zanotti – Chief Executive Officer*				
Fixed compensation	63,206	63,206	0	0
Annual variable compensation	0	14,953	0	0
Multi-year variable compensation	0	0	0	0
Exceptional compensation	0	0	0	0
Compensation paid for directorships	0	0	0	0
Benefits in kind	0	0	0	0
Total	**63,206**	**78,159**	0	0

(1) In respect of the financial year. (2) During the financial year.

** Mr Daniele Zanotti was appointed Chief Executive Officer of the Company on 27 March 2018 and resigned from his position on 19 May 2019.*

Table No. 3: Table of compensation and other items received by non-executive corporate officers

The following table shows the compensation received by the Company's non-executive corporate officers during the 2019 and 2020 financial years.

Table of compensation for directorships and other compensation received by non-executive corporate officers				
Non-executive corporate officers	Amounts allocated in respect of the 2019 financial year	Amounts paid during the 2019 financial year	Amounts allocated in respect of the 2020 financial year	Amounts paid during the 2020 financial year
Michel Finance				
Directors' compensation	0	0	0	0
Other compensation (including allocation of BSPCEs)	1,195,569	1,160,016	486,163	477,966
Truffle Capital represented by Philippe Pouletty				
Directors' compensation	0	0	0	0
Other compensation	0	0	0	0
Patrick Coulombier				
Directors' compensation	11,000	11,000	7,750	7,750
Other compensation	2,000	2,000	3,000	3,000
Daniel Hayoz				
Directors' compensation	11,500	11,500	7,750	7,750
Other compensation	3,000	3,000	3,000	3,000
Dominique Carouge				
Directors' compensation	0	0	1,500	1,500
Other compensation	0	0	1,000	1,000
Christian Latrémouille*				
Directors' compensation	11,500	11,500	7,750	7,750
Other compensation	0	0	0	0
Fate represented by Benoit Adelus*				
Directors' compensation	0	0	0	0
Other compensation	0	0	0	0
Substainable Development Partner International represented by Jean-François Le Bigot*				
Directors' compensation	0	0	0	0
Other compensation	0	0	0	0
Jean-Michel Malbrancq*				

Directors' compensation	12,250	12,250	7,750	7,750
Other compensation	2,000	2,000	1,000	1,000
Vincent Gardès				
Directors' compensation	12,250	12,250	3,500	3,500
Other compensation	60,000	60,000	0	0
Reinhard Ambros*				
Directors' compensation	8,250	8,250	0	0
Other compensation	2,000	2,000	0	0
José Da Gloria*				
Directors' compensation	12,250	12,250	4,250	4,250
Other compensation	2,000	2,000	2,875	2,875
Thierry Herbreteau*				
Directors' compensation	5,000	5,000	2,250	2,250
Other compensation	1,000	1,000	0	0
Total	**1,349,569**	**1,314,016**	**528,969**	**521,070**

* Mr Christian Latrémouille, Fate represented by Mr Benoit Adelus, Substainable Development Partner International represented by Mr Jean-François Le Bigot, Mr Jean-Michel Malbrancq, Mr Vincent Gardès, Mr Reinhard Ambros, Mr José Da Gloria and Mr Thierry Herbreteau are no longer directors of the Company as at the date of approval of the Registration Document.

** In respect of his office as Chief Executive Officer, Mr Michel Finance received conditional compensation paid in the form of founders' share warrants (BSPCEs) during the 2019 and 2020 financial years.

In 2019 and 2020, the compensation of each director in respect of his/her term of office was based on the number of Board meetings held during each financial year, the actual attendance at the Board of Directors of said director, and his/her physical presence or attendance via videoconferencing. Other compensation corresponds to various assignments carried out (see section 17.2 of the Registration Document) or to participation in the Audit Committee or the Compensation and Governance Committee.

Table No. 4: Share subscription or purchase options granted to each executive corporate officer by the Company or any Group company during the 2020 financial year

Name of the executive corporate officer	Plan number and date	Type of options (purchase or subscription)	Value of stock options according to the method used for the consolidated financial statements	Number of stock options granted during the financial year	Strike price	Exercise period
Michel Finance	BSPCE-2020-4 8 December 2020	BSPCEs	€180,978	87,675	€5.89	7 December 2030

Table No. 5: Share subscription or purchase options exercised during the 2020 financial year by each executive corporate officer

None.

Table No. 6: Bonus shares granted to each corporate officer during the 2020 financial year

None.

Table No. 7: Bonus shares granted and made available to each executive corporate officer during the 2020 financial year

None.

Table No. 8: History of share subscription or purchase options

Share subscription warrants (BSA)

Please refer to the tables in section 19.1.4.1 "*Share subscription warrants*" of the Registration Document.

Founders' share warrants

Please refer to the tables in section 19.1.4.2 "*Company founders' share warrants plan*" of the Registration Document.

Table No. 9: Share subscription or purchase options granted to the top ten employees who are not corporate officers and options exercised by them

Total number of stock options granted/shares subscribed or purchased		Weighted average exercise price	BSPCE-2020-2	BSPCE-2020-3	BSPCE-2020-4	BSPCE-2020-5
Stock options granted, during the financial year, by the Company and any company included in the scope for granting stock options to the ten employees of the issuer and of any company included in this scope, for which the number of stock options thus granted is higher (aggregate data)	8 December 2020	€5.89	226,300	75,000	47,260	75,000
Stock options in the issuer and the companies referred to above, exercised during the financial year by the ten employees of the Company and these companies, whose number of stock options thus purchased or subscribed is the highest (aggregate data)	-	-	-	-	-	-

Table No. 10: Summary of bonus share awards

None.

Table No. 11: Details of the compensation conditions and other benefits granted to executive corporate officers

The table below provides details of the conditions for compensation and other benefits granted to executive corporate officers.

Executive corporate officers	Employment contract		Supplemental pension plan		Compensatory payments and benefits due or likely to be due as a result of termination or change in position		Compensatory payments relating to a non-compete clause	
	Yes	No	Yes	No	Yes	No	Yes	No
Mr Michel Finance – Chairman and Chief Executive Officer		X		X		X		X
Start date as Chief Executive Officer:	Board of Directors' meeting of 20 May 2019							
End date of term of office of Chief Executive Officer:	Ordinary General Meeting of Shareholders' to approve the financial statements for the year ending 31 December 2022							

13.2. Sums provisioned or otherwise recognised by the Company for the purposes of payment of pensions, retirement income or other benefits to directors and executives

The Company has not provisioned any sums for the purpose of paying pensions, retirement and other benefits to corporate officers.

The Company has not paid any severance or sign-on bonuses to corporate officers.

14. ADMINISTRATIVE AND MANAGEMENT BODIES

14.1. Management of the Company

14.1.1. Executive Management organisational procedures

The Company is a French corporation (*société anonyme*) with a Board of Directors, the composition of which is detailed in section 12.1.2 of the Registration Document.

The Board of Directors may opt to separate the duties of the Chairman and Chief Executive Officer or have a single person hold both positions. As mentioned in the Middlenext Corporate Governance Code to which the Company will refer as from when the Company's shares are admitted to trading on the Euronext Paris regulated market, applicable law indicates no preference between those two options, and it is up to the Company's Board of Directors to choose between the two methods of Executive Management based on its own criteria and requirements.

The Company opted for a single position for these two duties, as decided by the Board of Directors' meeting on 14 May 2020. The office of Chief Executive Officer, revocable at any time by the Board of Directors, is thus performed by Mr Michel Finance, who also chairs the Company's Board of Directors.

14.1.2. Restrictions on the powers of the Chief Executive Officer

The Chief Executive Officer, who assumes the Executive Management of the Company, is vested with the broadest powers to act in all circumstances on the Company's behalf. He/she exercises his/her powers within the scope of the Company's corporate purpose and subject to the powers expressly granted by law to shareholders' meetings and to the Board of Directors. The Chief Executive Officer shall represent the Company in its relations with third parties.

On 18 February 2021, the Board of Directors limited the powers of the Chief Executive Officer on the following matters:

- the adoption or substantial modification of the business plan and/or annual budget or any expenditure commitment not provided for in the annual budget exceeding a total cumulative amount of €500,000;
- the acquisition, subscription, or equity investment in/of all or nearly all of the assets of any company, group or entity of any kind by the Company other than for short-term investment purposes, as well as entering into a strategic alliance or a significant technology licensing agreement;
- the transfer, sale, acquisition or pledge of equity securities, business assets or activities, any intellectual property rights by the Company and/or its subsidiaries, as well as to any person whatsoever, regardless the legal terms and conditions, for an amount greater than €250,000; as well as the signing of any letter of intent or other commitment in connection with any transaction involving the securities and/or substantial assets of the Company and/or one of its subsidiaries;
- the subscription of any loan other than bonds or any form of debt other than any credit line taken out in the ordinary course of business for an amount greater than €1,000,000;
- any decision to initiate, conduct or terminate (in particular by way of settlement) a legal action, a dispute, or any other official procedure when the amount in question exceeds €250,000;
- any decision to appoint or dismiss a corporate officer and/or an employee whose total gross annual compensation (including bonuses) is greater than €250,000;
- the conclusion, modification or termination of any agreements, covenants or commitments between the Company and the shareholders, corporate officers, holders of securities, directors and observers – and any person belonging to their family circle for natural persons, or any affiliated company for legal entities – (including license agreements, current account advance

agreements, service agreements, etc.), as well as any agreements falling within the scope of the provisions of Article L. 225-38 of the French Commercial Code;

- the appointment of a financial intermediary for any new capital raising, merger-acquisition transaction, total or partial sale of business assets, or any equivalent transaction;
- any significant change in the Company's business, including through the creation of a new business or the discontinuation of an existing business.

14.1.3. Powers of the Board of Directors

The Board of Directors determines the Company's overall strategy and ensures that it is implemented in accordance with its corporate interests of the Company, taking into consideration the environmental and social issues associated with its operations. With due respect to the powers expressly given to shareholders' meetings and within the limits of the corporate purpose, it addresses all questions related to the Company's proper functioning and governs, by its decisions, the affairs that concern it.

The Board of Directors conducts checks and controls as it deems appropriate.

Each director receives all the information required to perform his/her duties and may ask for all documents that he/she deems useful.

14.1.4. Expiry date of term of office

Refer to section 12.1.1 of the Registration Document.

14.2. Service agreements between directors and the Company or its Subsidiary

The Company entered into an employment contract with Mr Daniel Hayoz, director of Affluent Medical, on 9 April 2018, regarding his role as the Company's medical expert. Under the terms of his employment contract, Mr Daniel Hayoz receives a lump-sum compensation of €3,000 per year.

14.3. Special committees

At its meeting of 27 March 2018, the Board of Directors decided to set up an Audit Committee and a Compensation and Governance Committee to assist it in its duties. The role, scope and operating procedures of the Audit Committee and the Compensation and Governance Committee were defined at the same Board meeting and amended by the Board of Directors on 18 February 2021, subject to the condition precedent of the admission of the Company's shares to trading on the Euronext Paris regulated market. These changes will come into effect on the date of the admission of the Company's shares to trading on the Euronext Paris regulated market.

14.3.1. Audit Committee

14.3.1.1. Composition

The Audit Committee is composed of at least two members. The members of the Audit Committee are appointed by the Board of Directors among the members of the Board of Directors, excluding executive corporate officers. They are appointed for a fixed term that may not exceed their term of office on the Board of Directors and may be dismissed at any time and without cause by the Board of Directors. Their terms of office on the Audit Committee are renewable without limitation.

The Audit Committee may invite any person, either internal or external to the Company, to participate in its meetings and its work.

The members of the Audit Committee must have financial or accounting expertise and at least one member must be independent in accordance with the provisions of the Middlenext Code.

The Audit Committee Chairman is appointed by the Board of Directors among its independent members.

The members of the Audit Committee do not receive any compensation other than that provided for by law. Their duties on the Audit Committee may be taken into account to determine the distribution of said compensation.

At the date of approval of the Registration Document, the members of the Audit Committee are:

- - Mr Dominique Carouge (Chairman);
- - Ms Claire Corot.

14.3.1.2. Duties and responsibilities

The Audit Committee monitors matters relating to the preparation and control of accounting and financial information and shall make recommendations to the Board of Directors for its ongoing supervision of the Company's management, as provided for by law and the Company's bylaws.

Without prejudice to the Board's powers, the Audit Committee is tasked in particular with:

(i) monitoring:

- the process for preparing financial information and formulating, where appropriate, recommendations to guarantee its integrity,
- the effectiveness of internal control and risk management systems,
- the statutory audit of the Company and consolidated financial statements by the Statutory Auditors,
- the selection process of the Statutory Auditors,
- the independence of the Statutory Auditors;

(ii) approving:

- non-audit services provided by the Statutory Auditors and the level of fees allowed for non-audit services provided by the Statutory Auditors,
- all budgets for legal audits and other assignments provided by the Statutory Auditors; and

(iii) verifying that:

- the services provided by the Statutory Auditors correspond to what is authorised by the law and regulations.

The Audit Committee must also issue a recommendation on the Statutory Auditors proposed for appointment by the General Meeting and/or upon renewal of their term of office.

The Chairman of the Audit Committee ensures that the reports of the Audit Committee's activities made to the Board of Directors enable it to be fully informed, thereby facilitating its deliberations.

If, during the course of its work, the Audit Committee detects a significant risk that in its view is not being adequately handled, the Chairman of the Audit Committee shall immediately alert the Chairman of the Board of Directors.

The Audit Committee's task is less to go into detail about the financial statements than to monitor the processes involved in preparing them and assessing the validity of the methods chosen to process material transactions.

As such, the Audit Committee may review the Company's annual financial statements as they will be presented to the Board of Directors, interview the Statutory Auditors and the Chief Financial Officer, and be informed of their analyses and findings.

In the context of their duties, the members of the Audit Committee have the same rights of information as those described in section 1.6.

The Audit Committee may consult outside experts at the Company's expense once this request has been approved by the Chairman of the Board of Directors or of the Audit Committee or by the Chief Executive Officer, and subject to reporting back to the Board thereon.

14.3.1.3. Operating procedures

The Audit Committee meets whenever the Chairman of the Audit Committee or of the Board of Directors deems it useful to do so and at least two times per year, and particularly before the publication of the financial statements. The Audit Committee is convened by any means within a reasonable time frame before the meeting by the Chairman of the Audit Committee, the Chairman of the Board of Directors, the Chief Executive Officer or any person to whom one of the aforementioned has delegated the powers required to convene such a meeting.

The Audit Committee meets at the Company's registered office or in any other location stated in the meeting notice. It may also meet *via* videoconference or any other telecommunication means specified in Article 1.4 of the Company's Internal Regulations.

Meetings are chaired by the Chairman of the Audit Committee or, in his/her absence, by another member designated by the Audit Committee to chair the meeting.

An Audit Committee member may be represented by another Audit Committee member.

The Audit Committee can only validly deliberate if two-thirds of its members are present or represented.

The Chairman of the Audit Committee regularly reports to the Board of Directors on the Audit Committee's work and shall immediately inform it of any difficulties encountered.

The recommendations of the Audit Committee are adopted by simple majority; in the event of a tie, the Chairman of the Audit Committee has the casting vote.

Minutes of the meeting may be prepared at the end of each meeting, if the members consider it necessary. These are signed by the meeting chairman and at least one Audit Committee member.

The annual report must include an account of the Audit Committee's activities during the financial year just ended.

14.3.2. Compensation and Governance Committee

14.3.2.1. Composition

The Compensation and Governance Committee is composed of at least two members. Compensation and Governance Committee members are appointed by the Board of Directors among its members.

They are appointed for a fixed term that may not exceed, as applicable, their term of office on the Board of Directors and may be dismissed at any time and without cause by the Board of Directors. Their terms of office on the Compensation and Governance Committee are renewable without limitation. Executive corporate officers may also be appointed but executive corporate officers may not take part in any deliberations concerning them.

The Compensation and Governance Committee may invite any person, either internal or external to the Company, to participate in its meetings and its work.

The Chairman of the Compensation and Governance Committee is appointed by the Board of Directors, wherever possible from among the independent directors.

The members of the Compensation and Governance Committee receive no compensation other than that provided for by law. Their duties within the Compensation and Governance Committee may be taken into account in determining the distribution of said compensation.

At the date of approval of the Registration Document, the members of the Compensation and Governance Committee are:

- Truffle Capital, represented by Mr Philippe Pouletty (Chairman);

- Mr Patrick Coulombier.

14.3.2.2. Duties and responsibilities

The role of the Compensation and Governance Committee is to make recommendations to the Board of Directors regarding the appointment and compensation of corporate officers, chief operating officers and support function directors, as well as the appointments and internal compensation and profit-sharing policy. In particular, it must:

(a) make recommendations and proposals to the Board of Directors concerning the appointment, in particular in efforts to achieve greater gender diversity on the Board of Directors, the compensation policy, including in particular the pension and welfare plan, supplementary pension benefits, benefits in kind, various financial rights of the Company's executives and corporate officers, the allocation of bonus shares, warrants, share subscription or share purchase options, for the benefit of employees, executives, consultants or other employees of the Company and, where applicable, of its subsidiaries, in accordance with legal provisions;

(b) define the rules for setting the variable portion of the compensation of executive corporate officers and monitor the application thereof;

(c) propose a general policy for the allocation of bonus shares or performance shares, warrants, stock options or share purchase options and determine the frequency depending on the categories of beneficiaries and the performance conditions where applicable;

(d) examine the system for allocating compensation among the members of the Board of Directors, particularly depending on their participation in the Committees;

(e) provide its opinion to Executive Management on compensation of principal senior executives; and

(f) discuss the qualification of each independent director at the time of his/her appointment and then the performance of his/her office, if applicable.

In connection with their duties, Compensation and Governance Committee members have the same information rights as those described in section 1.6. of the Board of Directors' Internal Regulations.

14.3.2.3. Operating procedures

The Compensation and Governance Committee meets when the Chairman of the Compensation and Governance Committee or of the Board of Directors deems it useful and at least twice a year. The Compensation and Governance Committee may be convened by any means within a reasonable time frame before the meeting by the Chairman of the Compensation and Governance Committee or of the Board of Directors, or any person to whom one of the aforementioned has delegated the powers required to convene such a meeting.

The Compensation and Governance Committee meets at the Company's registered office or in any other location stated in the meeting notice. It may also meet *via* videoconference or any other telecommunication means specified in Article 1.4 of the Company's Internal Regulations.

Meetings are chaired by the Chairman of the Compensation and Governance Committee or, in his/her absence, by another member designated by the Compensation and Governance Committee to chair the meeting.

A member of the Compensation and Governance Committee may be represented by another member of the Compensation and Governance Committee.

The Compensation and Governance Committee can only validly deliberate if two-thirds of its members are present or represented.

The Chairman of the Compensation and Governance Committee regularly reports to the Board of Directors on the Compensation and Governance Committee's work and shall immediately inform it of any difficulties encountered.

The recommendations of the Compensation and Governance Committee are adopted by simple majority; in the event of a tie, the Chairman of the Compensation and Governance Committee has the casting vote.

Minutes of the meeting may be prepared at the end of each meeting, if the members consider it necessary. These are signed by the meeting chairman and at least one Compensation and Governance Committee member.

The Chairman of the Compensation and Governance Committee ensures that the reports of the Compensation and Governance Committee's activities made to the Board of Directors allow it to be fully informed, thereby facilitating its deliberations.

The annual report must include an account of the Compensation and Governance Committee's activities during the financial year just ended.

The Compensation and Governance Committee reviews the Company's draft report on executive compensation.

14.4. Observers

Article 12.6 of the bylaws provides that the Company has an Advisory Board composed of a maximum of five (5) observers who may be appointed by a decision of the Ordinary General Meeting or the Board of Directors for a period of three (3) years which ends at the end of the Ordinary General Meeting held to approve the financial statements for the previous financial year and held in the year in which their term of office expires.

Observers may be individuals or legal entities and may or may not be Company shareholders. When a legal entity is appointed as an observer, it shall perform its duties through its legal representative or a permanent representative that it designates for that purpose.

They may be dismissed by the Ordinary General Meeting or the Board of Directors at any time, at will, and without notice.

They are invited to attend all the meetings of the Company's Board of Directors in the same way the directors are invited. They have the same right to information as the directors.

They participate in the meetings of the Company's Board of Directors in an advisory capacity with no say in the decision-making process.

Observers shall be bound to confidentiality with respect the Board of Directors' decisions and other information received as part of their role.

Observers may receive compensation for their role, as determined by decision of the Board of Directors. In any event, observers may be reimbursed for reasonable expenses incurred as part of their assignment as members of the Board of Directors, subject to providing receipts.

As at the date of approval of the Registration Document, 4 observers were appointed (refer to section 12.1.2 of the Registration Document).

14.5. Statement related to corporate governance

As part of its development and with a view to the admission of its shares to trading on the Euronext Paris regulated market, the Company has undertaken a comprehensive review of the principles of corporate governance.

For the sake of transparency and public information, and in accordance with Article L. 22-10-10 of the French Commercial Code, the Company intends to comply, as from the admission of its shares to trading on the Euronext Paris regulated market, with the Middlenext Corporate Governance Code for listed companies as amended in September 2016 (insofar as the principles it contains will be compatible with the organisation, size, resources and shareholder structure of the Company).

The items listed in the following table are basic descriptions of the initiatives already taken by the Company in this regard or its commitments for the future. The table summarizes the Company's position on each of the recommendations set out in the Middlenext Corporate Governance Code:

Middlenext Code recommendation	Adopted	Will be adopted if applicable	Will not be adopted if applicable
Supervisory power			
R1. Board member ethics	X	--	--
R2. Conflicts of interest	X	--	--
R3. Composition of the Board – Presence of independent directors	X	--	--
R4. Board member information	X	--	--
R5. Organisation of the Board and committee meetings	X	--	--
R6. Establishment of committees	X	--	--
R7. Introduction of Board internal regulations	X	--	--
R8. Selection of each Board member	X	--	--
R9. Directors' terms of office	X	--	--
R10. Directors' compensation	X	--	--
R11. Establishment of an assessment of the Board's work	--	X[(1)]	--
R12. Relationswith "shareholders"	X	--	--
Executive power			
R13. Definition and transparency of executive corporate officers' compensation	X	--	--
R14. Preparation for executives' succession	--	X[(2)]	--
R15. Concurrent corporate offices and employment contracts	X	--	--
R16. Severance benefits	X	--	--
R17. Supplemental retirement plans	X	--	--

Middlenext Code recommendation	Adopted	Will be adopted if applicable	Will not be adopted if applicable
R18. Stock options and allocation of bonus share	X	--	--
R19. Review of the items for monitoring	X	--	--

(1) As part of the admission of the Company's shares to trading on the Euronext Paris regulated market, the Company plans to adopt this recommendation during the year and set up a procedure to periodically evaluate the Board's work in order to comply with best governance practices applicable to its status.

(2) As part of the admission of the Company's shares to trading on the Euronext Paris regulated market, the Company intends to prepare a succession plan for its executive officers as soon as possible.

15. EMPLOYEES

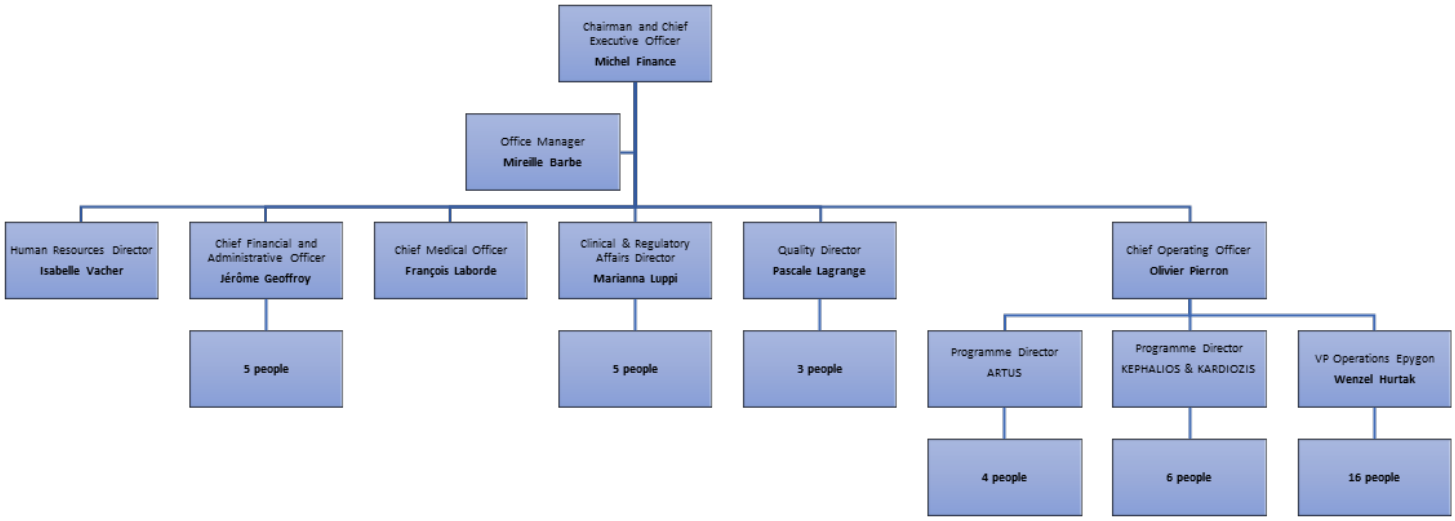
15.1. Number of employees and breakdown by function

The Group's workforce totalled 50 employees at the date of approval of the Registration Document.

As at 31 December 2018, 2019 and 2020, the Group's workforce was broken down as follows:

Workforce at year-end	2018	2019	2020
Affluent Medical *(Holding company)*	7	10	12
Epygon	0	1	1
Epygon Italie	18	16	17
Kardiozis	2	2	2
Kephalios	9	9	8
MyoPowers Medical Technologies France	2	5	6
Medev Europa	-	-	0
TOTAL	**38**	**43**	**46**

At the date of approval of the Registration Document, the Group's operational organisation chart is as follows:



The Company's key managers have extensive experience in their respective fields. These experiences are summarised in section 5.3.1. of the Registration Document.

15.2. Shareholdings and stock options of corporate officers and members of management

At the date of approval of the Registration Document, the direct and indirect shareholdings of the members of the Board of Directors and the members of management as well as the number of securities giving access to the Company's share capital are as follows:

Corporate officer/Executive	Undiluted capital			BSPCEs	BSAs	Diluted capital		
	Number of directly held shares	Number of shares held by associated companies	In %	Number of shares upon exercise of BSPCEs	Number of shares upon exercise of BSAs	Number of directly held shares	Number of shares held by associated companies	In %
Michel Finance *Chairman and Chief Executive Officer*	0	0	0%	588,675	0	588,675	0	3.13%
Patrick Coulombier *Director*	0	0	0%	36,168	0	36,168	0	0.19%
Daniel Hayoz *Director*	0	0	0%	123,300	0	123,300	0	0.65%
Truffle Capital *Director*	0	10,674,399	69.96%	0	0	0	10,674,399	56.69%
Dominique Carouge *Director*	0	0	0%	0	32,080	32,080	0	0.17%
TOTAL	**0**	10,674,399	69.96%	**748,143**	**32,080**	**780,223**	**10,674,399**	**60.81%**

15.3. Employees' shareholding in the Company

Certain employees (including the Group's founders) hold founders' share warrants (BSPCEs) which, as at the date of approval of the Registration Document, may give them a stake of 13.34% of the share capital of the Company on a fully diluted basis in the event of full exercise (refer to sections 19.1.4.1, 19.1.4.2 and 19.1.4.3).

15.4. Employee incentive plans and profit-sharing agreements

Not applicable.

16. MAJOR SHAREHOLDERS

16.1. Breakdown of capital and voting rights

The detailed table of the Company's shareholding structure at the date of approval of the Registration Document below breaks down the Company's share capital and voting rights on an undiluted basis and on a diluted basis after taking into account a double voting right as provided for in Article 11 of the Company's bylaws, which will be in force on the date the Company's shares are admitted to trading on the Euronext Paris regulated market.

Shareholders	Breakdown of capital and voting rights on an undiluted basis				Breakdown of capital and voting rights on a diluted basis[5]			
	Number of shares: [4]	% of share capital	Number of voting rights	% of voting rights	Number of shares	% of share capital	Number of voting rights	% of voting rights
Funds and companies managed by Truffle Capital[1]	10,674,399	69.96%	19,089,137	68.54%	10,674,399	56.69%	19,089,137	60.74%
Other financial investors[2]	3,987,831	26.14%	7,958,685	28.57%	3,987,831	21.18%	7,958,685	25.33%
Founders, executives and members of the Board of Directors, the Advisory Board and committees[3]	594,124	3.89%	804,124	2.89%	2,895,514	15.38%	3,105,514	9.88%
Employees	470	0.00%	940	0.00%	1,271,360	6.75%	1,271,830	4.05%
TOTAL	**15,256,824**	**100.00%**	**27,852,886**	**100.00%**	**18,829,104**	**100.00%**	**31,425,166**	**100.00%**

(1) The funds and companies managed by Truffle Capital are: FCPI Fortune III, FCPI Truffle Fortune 4, FCPI Truffle Fortune 5, FCPI Truffle Fortune 6, FCPI UFF Innovation n°12, FCPI UFF Innovation n°14, FCPI UFF Innovation n°15, FCPI UFF Innovation n°16, FCPI UFF Innovation n°17, FCPI Innocroissance 2015, FCPI Innocroissance 2016, FCPI Innocroissance 2018, FCPI Innocroissance 2019, FCPI Truffle Biomedtech Crossover Fund, FCPI Truffle Innov FRR France, Truffle ISF PME 201, Meningose and Corazan.

(2) The other financial investors are: Holding Incubatrice Serie I, Holding Incubatrice Serie II, MyoPowers Medical Technologies SA, Novartis Bioventures, MitralFlex, Fondation Hôpital Saint Joseph, Simone Merkle.

Holding Incubatrice Serie I holds 1,901,026 shares representing 12.46% of the share capital and 13.65% of the voting rights on an undiluted basis and 10.10% of the capital and 12.10% on a diluted basis.

Holding Incubatrice Serie II holds 795,000 shares representing 5.21% of the capital and 5.71% of the voting rights on an undiluted basis and 4.22% of the capital and 5.06% on a diluted basis.

(3) Note that this figure includes the 142,248 share subscription warrants (BSAs) and 1,989,363 founders' share warrants (BSPCEs) issued and allocated to the Company's founders, executives and members of the Board of Directors and committees (see sections 19.1.4.1. and 19.1.4.2. regarding the terms and conditions of the BSAs and BSPCEs issued and granted).

(4) Including category A preference shares, which will be automatically converted into ordinary shares on the basis of a ratio of 1:1 upon the admission of the Company's shares to trading on the Euronext Paris regulated market.

(5) Including the exercise of the 377,407 share subscription warrants (BSAs) and the 3,194,783 founders' share warrants (BSPCEs) (refer to sections 19.1.4.1., 19.1.4.2. and 19.1.4.3. for the terms and conditions of OCAs, BSAs and BSPCEs issued and granted).

The companies Holding Incubatrice Medical Devices and Holding Incubatrice Biotechnologie et Pharmacie were created and are given advice by Truffle Capital. It should be noted that no joint action has been taken between Holding Incubatrice Medical Devices, Holding Incubatrice Biotechnologie et Pharmacie and Truffle Capital and/or the funds managed by Truffle Capital.

Please refer to section 19.1.4. of the Registration Document for a detailed presentation of the conditions governing the exercise of securities giving access to the share capital and to section 19.1.7.1. of the Registration Document for a detailed presentation of changes in the share capital.

16.2. Major shareholders' voting rights

In accordance with Article 11 of the Company's bylaws, all fully paid-up shares (regardless their category) are entitled to double the voting rights granted to the other shares, in view of the proportion of the share capital they represent for which they have been registered for at least two years in the name of the same shareholder.

This right is also conferred upon their issuance in the event of a capital increase by incorporation of reserves, profits or issue premiums, to registered shares allocated free of charge to a shareholder at the rate of old shares for which he or she already benefits from this right.

16.3. Control of the Company

As at the date of approval of the Registration Document, on the basis of the Position-Recommendation No. 2021-02 "Guide for the preparation of universal registration documents – DOC 2021-02" published by the French Financial Markets Authority (*Autorité des Marchés Financiers* – AMF) on 8 January 2021 and for the purposes of this section of the Registration Document, it is specified here that the Company is controlled by entities (including mutual funds) managed by Truffle Capital, a French simplified joint stock company (*société par actions simplifiée*) with a share capital of €2 million, whose registered office is located at 5, rue de la Baume, 75008 Paris, registered in the Paris Trade and Companies Registry under number 432 942 647, approved by the AMF under number GP 01-029.

Collectively, those funds hold 10,674,399 shares representing 69.96% of the Company's capital and 68.54% of the voting rights on a non-diluted basis, and 10,674,399 shares representing 56.69% of the Company's capital and 60.74% voting rights on a fully diluted basis.

The measures taken by the Company to ensure that control is not exercised in an abusive manner include the presence of three independent directors on the Company's Board of Directors.

As of the date of approval of the Registration Document, there is a shareholders' agreement that will be automatically terminated on the date the Company's shares are admitted to trading on the Euronext Paris regulated market. To the Company's knowledge, there will be no concerted action between shareholders on the date on which the Company's shares are admitted to trading on the Euronext Paris regulated market and the termination of the shareholders' agreement.

16.4. Agreements that may result in a change in control

There are no particular items in the issuer's bylaws or internal regulations that could have the effect of delaying, deferring or preventing a change in control.

16.5. Pledges of the Company's shares

Not applicable.

17. RELATED-PARTY TRANSACTIONS

Related-party agreements existing to date are mentioned in the Statutory Auditors' special reports presented below.

17.1. Intra-group agreements and transactions with related parties

The Company has respectively entered into service agreements and management agreements with its subsidiaries Epygon, Kardiozis, Kephalios and MyoPowers authorised by the Boards of Directors of 9 April 2018 and 23 October 2018, the terms of which are set out in the Statutory Auditors' special reports on related-party agreements for the financial years ended on 31 December 2018, 2019 and 2020 as reproduced in section 17.2 below. The increase in amounts recorded between 2019 and 2020 is due to the increase in overheads of the Affluent Medical holding company, which re-invoices these costs to its subsidiaries Epygon, Kardiozis, Kephalios and MyoPowers, in particular as part of a reinforcement of the management teams and costs incurred to conduct clinical studies.

The Company entered into an employment contract with Mr Daniel Hayoz, director of Affluent Medical, on 9 April 2018, regarding his role as the Company's medical expert. Under the terms of his employment contract, Mr Daniel Hayoz receives a lump-sum compensation of €3,000 per year.

17.2. Statutory Auditors' special reports on related-party agreements for the financial years ended 31 December 2018, 2019 and 2020

17.2.1. Statutory Auditor's special report on related-party agreements for the financial year ended 31 December 2018[57]

Statutory Auditor's special report on related-party agreements

This is a translation into English of the special report of the statutory auditors on regulated agreements of the Company issued in French and it is provided solely for the convenience of English speaking users.

This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

(General Meeting to approve the financial statements for the year ended 31 December 2018)

Dear Shareholders
Affluent Medical
5, rue de la Baume
75008 Paris

In our capacity as Statutory Auditors of your company, we hereby present our report on related-party agreements.

It is our responsibility to inform you, based on the information provided to us, of the main terms and conditions as well as the reasons justifying the relevance for the company of the agreements which have

[57] It is stipulated that:
- Le Rancez is a consulting firm held and chaired by Mr Vincent Gardès, at that time, Chairman of the Board of Directors of Affluent Medical. The agreement signed had a renewable term of 12 months not renewable unless agreed by the parties. Invoicing was based on a flat rate per day worked with a minimum of 20 days, plus any costs and expenses incurred.
- ZDG Consulting is a consulting firm held and chaired by Mr José Da Gloria, at that time a director of Affluent Medical. The agreement signed for a term of three years included provision for invoicing based on a flat rate per day worked with no minimum number of days, plus any costs and expenses incurred.

been disclosed or which we may have identified as part of our engagement, without commenting on their relevance or substance or identifying other existing agreements. It is your responsibility, in accordance with Article R. 225-31 of the French Commercial Code, to assess the relevance of entering into these agreements for their approval.

In addition, it is our responsibility, where applicable, to provide you with the information required by Article R. 225-31 of the French Commercial Code relating to the implementations, during the financial year just ended, of agreements already approved by the General Meeting.

We performed the procedures we deemed necessary according to the professional doctrine of the *Compagnie nationale des commissaires aux comptes* for this mission. These procedures consisted in verifying the consistency of the information provided to us with the source documents from which such information has been extracted.

AGREEMENTS SUBMITTED FOR THE APPROVAL OF THE GENERAL MEETING

Agreements authorised and entered into during the past financial year
In accordance with Article L. 225-40 of the French Commercial Code, we have been informed of the following agreements entered into during the past financial year, which have already been approved by your Board of Directors.

1. Service agreement

- Company involved: Le Rancez
- Person concerned: Mr Vincent Gardès (member of the Board of Directors)
- Nature and purpose:
    - Consulting and assistance in the development of partnerships (in particular industrial partnerships for the purpose of signing license agreements for the products developed by the Group) in the United States and/or Europe;
    - Assistance provided in building relationships between the Company and potential investors in Europe or the United States;
    - Assisting the Company's management team in business development, particularly in Europe and/or the United States.
- Terms and conditions: expenses recognised during the year amounted to €50,000.

This agreement was authorised by the Board of Directors on 26 October 2018.

2. Consulting contract

- Company concerned: ZDG Consulting
- Person concerned: Mr José Da Gloria (member of the Board of Directors)
- Nature and purpose:
    - Support for the structuring of the Company (organisational chart; missions, etc.);
    - Strategic support for the Company (strategic plan, implementation of success tree, etc.);
    - Advisory work relating to relationships with banks and credit organisations;
    - Support in the context of financing activities and Company refinancing (IPO, ABB, secondary offering, debt, etc.).
- Terms and conditions: expenses recognised during the financial year amounted to €12,633.

This agreement was authorised by the Board of Directors on 23 October 2018.

3. Employment contract, medical expert

- Person involved: Mr Daniel Hayoz (director)
- Nature and purpose: employment contract between the Company and Mr Daniel Hayoz, director.
- Terms and conditions: compensation received during the financial year amounted to €1,615.

This agreement was authorised by the Board of Directors on 9 April 2018.

4. Service agreement

- Companies concerned: Kephalios, Kardiozis and Epygon
- Nature and purpose: the agreement provides for consulting and assistance services:
    - for financial matters and cash management;
    - for accounting, management control and human resources;
    - for matters relating to the supply chain, purchases and industrialisation;
    - relating to preclinical and clinical studies;
    - for matters relating to insurance, quality control and regulatory issues;
    - for marketing, promotion and communication;
    - for research and development.
- Terms and conditions: in exchange for these services, compensation will be equal to the amount (excluding tax) of the costs incurred, plus a margin equal to 5% of said expenses. The income recognised during the financial year amounted to €2,431,318.

This agreement was authorised by the Board of Directors on 9 April 2018.

5. Cash management agreement

- Companies concerned: Kephalios, Kardiozis and Epygon (Participating Companies)
- Nature and purpose: the Parties agree to pool their available cash resources under the management of Affluent Medical SA (Centralising Company), which will be responsible for coordinating all of the Group's cash requirements and surpluses, and thus optimise cash management for the entire Group, and as a result, reduce financial and banking fees, increase the financial resources of each Party and ensure fair compensation of cash surpluses.
- Terms and conditions: the sums made available to the Centralising Company by the Participating Companies are compensated at a rate of 0.5%, set on the first working day of each month. The sums made available to the Participating Companies by the Centralising Company are compensated at a rate of 0.5% within the limit of the maximum deductible amount approved by the French tax authorities.

This agreement was authorised by the Board of Directors on 23 October 2018.

Prepared in Neuilly-sur-Seine, 24 May 2019

The Statutory Auditor
PricewaterhouseCoopers Audit

Thierry Charron

17.2.2. Statutory Auditor's special report on related-party agreements for the financial year ended 31 December 2019[58]

Statutory Auditor's special report on related-party agreements

(General Meeting to approve the financial statements for the year ended 31 December 2019)

Dear Shareholders

Affluent Medical

Les Pléiades III – Bâtiment B – 320, avenue Archimède

13100 Aix-en-Provence (France)

In our capacity as Statutory Auditors of your company, we hereby present our report on related-party agreements.

It is our responsibility to inform you, based on the information provided to us, of the main terms and conditions as well as the reasons justifying the relevance for the company of the agreements which have been disclosed or which we may have identified as part of our engagement, without commenting on their relevance or substance or identifying other existing agreements. It is your responsibility, in accordance with Article R. 225-31 of the French Commercial Code, to assess the relevance of entering into these agreements for their approval.

In addition, it is our responsibility, where applicable, to provide you with the information required by Article R. 225-31 of the French Commercial Code relating to the implementations, during the financial year just ended, of agreements already approved by the General Meeting.

We performed the procedures we deemed necessary according to the professional doctrine of the *Compagnie nationale des commissaires aux comptes* for this mission. These procedures consisted in verifying the consistency of the information provided to us with the source documents from which such information has been extracted.

AGREEMENTS SUBMITTED FOR THE APPROVAL OF THE GENERAL MEETING

Agreements authorised and entered into during the financial year just ended

We hereby inform you that we have not been notified of any agreement that has been authorised and entered into during the financial year just ended requiring the approval of the General Meeting in accordance with the provisions of Article L. 225-38 of the French Commercial Code.

AGREEMENTS ALREADY APPROVED BY THE GENERAL MEETING

[58] It is stipulated that:

- Le Rancez is a consulting firm held and chaired by Mr Vincent Gardès, at that time, Chairman of the Board of Directors of Affluent Medical. The agreement signed had a renewable term of 12 months not renewable unless agreed by the parties. Invoicing was based on a flat rate per day worked with a minimum of 20 days, plus any costs and expenses incurred.
- ZDG Consulting is a consulting firm held and chaired by Mr José Da Gloria, at that time a director of Affluent Medical. The agreement signed for a term of three years included provision for invoicing based on a flat rate per day worked with no minimum number of days, plus any costs and expenses incurred.

Agreements approved during previous financial years the performance of which continued during the financial year just ended

In accordance with Article R. 225-30 of the French Commercial Code, we have been notified that the performance of the following agreements, already approved by the General Meeting during previous financial years, continued during the financial year just ended.

1. Service agreement

- Company involved: Le Rancez

- Person concerned: Mr Vincent Gardès (former member of the Board of Directors)

- Nature and purpose:

  - Consulting and assistance in the development of partnerships (in particular industrial partnerships for the purpose of signing license agreements for the products developed by the Group) in the United States and/or Europe;

  - Assistance provided in building relationships between the Company and potential investors in Europe or the United States;

  - Assisting the Company's management team in business development, particularly in Europe and/or the United States.

- Terms and conditions: no expense recognised in financial year 2019.

This agreement was authorised by the Board of Directors on 26 October 2018.

2. Consulting contract

- Company concerned: ZDG Consulting

- Person concerned: Mr José Da Gloria (member of the Board of Directors)

- Nature and purpose:

  - Support for the structuring of the Company (organisational chart; missions, etc.);
  - Strategic support for the Company (strategic plan, implementation of success tree, etc.);
  - Advisory work relating to relationships with banks and credit organisations;
  - Support in the context of financing activities and Company refinancing (IPO, ABB, secondary offering, debt. etc.).

- Terms and conditions: expenses recognised during the financial year amounted to €546.51.

This agreement was authorised by the Board of Directors on 23 October 2018.

3. Employment contract, medical expert

- Person involved: Mr Daniel Hayoz (director)

- Nature and purpose: employment contract between the Company and Mr Daniel Hayoz, director.

- Terms and conditions: compensation received during the financial year amounted to €3,000.

This agreement was authorised by the Board of Directors on 9 April 2018.

4. Service agreement

- Companies involved: Kephalios, Kardiozis, Myopowers Medical Techonologies France and Epygon (Participating Companies)

- Nature and purpose: the agreement provides for consulting and assistance services:

- for financial matters and cash management;
- for accounting, management control and human resources;
- for matters relating to the supply chain, purchases and industrialisation;
- relating to preclinical and clinical studies;
- for matters relating to insurance, quality control and regulatory issues;
- for marketing, promotion and communication;
- for research and development.

- Terms and conditions: in exchange for these services, compensation will be equal to the amount (excluding tax) of the costs incurred, plus a margin equal to 5% of said expenses. The income recognised during the financial year amounted to €2,797,692.

This agreement was authorised by the Board of Directors on 9 April 2018.

5. Cash management agreement

- Companies involved: Kephalios, Kardiozis, Myopowers Medical Techonologies France and Epygon (Participating Companies)

- Nature and purpose: the Parties agree to pool their available cash resources under the management of Affluent Medical SA (Centralising Company), which will be responsible for coordinating all of the Group's cash requirements and surpluses, and thus optimise cash management for the entire Group, and as a result, reduce financial and banking fees, increase the financial resources of each Party and ensure fair compensation of cash surpluses.

- Terms and conditions: the sums made available to the Centralising Company by the Participating Companies are compensated at a rate of 0.5%, set on the first working day of each month. The sums made available to the Participating Companies by the Centralising Company are compensated at a rate of 0.5% within the limit of the maximum deductible amount approved by the French tax authorities.

This agreement was authorised by the Board of Directors on 23 October 2018.

Prepared in Neuilly-sur-Seine,

The Statutory Auditor
PricewaterhouseCoopers Audit

Thierry Charron

17.2.3. Statutory Auditor's special report on related-party agreements for the financial year ended 31 December 2020[59]

PricewaterhouseCoopers Audit
63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

Expertea Audit
60, boulevard Jean Labro
13016 Marseille

Statutory Auditors' special report on related-party agreements

[59] It is stipulated that:
- ZDG Consulting is a consulting firm held and chaired by Mr José Da Gloria, at that time a director of Affluent Medical. The agreement signed for a term of three years included provision for invoicing based on a flat rate per day worked with no minimum number of days, plus any costs and expenses incurred.
- the increase in the amount of the agreement for services provided to Subsidiaries is explained by the increase in the structural costs of Affluent Medical, the Group’s holding company.
-

(General Meeting to approve the financial statements for the year ended 31 December 2020)

Dear Shareholders

Affluent Medical

Les Pléiades III – Bâtiment B

320, Avenue Archimède

13100 Aix-en-Provence (France)

In our capacity as Statutory Auditors of your company, we hereby present our report on related-party agreements.

It is our responsibility to inform you, based on the information provided to us, of the main terms and conditions as well as the reasons justifying the relevance for the company of the agreements which have been disclosed or which we may have identified as part of our engagement, without commenting on their relevance or substance or identifying other existing agreements. It is your responsibility, in accordance with Article R. 225-31 of the French Commercial Code, to assess the relevance of entering into these agreements for their approval.

In addition, it is our responsibility, where applicable, to provide you with the information required by Article R. 225-31 of the French Commercial Code relating to the implementations, during the financial year just ended, of agreements already approved by the General Meeting.

We performed the procedures we deemed necessary according to the professional doctrine of the *Compagnie nationale des commissaires aux comptes* for this mission. These procedures consisted in verifying the consistency of the information provided to us with the source documents from which such information has been extracted.

AGREEMENTS SUBMITTED FOR THE APPROVAL OF THE GENERAL MEETING

Agreements authorised and entered into during the financial year just ended

We hereby inform you that we have not been notified of any agreement that has been authorised and entered into during the financial year just ended requiring the approval of the General Meeting in accordance with the provisions of Article L. 225-38 of the French Commercial Code.

AGREEMENTS ALREADY APPROVED BY THE GENERAL MEETING

Agreements approved during previous financial years the performance of which continued during the financial year just ended

In accordance with Article R. 225-30 of the French Commercial Code, we have been notified that the performance of the following agreements, already approved by the General Meeting during previous financial years, continued during the financial year just ended.

1. Consulting contract

- Company concerned: ZDG Consulting

- Person concerned: Mr José Da Gloria (former member of the Board of Directors)

- Nature and purpose:

  - Support for the structuring of the Company (organisational chart; missions, etc.);

- Strategic support for the Company (strategic plan, implementation of success tree, etc.);
- Advisory work relating to relationships with banks and credit organisations;
- Support for financing activities and Company refinancing (IPO, ABB, secondary offering, debt. etc.).

- Terms and conditions: expenses recognised during the financial year amounted to €2,046.

Relevance for the company: benefit from the experience of ZDG Consulting, a company managed by Mr José da Gloria, in the field of strategic and financial development.

This agreement was authorised by the Board of Directors on 23 October 2018.

2. Employment contract, medical expert

- Person involved: Mr Daniel Hayoz (director)

- Nature and purpose: employment contract between the Company and Mr Daniel Hayoz, director.

- Terms and conditions: compensation received during the financial year amounted to €3,000.

This agreement was authorised by the Board of Directors on 9 April 2018.

3. Service agreement

- Companies involved: Kephalios, Kardiozis, Myopowers Medical Techonologies France and Epygon (Participating Companies)

- Nature and purpose: the agreement provides for consulting and assistance services:

- for financial matters and cash management;
- for accounting, management control and human resources;
- for matters relating to the supply chain, purchases and industrialisation;
- relating to preclinical and clinical studies;
- for matters relating to insurance, quality control and regulatory issues;
- for marketing, promotion and communication;
- for research and development.

- Terms and conditions: in exchange for these services, compensation will be equal to the amount (excluding tax) of the costs incurred, plus a margin equal to 5% of said expenses. The income recognised during the financial year amounted to €3,757,171.

This agreement was authorised by the Board of Directors on 9 April 2018.

4. Cash management agreement

- Companies involved: Kephalios, Kardiozis, Myopowers Medical Techonologies France and Epygon (Participating Companies)

- Nature and purpose: the Parties agree to pool their available cash resources under the management of Affluent Medical SA (Centralising Company), which will be responsible for coordinating all of the Group's cash requirements and surpluses, and thus optimise cash management for the entire Group, and as a result, reduce financial and banking fees, increase the financial resources of each Party and ensure fair compensation of cash surpluses.

- Terms and conditions: the sums made available to the Centralising Company by the Participating Companies are compensated at a rate of 0.5%, set on the first working day of each month. The sums made available to the Participating Companies by the Centralising Company are compensated at a rate of 0.5% within the limit of the maximum deductible amount approved by the French tax authorities.

This agreement was authorised by the Board of Directors on 23 October 2018.

Prepared at Neuilly-sur-Seine and Marseille, on 22 March 2021

The Statutory Auditors

PricewaterhouseCoopers Audit	Expertea Audit
Thierry Charron	Jérôme Magnan

18. FINANCIAL INFORMATION CONCERNING THE GROUP'S ASSETS, FINANCIAL POSITION AND RESULTS

18.1. Historical financial information

18.1.1. Consolidated historical financial information for the financial years ended 31 December 2018, 2019 and 2020

18.1.1.1. Historical financial information consolidated under IFRS for the financial years ended 31 December 2019 and 2020

Consolidated statement of financial position

Consolidated statement of financial position (in thousands of euros)	Notes	31/12/2020	31/12/2019	01/01/2019
ASSETS				
Goodwill	3	32,203	32,203	32,203
Other intangible assets	4.1	22,566	24,442	26,318
Property, plant and equipment (including right-of-use assets)	4.2	1,781	1,746	1,468
Investments accounted for using the equity method	5	14	414	1,580
Other non-current financial assets	6	351	331	140
Total non-current assets		**56,915**	**59,136**	**61,710**
Other current receivables	7	2,261	3,989	3,795
Cash and cash equivalents	8	5,650	2,126	3,339
Total current assets		**7,911**	**6,116**	**7,133**
Total assets		**64,826**	**65,252**	**68,843**
LIABILITIES AND EQUITY				
Equity				
Share capital	9	15,257	11,900	11,900
Premiums		62,683	47,701	47,646
Currency translation		21	24	-
Other items in comprehensive income		(22)	(20)	-
Reserves and earnings		(42,649)	(28,641)	(12,489)
Equity - attributable to shareholders of Affluent Medical		**35,289**	**30,964**	**47,058**
Non-controlling interests		-	-	-
Total shareholders' equity		**35,289**	**30,964**	**47,058**
Non-current financial liabilities	11	16,248	19,882	10,001
Non-current lease liabilities	11.4	731	811	597
Employee benefits obligations	12	117	86	45
Non-current provisions	13	228	103	-
Deferred tax liabilities	19	2,440	2,669	2,899
Derivative liabilities	11	-	995	713
Other non-current liabilities		9	234	525
Total non-current liabilities		**19,772**	**24,780**	**14,779**
Current financial liabilities	11	3,575	3,290	1,188
Current lease liabilities	11.4	226	202	119
Trade payables	14	2,352	3,704	3,703
Other current liabilities	14	2,261	2,043	1,854
Derivative liabilities	11	1,351	270	141
Total current liabilities		**9,765**	**9,508**	**7,006**

Total liabilities and equity	**64,826**	**65,252**	**68,843**

Consolidated income statement

Consolidated income statement (in thousands of euros)	Notes	31/12/2020 12 months	31/12/2019 12 months
Revenue		-	-
REVENUE		**-**	**-**
Other operating income	16	824	1,429
OPERATING EXPENSES			
Purchases consumed		(3,108)	(5,483)
External expenses	17.1	(3,563)	(3,899)
Personnel expenses	17.2	(4,694)	(3,607)
Taxes and duties		(67)	(34)
Provisions net of reversals		(125)	-
Other current operating income and expenses	17.3	46	14
Depreciation charge	4	(1,907)	(2,260)
CURRENT OPERATING INCOME		**(12,594)**	**(13,841)**
Other non-current operating income and expenses	18	-	-
OPERATING INCOME before share of net profit of associates and joint ventures accounted for using the equity method		**(12,594)**	**(13,841)**
Share of profit of associates and joint ventures accounted for using the equity method	5	(398)	(1,190)
OPERATING INCOME after share of net profit of associates and joint ventures accounted for using the equity method		**(12,992)**	**(15,031)**
Cost of net financial debt	19	(2,165)	(1,901)
Other financial income and expenses	19	32	1
Change in fair value of derivative liabilities	19	597	132
Pre-tax income		**(14,528)**	**(16,799)**
Income taxes	20	209	210
Net income (loss) for the period		**(14,319)**	**(16,589)**
Of which attributable to shareholders of Affluent Medical		(14,319)	(16,589)
Of which non-controlling interests		-	-

		31/12/2020	31/12/2019
Basic earnings per share (€/share)	21	**(1.07)**	**(1.39)**
Diluted earnings per share (€/share)	21	**(1.07)**	**(1.39)**

Consolidated statement of comprehensive income

Consolidated statement of comprehensive income (in thousands of euros)	31/12/2020 12 months	31/12/2019 12 months
Net income (loss) for the period	**(14,319)**	**(16,589)**
Actuarial gains and losses	(2)	(20)
Tax effect associated withthese items	-	-
Items that will not be reclassified to profit or loss	**(2)**	**(20)**
Currency translation adjustment	(3)	24
Items that may be reclassified to profit or loss	**(3)**	**24**
TOTAL Other comprehensive income (net of tax)	**(5)**	4
Consolidated statement of comprehensive income	**(14,324)**	**(16,585)**
Of which attributable to shareholders of Affluent Medical	*(14,324)*	*(16,585)*
Of which non-controlling interests	-	-

Change in consolidated equity

Change in consolidated equity	Note	*Capital Affluent Medical SA* *Number of shares*	Share capital	Premiums related to the share capital	Reserves and retained earnings	Currency translation	Other compre-hensive income	Equity - attributable to shareholders of Affluent Medical	Total non-controlling interests	Total share-holders' equity
			In thousands of euros							
As of 1 January 2019		*11,899,967*	**11,900**	**47,646**	**(12,489)**	**-**	**-**	**47,058**	**-**	**47,058**
Net income (loss) as of 31 December 2019			-	-	(16,589)	-	-	(16,589)	-	(16,589)
Other comprehensive income			-	-	-	24	(20)	4	-	4
Comprehensive income (loss)			**-**	**-**	**(16,589)**	**24**	**(20)**	**(16,585)**	**-**	**(16,585)**
Share-based compensation	10		-	-	437	-	-	437	-	437
Share subscription warrants (BSA)			-	55	-	-	-	55	-	55
As at 31 December 2019		*11,899,967*	**11,900**	**47,701**	**(28,641)**	**24**	**(20)**	**30,964**	**-**	**30,964**
Net income (loss) as at 31 December 2020			-	-	(14,319)	-	-	(14,319)	-	(14,319)
Other items in comprehensive income			-	-	-	(3)	(2)	(5)	-	(5)
Comprehensive income (loss)			**-**	**-**	**(14,319)**	**(3)**	**(2)**	**(14,324)**	**-**	**(14,324)**
Conversion of convertible bonds	11.3	*2,064,670*	2,065	8,652	(493)	-	-	10,224	-	10,224
Capital increase		*1,292,187*	1,292	6,319	-	-	-	7,611	-	7,611
Capital increase costs			-	-	(155)	-	-	(155)	-	(155)
Share-based compensation	10		-	-	959	-	-	959	-	959
Share subscription warrants (BSA)			-	11	-	-	-	11	-	11
As at 31 December 2020		*15,256,824*	**15,257**	**62,683**	**(42,649)**	**21**	**(22)**	**35,289**	**-**	**35,289**

Consolidated cash flow statement

Consolidated cash flow statement Amounts in thousands of euros	Notes	31/12/2020 12 months	31/12/2019 12 months
Cash flows from operating activities			
Net income (loss) for the period		**(14,319)**	**(16,589)**
Elimination of depreciation and amortisation of intangible and tangible assets, provisions and reversals of provisions	4, 13	2,465	2,384
Gains or losses on disposal of assets		-	3
Spreading of grants		(264)	(267)
Share-based payment expense		959	437
Interest expense, accrued interest, impact of amortised cost and accretion of advances		2,039	1,884
Change in fair value of derivatives	11.3	(597)	(132)
Share of profit of associates and joint ventures accounted for using the equity method	5	398	1,190
Income tax expense (including deferred taxes)	20	(209)	(210)
Gross cash flow before cost of net financial debt and taxes		**(9,528)**	**(11,302)**
(-) Change in working capital requirement		**613**	**(91)**
Including increase (decrease) in other non-current financial assets	6	(20)	(62)
Including increase (decrease) in other receivables	7	1,728	(194)
Including increase (decrease) in trade payables	14	(1,352)	(0)
Including increase (decrease) in tax and social security debts	14	240	251
Including increase (decrease) in other liabilities	14	17	(86)
Taxes paid		**(20)**	**(19)**
Cash flows from operating activities		**(8,936)**	**(11,412)**
Cash flows from investing activities			
Acquisitions of intangible assets	4.1	-	(3)
Acquisitions of property, plant and equipment	4.2	(304)	(196)
Sale price of assets sold		-	14
Cash flows from investing activities		**(304)**	**(185)**
Cash flows from financing activities			
Capital increase net of capital increase costs		7,456	-
Receipt of advances and conditional grants	11.1	2,755	3,659
Bank loans	11.2	2,140	-
Repayment of advances and innovation loans	11.1	-	-
Issue of bonds convertible into shares, net of fees	11.3	4,000	7,872
Reimbursements of convertible bonds		(1,952)	(516)
Gross financial interest paid		(715)	(775)
Other movements related to the pre-financing of the Research Tax Credit	11.5	(711)	276
Repayment of debt related to lease obligations	11.4	(222)	(184)
Share subscription warrants (BSA)		11	55
Cash flows from financing activities		**12,762**	**10,386**
Impact of exchange rate fluctuations			-
Increase (decrease) in cash		**3,522**	**(1,211)**
Opening cash and cash equivalents		2,126	3,336
Closing cash and cash equivalents		5,648	2,126
Increase (decrease) in cash		**3,522**	**(1,211)**

Cash and cash equivalents (including bank overdrafts)	**Notes**	**31/12/2020**	**31/12/2019**
Cash and cash equivalents	7	5,650	2,126
Bank overdrafts	7	(2)	(1)
Closing cash and cash equivalents (including bank overdrafts)		**5,648**	**2,126**

Notes to the consolidated financial statements

(Unless otherwise indicated, the amounts mentioned in these notes are in thousands of euros, except for data relating to shares. Some amounts may be rounded for the purpose of calculating the financial information contained in the consolidated financial statements. As a result, the totals in some tables may not correspond exactly to the sum of the previous figures.)

Note 1: Business and significant events

The information below constitutes the notes to the consolidated financial statements prepared in accordance with IFRS standards as of 31 December 2020 and 31 December 2019.

The consolidated financial statements of Affluent Medical SA were approved by the Board of Directors on 18 February 2021 and authorised for publication.

1.1 Information on the Group and its business

Affluent Medical is a French player in MedTech founded by Truffle Capital with the ambition of becoming a European leader in the treatment of heart and vascular diseases, which are the leading cause of death worldwide, and of urinary incontinence, which currently affects one in four adults.

Affluent Medical is developing innovative, next-generation minimally invasive implants to restore essential physiological functions in these areas. Affluent Medical's four medical devices are currently in the pre-clinical or clinical phase and the first medical device is expected to be marketed by 2022.

Head office address: 320, avenue Archimède – Les Pléiades III – Bâtiment B
13100 Aix-en-Provence, France
Trade and Companies Registry number: 837 722 560 RCS Aix-en-Provence.

Affluent Medical SA is hereinafter referred to as the "Company". The group formed by Affluent Medical SA and its subsidiaries is hereinafter referred to as the "Group".

1.2 Significant events of the financial years 2019 and 2020

During the 2020 financial year, the Company carried out several capital increases in cash:

- Issue of 390,490 A preferred shares for an amount of €2,300 thousand in May 2020 (€390 thousand in share capital and €1,910 thousand in issue premiums);
- Issue of 205,602 A preferred shares for €1,211 thousand in September 2020 (€206 thousand in share capital and €1,005 thousand in issue premiums);
- Issue of 696,095 preferred A preferred shares for an amount of €4,100 thousand in December 2020 (€696 thousand in share capital and €3,404 thousand in issue premiums).

The conversion of the convertible bonds ("**CB**") (Financing CB, 2018 CB and the first tranche of the 2019 CB) resulted in the issue of:

- 1,883,168 A preferred shares for €9,850 thousand in June 2020 (€1,883 thousand in share capital and €7,967 thousand in issue premiums);
- 181,502 A preferred shares for €867 thousand in September 2020 (€182 thousand in share capital and €685 thousand in issue premiums).

December 2020
The meeting of the Board of Directors of the Company held on 8 December 2020 decided to initiate an IPO on Euronext.

June 2020
Affluent Medical announced in June 2020 the launch of MINERVA, the first clinical trial of EPYGON in humans. Epygon is the first transcatheter mitral valve designed to restore physiological blood flow and treat left ventricular pathology, in particular in so-called "structural" patients.

On 19 June 2020, the 2018 convertible bonds (nominal value of €2,850 thousand), the 2018 Financing CB (nominal value of €3 million) and the first tranche of the 2019 CB (nominal value of €4 million) were converted (see Note 11.3 "*Loans and convertible bonds*").

April 2020

On 29 April 2020, the Company received from BPI France €1,759 thousand as part of the repayable advance for Project MIVANA (see Note 11.1.2 "*Project MIVANA repayable advance*").

On 8 April 2020, the Company entered into a contract with BPI France for a repayable advance of €1 million with a single payment and bearing interest at 1.14% for the "development of a disruptive medical device (adjustable mitral ring) to combat recurrent mitral insufficiency" (see Note 11.1.1 "*BPI Innovation loan*").

December 2019
Affluent Medical announced that it has implanted the first patient in the pivotal OPTIMISE II clinical study with Kalios, the minimally invasive adjustable mitral valve ring.
OPTIMISE II is a pivotal, prospective, non-randomised, single-arm, multi-centre, international study. It is planned to implant around 62 patients in a maximum of nine centers in four different countries in Europe (Italy, Austria, Germany and Switzerland).

On 10 December 2019, the Company signed a convertible bond loan agreement with Head Leader Limited, Truffle Biomedtech Crossover Fund and Truffle Innov FRR France enabling €8 million to be raised over a period of 60 months from the issue date, (see Note 11.3.4 "*Convertible Bond 2019*").
The Company was paid €4 million by the funds managed by Truffle Capital in December 2019. The payment of the €4 million from the Head Leader fund took place on 16 October 2020.

June 2019
Affluent Medical announced the strengthening of its management team. Michel Finance has been appointed Chief Executive Officer, Daniele Zanotti, Chief Technology Officer (formerly Chief Executive Officer), in charge of technological developments and programme execution, Professor François Laborde as Chief Medical Officer and Chief Scientific Officer, Marianna Luppi as Regulatory Affairs Director and Brian Burg as Cardiovascular Programmes Director.

This restructuring aims to:

- secure the large-scale manufacturing and production process for its devices;
- conduct and finalise clinical studies in Europe, the United States and China; and
- anticipate regulatory approvals and pre-marketing activities, with the intention of launching its first products in 2021.

March 2019
Under the PIAVE ARTUS repayable advance agreement, the Company received €3,659 thousand in March 2019 from BPI France (see Note 11.1 "*Repayable advances and innovation loan*").

February 2019
Affluent Medical announces positive results for its SCOPE 1 clinical trial validating the effectiveness of the KARDIOZIS technology. SCOPE 1 is a prospective, multi-centre, controlled, randomised clinical study evaluating the efficacy and clinical outcomes of the embolisation of the aneurysmal bag by thrombogenic fibres during conventional endovascular aneurysm repair (EVAR). The KARDIOZIS technology, validated by the

SCOPE 1 trial, could be integrated into endoprostheses already available on the market, *via* the establishment of strategic partnerships, but also into stents directly designed by AFFLUENT MEDICAL (currently in development).

Note 2: Accounting principles, rules and methods

2.1 Principles applied to the preparation of the financial statements

Declaration of conformity

The Group has prepared its consolidated financial statements for the years ended 31 December 2020 and 31 December 2019 in accordance with International Financial Reporting Standards, or IFRS, as published by the International Accounting Standards Board, or IASB, and adopted by the European Union. The term "IFRS" jointly means the international accounting standards (IAS and IFRS) and the interpretations of the Interpretations Committee (IFRS IC, and Standing Interpretations Committee, or SIC) of mandatory application for the year ended 31 December 2020.

These are the first consolidated financial statements of the Group prepared in accordance with IFRS 1 with a transition date of 1 January 2019.

The accounting principles and methods as well as the options adopted by the Company are described below.

Principles applied to the preparation of the financial statements

The Company's consolidated financial statements have been prepared in accordance with the historical cost convention, with the exception of certain categories of assets and liabilities in accordance with the provisions of IFRS. The categories concerned are mentioned in the following notes.

Going concern

The Company focuses on the invention and development of new medical devices. The Company's deficit position during the financial years presented is not unusual in relation to the stage of development of its products.

The Company has succeeded in financing its activities to date mainly through:

- successive capital increases;
- issue of convertible and non-convertible bonds;
- French Government guaranteed loans;
- repayable advances and subsidies;
- reimbursement of Research Tax Credit receivables.

On the closing date of these financial statements, the Board of Directors expects to continue to record losses in the medium-term and that its current resources will enable it to finance its activity until the end of May 2021 on the basis of the following:

- Consolidated net cash and cash equivalents as of 31 December 2020, which amounted to €5,650 thousand;
- The projected collection of the Research Tax Credit for the financial year 2020 for an amount of €509 thousand;
- Cash flow consumption forecasts by the Company for 2021;
- The setting up of a loan guaranteed by the State of €395 thousand in February 2021.

The Board of Directors has decided to adopt the following measures to ensure the financing of the Company beyond its liquidity horizon:

- Proposed Initial Public Offering of the Company's shares on Euronext Paris during the first half of 2021 (see Note 17 "*Operating expenses*");
- In the event that market conditions do not allow for the planned IPO, the Company could finance its future cash requirements through a combination of public or private capital increases, bank or bond financing, collaboration, licenses and development agreements or other forms of non-dilutive financing.

At the date of closing of the financial statements, the Board of Directors believes that it has reasonable assurance that it will find adequate financing. However, the Company cannot guarantee that it will succeed in obtaining it. The continuation of the business is therefore conditional on the success of the Company's planned IPO and the search for investors in the event that the IPO is postponed.

In this context, the going concern principle was adopted by the Board of Directors in view of the above data and assumptions and the measures implemented by management to ensure the Company's financing beyond May 2021.

If these measures are not successful, the Company may not be able to realise its assets and settle its debts in the normal course of its business (operating expenses, repayment of financial debts).

Accounting methods

For the preparation of its opening balance sheet, the Group complied with the provisions of IFRS 1 "First-time adoption of IFRS", which deals with the first-time adoption of international standards and exceptions to the principle of retrospective application of IFRS.

The transition date adopted by the Company is 1 January 2019.

IFRS 1 provides for exceptions to the retrospective application of IFRS at the date of transition; those used by the Company are as follows:

- With regard to IAS 19 "Employee Benefits", it was decided to recognise all cumulative actuarial gains and losses at the date of transition to IFRS;
- With respect to IFRS 16 "Leases", the Company has recognised its lease liabilities and right-of-use assets by applying the following approach to all leases:
    - Measurement of the lease liability at the date of transition to IFRS at the present value of the remaining lease payments, determined using its incremental borrowing rate at the date of transition to IFRS (see Note 19 "*Net financial income*");
    - Measurement of the asset recognised as a right-of-use asset at the date of transition to IFRS according to the amount of the lease liability, adjusted for the amount of rent paid in advance or payable that was recognised in the statement of financial position in respect of these leases immediately prior to the date of transition to IFRS;
- With respect to IFRS 3 "Business combinations", the Company has decided not to apply IFRS 3 retrospectively to business combinations that occurred before the date of transition to IFRS;
- The option to revalue property, plant and equipment at fair value was not taken at the date of transition.

The accounting methods described below have been applied consistently to all periods presented in the financial statements, after taking into account the new standards and interpretations described below:

- Amendments to the references to the Conceptual Framework in IFRS, published on 29 March 2018 by the IASB and approved by the European Union on 29 November 2019;
- Amendments to IAS 1 and IAS 8 "Modification of the definition of the term 'significant'", published on 31 October 2018 by the IASB and approved by the European Union on 29 November 2019;

- Amendments to IFRS 9, IAS 39 and IFRS 7 as part of the reform of benchmark interest rates, published on 26 September 2019 by the IASB and approved by the European Union on 15 January 2020;
- Amendments to IFRS 3 "Business Combinations" published on 22 October 2018 by the IASB and approved by the European Union on 21 April 2020.

These new texts adopted by the European Union had no significant impact on the Group's financial statements.

The standards, amendments and interpretations published by the IASB and not yet adopted by the European Union are as follows:

- Amendments to IAS 1 "Presentation of the financial statements: Classification of current and non-current liabilities" and "Classification of current and non-current liabilities – deferred from the effective date", published by the IASB on 23 January and 15 July 2020 respectively, the application of which is mandatory from 1 January 2023;
- Amendments to IFRS 3 "Business combinations", IAS 16 "Property, plant and equipment" and IAS 37 "Provisions, contingent liabilities and contingent assets", "Cycles of annual improvements to IFRS 2018-2020" published by the IASB on 14 May 2020, the application of which is mandatory from 1 January 2022;
- Amendments to IFRS 9, IAS 39, IFRS 4, IFRS 7 and IFRS 16 "Benchmark interest rate reform – Phase 2", published by the IASB on 27 August 2020, the application of which is mandatory from 1 January 2021.

The Company does not anticipate any significant impact of these standards, amendments and interpretations on its financial statements at the date of adoption.

2.2 Consolidation scope and methods

Scope

According to IFRS 10 "Consolidated financial statements", subsidiaries are all entities over which the Group has control. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement in the entity and has the ability to use its power over the entity to affect the amount of those returns.

Subsidiaries are fully consolidated from the date on which the Group obtains control. They are deconsolidated from the date the Group ceases to exercise control.

Entities controlled directly by the parent company and indirectly through other controlled entities are fully consolidated.

IFRS 11.16 "Partnership", defines joint ventures as a joint arrangement in which the partners that exercise joint control over the entity have rights to the net assets of the entity. Investments in joint ventures are accounted for using the equity method.

The scope of consolidation is as follows:

		31/12/2020			31/12/2019			01/01/2019		
	Country			Method			Method			Method
		% Group interest	% control		% holding	% control		% holding	% control	
Affluent Medical SA	France					Parent company				
Epygon SAS	France	100.00%	100.00%	FC	100.00%	100.00%	FC	100.00%	100.00%	FC
Kephalios SAS	France	100.00%	100.00%	FC	100.00%	100.00%	FC	100.00%	100.00%	FC
Kardiozis SAS	France	100.00%	100.00%	FC	100.00%	100.00%	FC	100.00%	100.00%	FC
MyoPowers Medical Technologies France	France	100.00%	100.00%	FC	100.00%	100.00%	FC	100.00%	100.00%	FC
Epygon Italie SRL	Italy	100.00%	100.00%	FC	100.00%	100.00%	FC	100.00%	100.00%	FC

MEDEV EUROPA SRL (1)	Romania	100.00%	100.00%	FC	N/A	N/A		N/A	N/A	
SHANGHAI EPYGON MEDICAL TECHNOLOGY	China	40.00%	40.00%	E	40.00%	40.00%	E	40.00%	40.00%	E
SHANGHAI MYOPOWERS MEDICAL TECHNOLOGY	China	40.00%	40.00%	E	40.00%	40.00%	E	40.00%	40.00%	E

(1) Company without operational activity created in 2020.
FC: Full consolidation
E: Equity method

2.3 Presentation currency

The Group's financial statements are prepared in euros (EUR).

2.4 Conversion method

2.4.1 Accounting for foreign currency transactions

Transactions in foreign currencies are initially recorded by the Group's entities in their respective functional currencies at the exchange rate prevailing on the date of initial recognition of the transaction.

Monetary assets and liabilities denominated in foreign currencies are translated into functional currency at the year-end closing exchange rate.

Differences resulting from the settlement or conversion of monetary items are recognised in profit or loss.

2.4.2 Translation of the financial statements of companies whose functional currency is not the Group's functional currency

The financial statements of companies whose functional currency is not the euro (EUR) are translated as follows:

- Elements in the statement of financial position are translated at the closing rate for the period;
- Income statement elements are translated at the average exchange rate for the period.

Foreign exchange differences resulting from conversion for consolidation purposes are recognised in the "Currency translation".

The exchange rates used for the preparation of the consolidated financial statements are as follows:

EXCHANGE RATE (for 1 EUR)	**31/12/2020**		**31/12/2019**		**01/01/2019**
	Average rate	Closing rate	Average rate	Closing rate	Rate of the day
Romanian Leu LEI/RON	4.8383	4.8683	N/A	N/A	N/A
Yuan Ren Min Bi - RMB	7.8747	8.0225	7.7355	7.8205	7.8751

2.5 Use of judgements and estimates

As part of the preparation of the financial statements in accordance with IFRS, the Group has made judgements and estimates that could affect the reported amounts of assets and liabilities at the date of preparation of the financial statements, and the reported amounts of income and expenses for the period.

These estimates are based on the going concern assumption by the Group's management and are prepared in accordance with information available at the time these judgements and estimates were made. These estimates

are assessed on an ongoing basis and are based on past experience and various other factors considered reasonable, which form the basis for assessing the carrying amount of assets and liabilities. The estimates may be revised due to changes in the underlying or as a result of new information. Actual results may differ significantly from these estimates in line with assumptions or different conditions.

The significant estimates or judgements made by the Group concern the following items:

- Determining the conditions for capitalising development costs:
  - Development costs are recognised as intangible assets when all six criteria provided for by IAS 38 are met,
  - The assumptions used are detailed in Note 4.1 "*Intangible assets*";

- The recoverable amount of the technologies developed internally and the estimated useful life of the technology (see Notes 4.1 "*Intangible assets*" and 4.3 "*Impairment of intangible assets and property, plant and equipment*");

- Allocation of share subscription warrants ("BSA") and founder share warrants ("BSPCE") granted to employees, executive directors and external service providers:
  - The determination of the fair value of share-based payments is based on the Black & Scholes option pricing model, which takes into account assumptions about complex and subjective variables. These variables include the value of the shares, the expected volatility of the value of the share over the life of the instrument and the current and future behaviour of the holders of these instruments,
  - The valuation assumptions adopted are set forth in Note 10 "*Share-based payments*";

- The recognition of deferred tax assets:
  - The determination of the amount of deferred tax assets that may be recognised requires management to make estimates both on the consumption period of the tax loss carryforwards, and on the level of future taxable incomes, with regard to tax management strategies, and
  - The accounting principles applied by the Company in terms of recognition of deferred tax assets are set forth in Note 20 "*Income tax"*;

- Determination of the recoverable amount of goodwill:
  - The value in use of the Company's CGUs is calculated using the discounted cash flow (DCF) method. The Company's management uses estimates to determine:
    - future cash flows over the period from 2021 to 2030,
    - the perpetual growth rate,
    - the discount rate.
  - The valuation assumptions adopted are described in Note 4.3 **"***Impairment of intangible assets and property, plant and equipment***"**;

- Determination of the fair value of convertible bonds (Financing CB and 2019 CB) and non-convertible bonds with equity warrants issued to Kreos Capital:
  - The determination of the fair value of derivative liabilities is based on the Black & Scholes option pricing model, which takes into account assumptions on unobservable data that are estimated by the Company. These variables include the value of the Company's securities and the expected volatility of the share price over the life of the instrument,
  - The valuation assumptions used are set forth in Note 11.3 "*Loans and convertible bonds*";

- Determination of the debt component and the equity component of convertible bonds (2018 CB):
    - The debt component is determined by discounting the contractual flows at the rate that would have been obtained for a similar debt without the conversion option. There is a high risk of subjectivity regarding the rate used. The "equity" component corresponds to the difference between the cash received and the value of the debt as determined above,
    - The assumptions used are presented in Note 11.3 "*Loans and convertible bonds*";

- Determining the variable portion of interest due on repayable advance contracts:
    - The repayable advances on the MIVANA and PIAVE projects include additional payments that depend on the success of the project and the level of revenue generated by the Company.
    - The assumptions used are set forth in Notes 11.1.2 "*Project MIVANA repayable advance*" and 11.1.3 "*Project PIAVE ARTUS repayable advance*".

2.6 Impact of the Covid-19 health crisis on the consolidated financial statements as of 31 December 2020

Activities were affected by Covid-19 in financial year 2020. In particular, the Company faced minor delays in its clinical study programmes due to the mobilisation of hospitals to contain the health crisis.

The Company has adapted its organisation and working methods by using teleworking and limiting travel.

During the first half of 2020, short-time working measures were implemented to minimise the impacts of these delays. As such, the Company received compensation for short-time working hours, which was deducted from personnel expenses (see Note 17.2 "*Personnel expenses*").

At the closing date of the financial statements, the Covid-19 epidemic had a limited impact on the Company's financial statements at 31 December 2020 and did not call into question the value of the fixed assets.

Note 3: Goodwill

On 27 March 2018, the Company benefited from the contribution of shares in EPYGON SAS, KARDIOZIS SAS, KEPHALIOS SAS and MYOPOWERS MEDICAL TECHNOLOGIES France.

The Company has decided not to apply IFRS 3 retrospectively to business combinations occurring before the IFRS transition date (see Note 2 "*Accounting principles, rules and methods*"). Accordingly, the allocation of the purchase price made in the previous framework has been maintained.

In particular, technologies developed internally were valued at a net €25,878 thousand (see Note 4.1 "*Intangible assets*").

The difference between the acquisition cost of the securities and the total measurement of the assets and liabilities identified at the acquisition date constitutes goodwill.

Goodwill is allocated to four CGUs, generally corresponding to a company:

Goodwill **(Amount in thousands of euros)**	**31/12/2020**	**31/12/2019**	**01/01/2019**
Epygon SAS	10,722	10,722	10,722
Kardiozis SAS	5,422	5,422	5,422
Kephalios SAS	8,698	8,698	8,698
MyoPowers Medical Technologies France	7,361	7,361	7,361
TOTAL	**32,203**	**32,203**	**32,203**

In accordance with IAS 36, the Company performs an annual impairment test on goodwill, the procedures for which are presented in Note 4.3 "*Impairment of intangible assets and property, plant and equipment*".

Note 4: Intangible assets and property, plant and equipment

4.1 Intangible assets

Accounting principles

Research and development costs

Research costs are systematically recognised as expenses.

According to IAS 38, development costs are recognised as intangible assets only if all of the following criteria are met:

a) It is technically feasible to complete the development of the project,
b) Company's intention to complete the project,
c) Its capacity to use the intangible asset,
d) Proof of the probability of future economic benefits associated with the asset,
e) Availability of technical, financial and other resources to complete the project, and
f) Reliable evaluation of development expenses.

Capitalised costs are directly attributable to the production of the asset, which include:

- The costs of services used or consumed to generate the intangible asset,
- Salaries and employee expenses incurred to generate the asset.

The initial measurement of the asset is the sum of expenses incurred starting on the date on which the development project meets the above criteria. Expenses cease to be capitalised when the intangible asset is ready for use. In accordance with industry practices, this end-of-development date is the same as the date on which regulatory registration (CE marking or FDA approval) is carried out. The portion of the Research Tax Credit relating to these expenses is recorded as a deduction from assets.
According to the Company's management, and due to the uncertainties inherent in the development of the Company's products, the criteria required for development costs to be recognised as an asset, as defined by IAS 38, "Intangible assets", are not met.

Patents and Software

Costs related to the acquisition of patents and software licences are capitalised on the basis of the costs incurred to acquire the patents and put the software into service.

Technologies developed in-house

Technologies developed internally were recognised for an amount of €25,878 thousand following the allocation of the acquisition price in a business combination prior to the date of transition to IFRS. The Company has decided not to retrospectively apply IFRS 3 (see Note 2 "*Accounting principles, rules and methods*").

These internally developed technologies were valued using the discounted cash flow method and are amortised over 15 years, which corresponds to the residual term of patent protection for the technologies concerned. Amortisation of these intangible assets is recognised in the income statement under "Depreciation and amortisation".

Other intangible assets

In accordance with the criteria of IAS 38, acquired intangible assets are recognised as assets at their acquisition cost.

Depreciation period and expense

When fixed assets have a finite useful life, depreciation is calculated on a straight-line basis in order to break down the cost over their estimated useful life, *i.e.*:

Items	Depreciation periods
Development costs	Estimated useful life of the project
Technologies	Estimated useful life of 15 years corresponding to the average residual patent protection period
Patents	Estimated useful life of patents
Software licences and development	1 to 5 years

Statement of changes in intangible assets

INTANGIBLE ASSETS (Amount in thousands of euros)	Patents and similar rights	Software and other intangible assets	Total
Gross value			
Statement of financial position at 1 January 2019	**28,509**	**159**	**28,668**
Acquisition	3	0	3
Disposal and reclassification	-	-	-
Statement of financial position as at 31 December 2019	**28,512**	**159**	**28,671**
Acquisition	-	-	-
Disposal and reclassification	-	-	-
Statement of financial position as at 31 December 2020	**28,512**	**159**	**28,671**
Amortisations			
Statement of financial position at 1 January 2019	**2,297**	**53**	**2,350**
Increase	1,852	27	1,879
Decrease	-	-	-
Statement of financial position as at 31 December 2019	**4,150**	**79**	**4,229**
Increase	1,849	27	1,876
Decrease	-	-	-
Statement of financial position as at 31 December 2020	**5,999**	**106**	**6,104**
NET BOOK VALUE			
Statement of financial position at 1 January 2019	**26,211**	**106**	**26,318**
Statement of financial position as at 31 December 2019	**24,362**	**80**	**24,442**
Statement of financial position as at 31 December 2020	**22,513**	**53**	**22,566**

Patents and similar rights consist of technologies developed in-house, details of which are given below:

INTERNALLY DEVELOPED TECHNOLOGIES (Amount in thousands of euros)	31/12/2020	31/12/2019	01/01/2019
Gross values			
EPYGON	9,786	9,786	9,786
KARDIOZIS	2,223	2,223	2,223
KEPHALIOS	8,207	8,207	8,207
MYOPOWERS	8,280	8,280	8,280
Total	**28,496**	**28,496**	**28,496**
Amortisations			
EPYGON	1,946	1,306	666
KARDIOZIS	427	281	134
KEPHALIOS	1,598	1,058	518
MYOPOWERS	2,018	1,498	977
Total	**5,990**	**4,143**	**2,296**
Net book value			
EPYGON	7,840	8,480	9,120
KARDIOZIS	1,796	1,942	2,089
KEPHALIOS	6,609	7,149	7,689
MYOPOWERS	6,262	6,782	7,302
Total	**22,507**	**24,354**	**26,201**

4.2 Property, plant and equipment

Accounting principles

Property, plant and equipment are valued at their acquisition cost. Fixed assets are depreciated over the actual useful life of the asset.

The depreciation periods and methods applied are as follows:

Items	Depreciation period
Furniture	10 years
IT equipment	3 years
Office equipment	5 to 10 years
Plant and equipment	5 to 10 years

Leases

Assets financed by leases in accordance with IFRS 16 relating to leases and which do not meet the criteria for exemptions (leases of "low value", less than $5 thousand and short-term leases less than 12 months) are recognised on the asset side of the balance sheet. The corresponding debt is recognised as a liability under "Financial debt".

The lease terms used by the Company reflect the non-cancellable terms of each contract, plus any extension or termination options that the Group is reasonably certain to exercise or not for all of the leases periods covered by the extension options. For leases of vehicles, laboratory equipment or IT, the term used is that of the contracts.

PROPERTY, PLANT AND EQUIPMENT (Amount in thousands of euros)	Buildings (right-of-use)	Plant and equipment	Plant and equipment (right-of-use)	IT equipment	IT equipment (right-of-use)	Other tangible assets	Office equipment (right-of-use)	Transport equipment (right-of-use)	Total	Of which rights-of-use
Gross value										
Statement of financial position at 1 January 2019	**801**	**870**	**-**	**73**	**-**	**64**	**-**	**-**	**1,807**	**801**
Acquisition	307	67	83	8	15	121	15	61	676	480
Disposal and reclassification	-	(12)	-	(3)	-	(4)	-	-	(19)	-
Statement of financial position as at 31 December 2019	**1,107**	**924**	**83**	**77**	**15**	**181**	**15**	**61**	**2,464**	**1,281**
Acquisition	112	231	11	7	-	66	-	44	471	167
Disposal and reclassification	-	-	-	-	-	-	-	-	-	-
Statement of financial position as at 31 December 2020	**1,219**	**1,155**	**94**	**84**	**15**	**247**	**15**	**105**	**2,934**	**1,448**
Amortisations										
Statement of financial position at 1 January 2019	**101**	**189**	**-**	**36**	**-**	**13**	**-**	**-**	**339**	**101**
Increase	174	152	5	17	3	16	3	12	382	197
Decrease	-	(1)	-	(0)	-	(1)	-	-	(3)	-
Statement of financial position as at 31 December 2019	**275**	**340**	**5**	**53**	**3**	**27**	**3**	**12**	**718**	**298**
Increase	180	173	18	13	5	19	3	25	435	231
Decrease	-	-	-	-	-	-	-	-	-	-
Statement of financial position as at 31 December 2020	**455**	**512**	**23**	**65**	**8**	**46**	**6**	**37**	**1,153**	**529**
Net book value										
Statement of financial position at 1 January 2019	**699**	**681**	**-**	**37**	**-**	**51**	**-**	**-**	**1,468**	**699**
Statement of financial position as at 31 December 2019	**832**	**584**	**78**	**25**	**13**	**154**	**12**	**49**	**1,746**	**983**
Statement of financial position as at 31 December 2020	**763**	**643**	**71**	**19**	**8**	**201**	**9**	**68**	**1,781**	**918**

Rights-of-use assets

Rights-of-use assets, recorded in accordance with IFRS 16 “Leases”, consist mainly of rights-of-use assets relating to the premises occupied by the Company in Paris, Aix-en-Provence, Besançon and Colleretto Giacosa (Italy); laboratory equipment; IT equipment and vehicles.

In financial year 2019, the Company entered into a new lease for its premises in Aix-en-Provence and leased laboratory equipment and transport vehicles.

In financial year 2020, the Company renewed the lease for its premises in Besançon and set up new vehicle leases.

4.3 Impairment of intangible assets and property, plant and equipment

Accounting principles

Impairment assets with an indefinite useful life are not amortised and are subject to an annual impairment test.

Fixed assets undergoing depreciation are tested for impairment whenever there is an internal or external indication that they may have suffered a loss in value.

Indices of technology impairment include:

- Mixed or negative results from pre-clinical and clinical trials;
- Delayed or non-compliance with the development schedule for medical devices;
- The delay in the date of first marketing;
- Any actions by third parties in opposition to the Company’s intellectual property;
- The arrival on the market of innovative competing technologies that could call into question the assumptions of projected market penetration rates or the conclusion of partnerships.

The impairment test consists of comparing the net book value of the asset tested with its recoverable amount.

The test is carried out at the level of the Cash Generating Unit (CGU), which is the smallest group of assets that includes the asset and whose continued use generates cash inflows largely independent of those generated by the cash generating unit of other assets or groups of assets.

An impairment loss is recorded in the amount of the excess of the carrying amount over the recoverable amount of the asset. The recoverable amount of an asset is its fair value less costs to sell or its value in use, whichever is greater.

Fair value less selling costs is the amount that can be obtained from the sale of an asset in an arm’s length transaction between knowledgeable and willing parties, less costs of exit.

Value in use is the present value of the expected future cash flows expected from the continued use of an asset and its disposal at the end of its useful life. Value in use is determined from estimated cash flows of plans or budgets established over ten years. Projections over a ten-year period are used in view of the long development cycles of the Company’s activities.

Flows beyond ten years are extrapolated by applying a constant growth rate, and discounted using long-term market rates after tax that reflect market estimates of the value of money over time and risks specific to the assets. Indeed, they require a series of research and development phases over several years, followed by the launch of products and a significant increase in revenues over several years until an expected level of penetration of the target market is reached.

The terminal value is determined from the perpetual discounting of the last cash flow of the test.

Annual impairment test of goodwill

The Group carried out annual impairment tests on goodwill (€32,203 thousand as at 31 December 2020, see Note 3 "*Goodwill*") at the end of the financial years presented.
For the purposes of goodwill impairment tests, the Group is divided into four CGUs or groups of CGUs, which generally correspond to one company.

The key assumptions used by the Company as at 31 December 2020 are based on:

- Estimates of the development cycle of clinical trials, dates of marketing of medical devices, market penetration or establishment of partnerships;
- Discount rates (WACC) applied to forecasts of around 12% for all CGUs;
- Perpetual growth rates of the operating normative flow beyond the ten-year projection of around 2%.

As of 31 December 2020, based on internal valuations, the Group concluded that the recoverable amount of the CGUs tested exceeded their carrying amount. The Group's management believes that any reasonable change in the key assumptions mentioned above would result in the recoverable amount of the CGUs being significantly lower than their carrying amount.

In particular:

- an increase in the discount rate of 100 basis points would not give rise to a risk of impairment;
- a decrease in long-term growth rates of 100 basis points would not give rise to a risk of impairment;
- a one-year delay in the market launch date and a decrease in revenue or market penetration estimates by 10% would not generate any risk of impairment.

Impairment test of assets subject to amortisation or depreciation

Depreciable fixed assets mainly comprise technologies developed in-house, for which the net book value as of 31 December 2020 amounts to €22,497 thousand (see Note 4.1 "*Intangible assets*").

Minor delays in the implementation of the Company's clinical programmes in 2020 due to the Covid-19 health crisis (see Note 2.6 "*Impact of the Covid-19 health crisis on the consolidated financial statements at 31 December 2020*") were not considered as an indication of impairment.

Note 5: Investments in companies accounted for under the equity method

Accounting principles

Under the equity method, the investment in a joint venture is initially recognised at acquisition cost and subsequently adjusted for the Group's share of profit or loss and other comprehensive income. Any dividends received are recorded as a reduction of the net book value of the investment.

Joint-venture contracts

On October 2017, Epygon and MyoPowers entered into joint-venture agreements with Shanghai Zuquan Investment Management Company Limited under the terms of which the parties agreed to form Shanghai Epygon Medical Technology Co., Ltd and Shanghai MyoPowers Medical Technology Co., Ltd (the "Joint Ventures"), for the purpose of researching, developing, manufacturing and marketing in China (including continental China, Hong Kong, Macao and Taiwan) of medical devices developed or being developed by the subsidiaries Epygon and MyoPowers respectively and which will be selected jointly by the parties.

In this context, the companies Epygon and Myopowers granted the Joint Ventures an exclusive licence for the development, registration, manufacture and marketing of the medical devices of the companies in Mainland China for the remaining term of protection of the patents until 26 April 2033 and 21 December 2032 respectively.

After the Chinese authorities obtained the official operating authorisation in 2018, the Company invested in the two Joint Ventures and holds 40% of the share capital.

Shanghai Zuquan Investment Management Company Limited holds 60% of the share capital and will assume the excess expenses beyond the capital payment without this leading to a reduction in the ownership of Epygon and MyoPowers in the Joint Ventures.

Following the analysis of the contractual provisions relating to the Joint Ventures, it was determined in accordance with IFRS 11 "Partnership", that the partners exercise joint control over the Joint Ventures. They are called joint ventures.

Data on joint ventures

VALUE OF EQUITY-ACCOUNTED SHARES (Amounts in thousands of euros)	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total equity accounted shares
Statement of financial position at 1 January 2019	**768**	**813**	**1,580**
Share of income of equity affiliates	(510)	(680)	(1,190)
Translation differences	11	13	24
Statement of financial position as at 31 December 2019	**269**	**146**	**414**
Share of income of equity affiliates	(253)	(145)	(398)
Translation differences	(2)	(1)	(3)
Statement of financial position as at 31 December 2020	**14**	**-**	**14**

The data relating to joint ventures are as follows:

DATA ON JOINT VENTURES (Amount in thousands of euros)	31/12/2020			31/12/2019		
	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total
Revenue	-	-	-	-	-	-
Operating income	(633)	(868)	**(1,501)**	(1,274)	(1,700)	**(2,975)**
Net income (loss)	(633)	(868)	**(1,501)**	(1,274)	(1,700)	**(2,975)**
Percentage held	**40.00%**	**40.00%**	**40.00%**	**40.00%**	**40.00%**	**40.00%**
Theoretical share of net income of equity affiliates	(253)	(347)	(601)	(510)	(680)	(1,190)
Share of net income of equity affiliates (1)	(253)	(145)	(398)	(510)	(680)	(1,190)

(1) The Company recognises the share of income from the Joint Ventures. Shanghai Epygon Medical Technology Co., Ltd, and Shanghai MyoPowers Medical Technology as follows:

- When the share of the investor in the losses of a joint venture exceeds the carrying amount, the Group ceases to recognise its share of subsequent losses;
- When the share is reduced to zero, additional losses are not subject to a provision;

- If the investee subsequently generates profits, the Group will only resume recognition of its share of the profits when this share is equal to or greater than its share of the net unrecognised losses.

The equity value was determined on the basis of the share of equity.

DATA ON JOINT VENTURES (Amount in thousands of euros)	31/12/2020			31/12/2019			01/01/2019		
	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total
ASSETS									
Non-current assets	**2**	**1**	**343**	**6**	**3**	**9**	**12**	**11**	**23**
Inventories	-	-	**-**	-	-	**-**	-	-	**-**
Receivables	-	-	**-**	-	-	**-**	-	-	**-**
Other current receivables	1	1	**160**	1	2	**3**	3	4	**7**
Cash and cash equivalents	258	176	**434**	672	364	**1,036**	1,919	2,032	**3,951**
Total current assets	**259**	**177**	**594**	**673**	**366**	**1,038**	**1,922**	**2,035**	**3,958**
Total assets	**261**	**178**	**937**	**679**	**368**	**1,047**	**1,934**	**2,046**	**3,981**
LIABILITIES AND EQUITY									
Equity	**34**	**(498)**	**34**	**672**	**364**	**1,036**	**1,919**	**2,032**	**3,951**
Non-current liabilities	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Current liabilities	**227**	**676**	**903**	**7**	**4**	**11**	**15**	**15**	**30**
Total liabilities and equity	**261**	**178**	**937**	**679**	**368**	**1,047**	**1,934**	**2,046**	**3,981**
Theoretical equity value of the Group in shareholders' equity	**14**	**(199)**	**(186)**	**269**	**146**	**414**	**768**	**813**	**1,580**
Equity value retained by the Group in shareholders' equity	**14**	**-**	**14**	**269**	**146**	**414**	**768**	**813**	**1,580**

Note 6: Financial assets

Accounting principles

As at 31 December 2019 and 31 December 2020, the Company's financial assets are classified into two categories according to their nature and intention to hold them, in accordance with IFRS 9:

- Financial assets at fair value through profit or loss; and
- Financial assets at amortised cost.

All financial assets are initially recognised at fair value plus acquisition costs. All purchases and sales of financial assets are recognised on the settlement date.

Financial assets cease to be recognised in the statement of financial position when the rights to receive cash flows from these assets expire or when they have been sold and the Company has transferred substantially all the risks and rewards of ownership.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss consist of cash and cash equivalents at 31 December 2019 and 31 December 2020.

Profits or losses arising from changes in the value of financial assets at fair value through profit or loss are presented in the "Financial result" in the income statement for the period in which they occur.
Other assets may also be voluntarily classified in this category.

Financial assets at amortised cost

Financial assets at amortised cost mainly include non-current financial assets, other loans and receivables, and trade receivables. They are measured at amortised cost using the effective interest rate method, adjusted for expected credit losses.

Impairment of financial assets at amortised cost

A financial asset is impaired using the expected loss method, taking into account defaults during the asset's holding period. The amount of expected losses is recorded in the statement of financial position. The impairment is recognised in the consolidated income statement.

Financial assets with a maturity of more than one year are classified as "non-current financial assets".

Other non-current financial assets

OTHER NON-CURRENT FINANCIAL ASSETS (Amount in thousands of euros)	KREOS security deposits	RTC pre-financing guarantee holdback	Other deposits and guarantees	TOTAL
Statement of financial position at 1 January 2019	**128**	**-**	**12**	**140**
Increases	128	17	45	190
Decreases	-	-	-	-
Statement of financial position as at 31 December 2019	**256**	**17**	**58**	**331**
Increases	-	-	25	25
Decreases	-	-	(5)	(5)
Statement of financial as at 31 December 2020	**256**	**17**	**78**	**351**

Security deposits were made when the non-convertible bonds were set up with KREOS Capital. They amounted to €128 thousand as at 1 January 2019 and at €256 thousand as at 31 December 2019 and 2020 (see Note 11.3.1 "*KREOS non-convertible bond*").

Note 7: Other receivables

Accounting principles

Research Tax Credit (RTC)

Research tax credits are granted by the French State to the Group's French companies to encourage them to carry out technical and scientific research. Companies that justify expenses that meet the required criteria are entitled to a tax credit that can be used to pay the corporate income tax due for the year in which the expenses were incurred and for the three following years, or, if necessary, be reimbursed for the excess portion.

In the absence of taxable income and given the status of community SME of the beneficiary companies, the receivable from the French State relating to the RTC is repayable in the year following that of its recognition.

The Research Tax Credit is recognised as a receivable for the period corresponding to the financial year in which the eligible expenses that gave rise to the tax credit were incurred.
The Research Tax Credit granted by the French State is a public subsidy, since the said credit is received independently of the Company's tax payments.

The Company recognises this receivable in "Other current receivables", given the expected repayment period. Research tax credits are presented in the consolidated income statement under "Other operating income". The Research Tax Credit may be audited by the French tax authorities.

Other receivables

Receivables are valued at their nominal value.

Other receivables include the nominal value of the Research Tax Credit, which is recorded when the eligible expenses giving rise to the research tax credit have been incurred.

Breakdown of other current receivables

OTHER RECEIVABLES (Amounts in thousands of euros)	31/12/2020	31/12/2019	01/01/2019
Research Tax Credit	509	2,109	1,951
Value added tax	1,038	1,324	1,157
Prepaid expenses (1)	175	295	349
Advances and payments on account	115	96	4
Miscellaneous	425	166	334
Total other current receivables	**2,261**	**3,989**	**3,795**

(1) Prepaid expenses are related to the Group's day-to-day business and mainly concern fees.

As at 31 December 2019, the Company had RTC receivables for an amount of €2,109 thousand.

In the course of the financial year 2020, RTC receivables evolved as follows:

- Inflows, for a total of €1,959 thousand; recognition of new RTC receivables of €509 thousand ;

Adjustment of €150 thousand.
As at 31 December 2020, the Company had RTC receivables for an amount of €509 thousand. These receivables correspond to the RTC for the financial year 2020 only.

As of 31 December 2019, a portion of the receivables related to the 2018 RTC and the 2019 RTC were pre-financed by FONDS COMMUN DE TITRISATION PREDIREC INNOVATION 2020, with NEFTYS CONSEIL as arranger. As a result, the Company recognised the following items:

- A debt, for the amount payable to NEFTYS upon receipt of the RTC;
- A security deposit for the amount of deductions made by NEFTYS on the receivables sold; and
- A current asset, for the amount of the receivable due by the French State.

In accordance with IFRS 9, the amount of debt owed to NEFTYS was calculated using the amortised cost method for each year:

- 2018 RTC: €164 thousand
- 2019 RTC: €505 thousand

The debt was paid during the financial year 2020.

Note 8: Cash and cash equivalents

Accounting principles

Cash and cash equivalents recognised in the statement of financial position include cash at bank and in hand, and term deposits with an original maturity of less than three months.

For the purposes of the cash flow statement, net cash includes cash and cash equivalents as defined above.

Breakdown of cash and cash equivalents for the periods presented

CASH AND CASH EQUIVALENTS (Amounts in thousands of euros)	31/12/2020	31/12/2019	01/01/2019
Bank accounts	5,650	2,126	3,339
Cash equivalents	-	-	-
Total cash and cash equivalents	**5,650**	**2,126**	**3,339**

Note 9: Capital

Composition of share capital

COMPOSITION OF SHARE CAPITAL	31/12/2020	31/12/2019	01/01/2019
Capital (in thousands of euros)	15,257	11,900	11,900
Number of shares	15,256,824	11,899,967	11,899,967
of which ordinary shares	4,049,422	4,049,422	4,049,422
of which Preferred A shares	11,207,402	7,850,545	7,850,545
Nominal value (in euros)	€1.00	€1.00	€1.00

The number of Company shares does not include share subscription warrants (BSA) or founder share warrants (BSPCE) granted to employees, managers, directors and external service providers and not yet exercised.

Change in share capital

During the 2020 financial year, the Company carried out several capital increases in cash:

- Issue of 390,490 A preferred shares for €2,300 thousand in June 2020 (€390 thousand in share capital and €1,910 thousand in issue premiums)
- Issue of 205,602 A preferred shares for €1,211 thousand in October 2020 (€206 thousand in share capital and €1,005 thousand in issue premiums)
- Issue of 696,095 A preferred shares for €4,100 thousand in December 2020 (€696 thousand in share capital and €3,404 thousand in issue premiums)

On 19 June 2020, the 2018 convertible bonds (nominal value of €2,850 thousand), the 2018 Financing CBs (nominal value of €3 million) and the first tranche of the 2019 CBs (nominal value of €4 million) were converted as well as accrued interest. These conversions resulted in the creation of 2,064,670 A preferred shares.

A Preferred shares

The main terms and conditions of A preferred shares are as follows:

- Pre-emptive distribution right in the event of a distribution of any kind whatsoever and right of preferential distribution of the sale price, enabling their holders to receive the subscription price of the Contributed A Shares or of the A Shares issued subsequent to the Contribution they hold;
- Right of permanent representation on the Board of Directors;
- Right to convene meetings of the Board of Directors;
- Specific law relating to quorum and majority rules for the Board of Directors;

- Enhanced right to information and right to audit.

As part of the Company's initial public offering, A preferred shares will be automatically converted into ordinary shares when the Company's securities are admitted on the stock market.

Capital management policy

The Group's policy is to maintain a sufficient financial base to preserve the confidence of investors and creditors and to support the future growth of the company. In this context, the Company continually arranges financing through the raising of additional funds, the issuing of bonds or financial debt.

Issue fees

Ancillary costs directly attributable to the issuing of shares or stock options are recognised, net of tax, as a deduction from equity.

Dividends

The Company did not pay any dividends during the years presented.

Note10: Share-based payments

Accounting principles

In accordance with IFRS 2, the cost of transactions settled in equity instruments is recognised as an expense in the period in which the rights to benefit from equity instruments are acquired, in exchange for an increase in equity.
The Group has applied IFRS 2 to all equity instruments granted to employees, members of the Board of Directors and external service providers such as consultants.
The fair value of stock options granted to employees is determined by applying the Black & Scholes option pricing model. The same applies to options granted to other natural persons providing similar services, insofar as the market value of the latter cannot be determined.
The evaluation methods used to estimate the fair value of the options are described below:

- The share price used is equal to the stock market price or the subscription price of investors or by reference to internal valuations;
- The risk-free rate is determined according to the expected term of the instruments;
- Volatility was determined on the basis of a sample of listed companies in the biotechnology sector, at the date of subscription of the instruments and over a period equivalent to the life of the option.
- The expected term for the instruments was estimated at six years.

10.1. Share subscription warrants (*Bons de souscription d'actions*, or BSA)

The following table summarises the information about the plans issued as well as the assumptions used for the valuation under IFRS 2:

		Characteristics of the plans			***Assumptions***			
Type	**Date of grant**	**Number of warrants granted**	**Contractual expiry date**	**Strike price**	***Expected term***	***Volatility***	***Risk-free rate***	**Initial total IFRS 2 valuation (in thousands of euros) (Black&Scholes)**

BSA 2018-1	09/04/2018	1,644	10 years	€5.00	6 years	34.36%	0.07%	**2**
BSA 2018-2	09/04/2018	131,520	10 years	€5.00	6 years	34.36%	0.07%	**169**
BSA 2018-4	23/10/2018	65,760	10 years	€6.10	6 years	35.08%	0.01%	**106**
BSA 2018-5	23/10/2018	65,000	10 years	€6.10	6 years	35.08%	0.01%	**105**
BSA 2020-1	08/07/2020	32,080	10 years	€5.89	6 years	39.94%	-0.60%	**58**

The plan **BSA2018-3** does not exist.
The plan **BSA 2018-1** does not include a vesting period: all warrants are exercisable as soon as they are allocated.
The plan **BSA 2018-2** has a vesting period of 48 months: one quarter after twelve months of their allocation then one forty-eighth over the following 36 months.
The plan **BSA 2018-4** has a vesting period of 48 months: one quarter after twelve months of their allocation then one forty-eighth over the following 36 months.
The plan **BSA 2018-5** includes a vesting period subject to performance conditions linked to the achievement of specific milestones in the development of the clinical trials to be measured for 30% as of 30 September 2019, for 20% as of 31 December 2020 and for 50% as of 31 December 2021.
The plan **BSA 2020-1** has a vesting period of 48 months: one quarter after twelve months of their allocation then one forty-eighth over the following 36 months.

Change in outstanding warrants

Number of outstanding options						
Type	**Date of grant**	**01/01/2019**	**Issued**	**Exercised**	**Lapsed**	**31/12/2019**
BSA 2018-1	09/04/2018	1,644	-	-	-	1,644
BSA 2018-2	09/04/2018	131,520	-	-	-	131,520
BSA 2018-4	23/10/2018	65,760	-	-	-	65,760
BSA 2018-5	23/10/2018	65,000	-	-	(19,500)	45,500
TOTAL		**263,924**	**-**	**-**	**(19,500)**	**244,424**

Number of outstanding options						
Type	Date of grant	31/12/2019	Issued	Exercised	Lapsed	31/12/2020
BSA 2018-1	09/04/2018	1,644	-	-	-	1,644
BSA 2018-2	09/04/2018	131,520	-	-	(79,851)	51,669
BSA 2018-4	23/10/2018	65,760	-	-	-	65,760
BSA 2018-5	23/10/2018	45,500	-	-	(13,000)	32,500
BSA 2020-1	08/07/2020	-	32,080	-	-	32,080
TOTAL		**244,424**	**32,080**	**-**	**(92,851)**	**183,653**

10.2 Founders' Share Warrants (*Bons de souscription de parts de créateur d'entreprise*, or BSPCE)

The following table summarises the information about the plans issued as well as the assumptions used for the valuation under IFRS 2:

		Characteristics of the plans			***Assumptions***			
Type	**Date of grant**	**Number of warrants granted**	**Contractual expiry date**	**Strike price**	***Expected term***	***Volatility***	***Risk-free rate***	**Initial total IFRS 2 valuation (in thousands of**

								euros) (Black&Scholes)
BSPCE 2018-1	09/04/2018	1,339,866	10 years	€5.00	6 years	34.36%	0.07%	2,195
BSPCE 2018-2	09/04/2018	961,741	10 years	€5.00	6 years	34.36%	0.07%	1,576
BSPCE 2018-3	09/04/2018	1,159,025	10 years	€5.00	6 years	34.36%	0.07%	1,899
BSPCE 2018-4	23/10/2018	16,440	10 years	€6.10	6 years	35.08%	0.01%	33
BSPCE 2018-5	23/10/2018	16,440	10 years	€6.10	6 years	35.08%	0.01%	33
BSPCE 2019-1	10/07/2019	150,000	10 years	€6.10	6 years	35.63%	-0.54%	299
BSPCE 2019-2	10/07/2019	300,600	10 years	€6.10	6 years	35.63%	-0.54%	599
BSPCE 2019-3	01/10/2019	200,400	10 years	€6.10	6 years	35.92%	-0.70%	399
BSPCE 2020-2	07/12/2020	226,300	10 years	€5.89	6 years	38.69%	-0.73%	467
BSPCE 2020-3	07/12/2020	75,000	10 years	€5.89	6 years	38.69%	-0.73%	155
BSPCE 2020-4	07/12/2020	134,935	10 years	€5.89	6 years	38.69%	-0.73%	279
BSPCE 2020-5	07/12/2020	75,000	10 years	€5.89	6 years	38.69%	-0.73%	155

There is no **issue of BSPCE 2020-1**.

The plan **BSPCE 2018-1** has no vesting period: all share warrants are exercisable as soon as they are allocated.
The plan **BSPCE 2018-2** has a vesting period of 48 months: one quarter after twelve months of their allocation then one forty-eighth over the following 36 months.
The plan **BSPCE 2018-3** has a vesting period subject to performance conditions linked to the achievement of specific milestones in the development of clinical trials and the implementation of significant partnership agreements, of which 53.19% as of 30 September 2019, 18.44% as of 31 December 2019 and 28.37% as of 31 December 2021.
The plan **BSPCE 2018-4** has a vesting period of 48 months: one quarter after twelve months of their allocation then one forty eighth over the following 36 months.
The plan **BSPCE 2018-5** has a vesting date of 30 September 2019, subject to a performance condition linked to the achievement of specific milestones in the development of clinical trials.
The plan **BSPCE 2019-1** has a vesting period for 50% of the warrants spread over 48 months: one quarter after 12 months of their allocation then one forty-eighth over the following 36 months and for 50% subject to performance conditions linked to the achievement of specific milestones in the development of clinical trials, of which 16.67% as of 31 December 2019, and 16.67% as of 31 December 2020, 16.67% as of 30 June 2021 and 50% as of 31 December 2021.
The plan **BSPCE 2019-2** has a vesting period extending from 31 December 2020 to 31 December 2021, subject to a performance condition linked to the achievement of specific milestones in the development of clinical trials, the implementation of significant partnership agreements and funding.
The plan **BSPCE 2019-3** has a vesting period of 36 months: one third after twelve months of their allocation then one thirty-sixth over the following 24 months.
The plan **BSPCE 2020-2** has a vesting period of 48 months: one quarter after twelve months of their allocation then one forty-eighth over the following 36 months.
The plan **BSPCE 2020-3** has a vesting period subject to performance conditions of which 50% as of 31 December 2021 related to the implementation of financing agreements and 50% as of 31 December 2023 related to the change in share price.
The plan **BSPCE 2020-4** has a vesting period subject to performance conditions, of which 64.98% as of 31 December 2021 are related to the implementation of financing agreements, and 26.46% as of 31 December 2022 are related to the achievement of specific milestones in the development of clinical trials, and 8.57% as of 30 June 2022 related to the achievement of specific milestones in the development of clinical trials.
The plan **BSPCE 2020-5** has a vesting period subject to performance conditions linked to the achievement of specific milestones in the development of clinical trials and the establishment of financing arrangements, of which 40% as of 31 December 2021, 40% as of 30 June 2022 and 20% as of 31 December 2022.

Change in outstanding options

Number of outstanding options						
Type	**Date of grant**	**01/01/2019**	**Issued**	**Exercised**	**Lapsed**	**31/12/2019**
BSPCE 2018-1	09/04/2018	1,339,866	-	-	-	1,339,866
BSPCE 2018-2	09/04/2018	961,741	-	-	(32,880)	928,861
BSPCE 2018-3	09/04/2018	1,159,025	-	-	(799,398)	359,627
BSPCE 2018-4	23/10/2018	16,440	-	-	(16,440)	-
BSPCE 2018-5	23/10/2018	16,440	-	-	(16,440)	-
BSPCE 2019-1	10/07/2019	-	150,000	-	(12,500)	137,500
BSPCE 2019-2	10/07/2019	-	300,600	-	-	300,600
BSPCE 2019-3	01/10/2019	-	200,400	-	-	200,400
TOTAL		**3,493,512**	**651,000**		**(877,658)**	**3,266,854**

Number of outstanding options						
Type	**Date of grant**	**31/12/2019**	**Issued**	**Exercised**	**Lapsed**	**31/12/2020**
BSPCE 2018-1	09/04/2018	1,339,866	-	-	-	1,339,866
BSPCE 2018-2	09/04/2018	928,861	-	-	(90,426)	838,435
BSPCE 2018-3	09/04/2018	359,627	-	-	-	359,627
BSPCE 2019-1	10/07/2019	137,500	-	-	-	137,500
BSPCE 2019-2	10/07/2019	300,600	-	-	-	300,600
BSPCE 2019-3	01/10/2019	200,400	-	-	-	200,400
BSPCE 2020-2	07/12/2020	-	226,300	-	-	226,300
BSPCE 2020-3	07/12/2020	-	75,000	-	-	75,000
BSPCE 2020-4	07/12/2020	-	134,935	-	-	134,935
BSPCE 2020-5	07/12/2020	-	75,000	-	-	75,000
Total		**3,266,854**	**511,235**	**-**	**(90,426)**	**3,687,663**

10.3 Expenses recognised in accordance with IFRS 2 during the periods presented

The Company recorded an expense relating to share-based compensation of €959 thousand as at 31 December 2020 and €437 thousand as at 31 December 2019.

The cumulative expense amounts to €4,951 thousand as at 31 December 2020, €3,993 thousand as at 31 December 2019 and €3,556 thousand as at 1 January 2019.

Note 11: Loans and financial liabilities

Accounting principles

Unless otherwise indicated, borrowings and financial liabilities are measured at amortised cost calculated using the effective interest rate method in accordance with IFRS 9.

The portion of borrowings at less than one year is presented under “Current financial liabilities”.

CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amounts in thousands of euros)	31/12/2020	31/12/2019	01/01/2019
Repayable advances and innovation loan	9,489	6,052	2,021
State guaranteed loans	2,155	-	-
Bonds	4,593	13,782	7,862
Other loans and liabilities	9	48	118
Non-current financial liabilities	**16,248**	**19,882**	**10,001**
Non-current lease liabilities	731	811	597
Non-current derivative liabilities	-	995	713
Total non-current financial liabilities	**16,978**	**21,687**	**11,311**
Repayable advances and innovation loan	-	-	-
State guaranteed loans	-	-	-
Pre-financing of Research Tax Credit receivables	-	669	354
Bonds	3,573	2,621	815
Other loans and liabilities	0	-	17
Bank overdrafts	2	1	2
Current financial liabilities	**3,575**	**3,290**	**1,188**
Current lease liabilities	226	202	119
Current derivative liabilities	1,351	270	141
Total current financial liabilities	**5,152**	**3,762**	**1,448**
Total financial liabilities	**22,131**	**25,449**	**12,759**

Redemption value/balance sheet value reconciliation

(amounts in thousands of euros)	Redemption value		Conversion option recognised under equity	Separation of derivatives Liabilities	Loan issuance fees	Amortised cost	Carrying amount at 31/12/2019
	01/01/2019	31/12/2019					
Lease liabilities	716	1,013	-	-	-	-	1,013
Repayable advances and innovation loan	2,010	6,032	-	-	-	20	6,052
Pre-financing of the RTC	360	669	-	-	-	-	669
KREOS bond	4,000	7,484	-	(285)	(186)	248	7,262
FINANCING CBs bond loan	3,124	3,304	-	(732)	-	158	2,730
2018 CB bond	2,981	3,152	(519)	-	-	164	2,797
2019 CB bond	-	4,009	-	(399)	-	4	3,614
Derivative liabilities	854	1,264	-	-	-	-	1,264
Other loans and liabilities	135	48	-	-	-	-	48
Bank overdrafts	2	1	-	-	-	-	1
Total financial liabilities	**14,182**	**26,976**	**(519)**	**(1,415)**	**(186)**	**594**	**25,449**

(amounts in thousands of euros)	Redemption value		Conversion option recognised under equity	Separation of derivatives liabilities	Accrued interest	Amortised cost	Carrying amount at 31/12/2020
	31/12/2019	31/12/2020					
Lease liabilities	1,013	957	-	-	-	-	957

Repayable advances	6,032	9,532	-	-	-	(42)	9,489
State guaranteed loans	-	2,140	-	-	15	-	2,155
Pre-financing of the RTC	669	-	-	-	-	-	-
KREOS bond	7,484	5,532	-	-	-	(49)	5,483
FINANCING CBs bond loan	3,304	-	-	-	-	-	-
2018 CB bond	3,152	-	-	-	-	-	-
2019 CB bond	4,009	4,034	-	(1,364)	-	14	(2,684)
Derivative liabilities	1,264	1,351	-	-	-	-	1,351
Other loans and liabilities	48	10	-	-	-	-	10
Bank overdrafts	1	2	-	-	-	-	2
Total financial liabilities	**26,976**	**23,556**	**-**	**(1,364)**	**15**	**(77)**	**22,131**

Statement of changes in financial debt

CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amounts in thousands of euros)	01/01/2019	Collec-tion	Repayment	Impact of amorti-sed cost	New financial liability for rights-of-use	Other changes related to pre-financing of the RTC	Grant	Security deposit	Fair value	Accrued interest	Conver-sion	Transfers between non-current and current liabilities	31/12/2019
Non-current lease liabilities	597	-	-	-	416	-	-	-	-	-	-	(202)	**811**
Repayable advances	2,021	3,659	-		-	-	-	-	-	372	-	-	**6,052**
Bond	7,862	4,000	-	424	-	-	-	-	-	360	-	1,136	**13,782**
Derivative liabilities	713	-	-	-	-	-	-	-	282	-	-	-	**995**
Other loans and liabilities	118	-	-	-	-	-	-	-	-	(70)	-	-	**48**
Non-current financial liabilities	**11,311**	**7,659**	**-**	**424**	**416**	**-**	**-**	**-**	**282**	**662**	**-**	**934**	**21,687**
Current lease liabilities	119	-	(184)	-	65	-	-	-	-	-	-	202	**202**
Pre-financing of the RTC	354	-	-	39	-	276	-	-	-	-	-	-	**669**
Bond	815	3,872	(516)	-	-	-	-	128	(543)	-	-	(1,136)	**2,621**
Derivative liabilities	141	-	-	-	-	-	-	-	129	-	-	-	**270**
Other loans and liabilities	17	-	-	-	-	-	-	-	-	(17)	-	-	**-**
Bank overdrafts	2	-	(1)	-	-	-	-	-	-	-	-	-	**1**
Current financial liabilities	**1,448**	**3,872**	**(701)**	**39**	**65**	**276**	**-**	**128**	**(413)**	**(17)**	**-**	**(934)**	**3,762**
Total financial liabilities	**12,759**	**11,531**	**(701)**	**463**	**480**	**276**	**-**	**128**	**(132)**	**645**	**-**	**-**	**25,449**

CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amount in thousands of euros)	31/12/2019	Collec-tion	Repayment	Impact of amorti-sed cost	New financial liability for rights-of-use	Other changes related to pre-financing of the RTC	Grant	Derivati-ves extinguish-ment	Fair value	Accrued interest	Conver-sion	Transfers between non-current and current liabilities	31/12/2020
Non-current lease liabilities	**811**	-	-	-	146	-	-	-	-	-	-	(226)	**731**
Repayable advances and innovation loan	**6,052**	2,755	-	13	-	-	(90)	-	-	758	-	-	**9,489**
State guaranteed loans	**-**	2,140	-	-	-	-	-	-	-	15	-	-	**2,155**
Bond	**13,782**	-	-	324	-	-	-	-	-	251	(9,543)	(221)	**4,593**
Derivative liabilities	**995**	-	-	-	-	-	-	(680)	767	-	(680)	(1,081)	**-**
Other loans and liabilities	**48**	-	-	-	-	-	-	-	-	(38)	-	-	**9**
Non-current financial liabilities	**21,687**	**4,895**	**-**	**337**	**146**	**-**	**(90)**	**(680)**	**767**	**987**	**(10,223)**	**(1,529)**	**16,978**
Current lease liabilities	**202**	-	(222)	-	20	-	-	-	-	-	-	226	**226**
Pre-financing of the RTC	**669**	-	-	42	-	(711)	-	-	-	-	-	-	**-**
Bond loan	**2,621**	4,000	(1,952)	14	-	-	-	-	(1,364)	34	(4,088)	221	**3,573**
Derivative liabilities	**270**	-	-	-	-	-	-	-	-	-	-	1,081	**1,351**
Other loans and liabilities	**-**	-	-	-	-	-	-	-	-	-	-	-	**-**
Bank overdrafts	**1**	1	-	-	-	-	-	-	-	-	-	-	**2**
Current financial liabilities	**3,762**	**4,001**	**(2,174)**	**57**	**20**	**(711)**	**-**	**-**	**(1,364)**	**34**	**-**	**1,529**	**5,152**
Total financial liabilities	**25,449**	**8,896**	**(2,174)**	**394**	**167**	**(711)**	**(90)**	**(680)**	**(597)**	**1,020**	**(10,223)**	**-**	**22,130**

11.1 Repayable advances and innovation loan

Accounting principles

The Group obtains a certain amount of public aid in the form of subsidy, repayable advances or an innovation loan.
They have been accounted for in accordance with IAS 20. As these are financial advances and loans granted at interest rates below the market rate, these advances and loans are valued in accordance with IFRS 9 at amortised cost:

- The interest rate benefit is determined by using a discount rate corresponding to a market rate at the grant date. The amount resulting from the interest rate advantage obtained (incremental debt ratio) upon the granting of repayable advances or non-interest bearing loans is considered as a subsidy recorded as income in the statement of comprehensive income.
- The financial cost of repayable advances or loans calculated at the market rate is then recorded in financial expenses.

Subsidies corresponding to the interest rate benefit are presented in other operating income. These advances are recorded in "Non-current financial liabilities" and "Current financial liabilities" according to their maturity.

In the event of a pronounced failure, the debt waiver granted is recorded as a subsidy. No failure was recognised by the company during the periods presented.

Repayable advances that do not benefit from an interest rate advantage are recognised at amortised cost.

Change in repayable advances and the innovation loan

CHANGE IN REPAYABLE ADVANCES AND THE INNOVATION LOAN (Amounts in thousands of euros)	BPI Innovation AFFLUENT MEDICAL	Project MIVANA - EPYGON	Project MIVANA - KEPHALIOS	Project PIAVE ARTUS - MYOPOWERS	Total
At 1 January 2019	**-**	**1,541**	**480**	**-**	**2,021**
(+) Collection	-	-	-	3,659	3,659
(-) Repayment	-	-	-	-	-
Accrued interest	-	216	74	81	372
As at 31 December 2019	**-**	**1,757**	**555**	**3,740**	**6,052**
(+) Collection	996	1,200	559	-	2,755
(-) Repayment	-	-	-	-	-
Accrued interest	-	360	145	254	758
Grants	(90)	-	-	-	(90)
Financial expenses	13	-	-	-	13
As at 31 December 2020	**919**	**3,317**	**1,259**	**3,994**	**9,489**

Breakdown of repayable advances and innovation loans by maturity, in redemption value

MATURITIES OF REIMBURSABLE ADVANCES AND INNOVATION LOANS, IN REDEMPTION VALUE (Amounts in thousands of euros)	BPI innovation AFFLUENT MEDICAL	Project MIVANA - EPYGON	Project MIVANA - KEPHALIOS	Project PIAVE ARTUS - MYOPOWERS	Total
As at 31 December 2020	**1,000**	**3,288**	**1,259**	**3,985**	**9,532**
Share at less than one year	-	-	-	-	**-**
Share between one and five years	900	2,319	892	3,659	**7,770**
Share at more than five years	100	969	367	326	**1,762**

11.1.1 BPI Innovation loan

On 8 April 2020, the Company entered into a contract with BPI France for a loan of €1 million with a single payment and bearing interest at 1.14% for the "development of a disruptive medical device (adjustable mitral ring) to combat recurrent mitral insufficiency".

The Company received a total of €1 million and met the conditions for the success of this project.

Following the success of the project, the repayment schedule is as follows: €50 thousand per quarter from 30 September 2022 to 30 June 2027 (20 payments).

Under IFRS, the loan bears a lower annual interest rate than the market, which means that the Company has benefited from a loan at a more favourable rate than market conditions. The difference between the amount of the loan at historical cost and the amount of the loan discounted at the marginal borrowing rate (3.10%) is considered as a subsidy received from the French government.

11.1.2 Project MIVANA repayable advance

On 28 September 2015, the companies KEPHALIOS and EPYGON, in partnership with the entities MDB TEXINOV and IFTH (French Institute of Textile and Clothing) entered into a contract with BPI France for:

- repayable advances of a maximum amount of €5,458 thousand (including €4,512 thousand for AFFLUENT MEDICAL Group companies) with payments in several instalments depending on the achievement of a "key milestone" and not bearing interest for the "development of innovative medical devices and techniques derived from the textile industry for the creation of a national cardiovascular sector";
- subsidies of a maximum of €3,122 thousand (including €1,957 thousand for AFFLUENT MEDICAL Group companies).

The aid granted by Bpifrance consist of subsidies and repayable advances.

Contract between EPYGON and Bpifrance
EPYGON received a total of €2,319 thousand in connection with this contract and met the conditions for success of key stages 1, 2 and 3, out of a total of 4 key stages.

Following the success of the key steps 1, 2 and 3, the repayment schedule is as follows:

- €500 thousand at 30 June 2022 (1 payment);
- €800 thousand at 30 June 2023 (1 payment);
- €1,100 thousand at 30 June 2024 (1 payment);
- €1,350 thousand at 30 June 2025 (1 payment).

The contract between Bpifrance and EPYGON provides for the payment of an additional payment once the company has repaid all the advances received. The Company undertakes, for a period of 5 (five) consecutive years after the date of termination of said repayment and once it has reached a cumulative amount of revenue excluding tax equal to or greater than €20,000,000 (twenty million euros), to pay 2% (two percent) of the annual revenue generated by the exploitation of the products developed thanks to the project.

- The amount of additional payments is capped at the sum of €6,000,000 (six million euros);
- The total period including fixed sum repayments and additional amounts is limited to 15 (fifteen) years.

As of 31 December 2020, based on EPYGON's revenue forecasts, the Company has made an estimate of the additional payments. The debt was recognised at amortised cost by recognising €969 thousand of accrued interest.

Contract between KEPHALIOS and Bpifrance

KEPHALIOS received a total of €892 thousand in connection with this contract and met the conditions for success of key stages 1, 2 and 3, out of a total of 4 key stages.

Following the success of the key steps 1, 2 and 3, the repayment schedule is as follows:

- €100 thousand at 30 June 2022 (1 payment);
- €250 thousand at 30 June 2023 (1 payment);
- €350 thousand at 30 June 2024 (1 payment);
- €450 thousand at 30 June 2025 (1 payment).

In addition to the provisional fixed repayment schedule, KEPHALIOS must pay an annual payment equal to:

- 30% (thirty percent) of the proceeds, excluding taxes, of the concession of intellectual property rights resulting from the project, received during the previous calendar year,
- 30% (thirty percent) of the proceeds generated by the sale of intellectual property rights arising from the project, as well as from the sale of prototypes, pre-series and models produced as part of the project.

The sums due to Bpifrance under the terms of this paragraph will be deducted as a priority and in accordance with the final instalment and, as appropriate, the preceding instalments.

The contract concluded between Bpifrance and KEPHALIOS provides for the payment of an additional payment once the company has repaid in full the advances received. The company undertakes, for a period of 5 (five) consecutive years after the date of termination of said repayment and once it has reached a cumulative amount of revenue excluding tax equal to or greater than €10,000,000 (ten million euros), to pay 2% (two percent) of the annual revenue generated by the exploitation of the products developed thanks to the project.

- The amount of additional payments is capped at the sum of €3,000,000 (three million euros).
- The total period including fixed sum repayments and additional amounts is limited to 15 (fifteen) years.

As of 31 December 2020, based on KEPHALIOS revenue forecasts, the Company has made an estimate of the additional payments. The debt was recognised at amortised cost by recognising accrued interest of €367 thousand.

11.1.3 Project PIAVE ARTUS repayable advance

On 21 July 2016, MYOPOWERS entered into a contract with Bpifrance for a repayable advance of a maximum amount of €7,796 thousand with payments in several tranches depending on the achievement of a "key milestone" and not bearing interest for the "development of an artificial urinary sphincter for the treatment of severe stress urinary incontinence".

The aid granted by Bpifrance breaks down into a subsidy for €201 thousand and a repayable advance for €7,796 thousand.

The Company received a total of €3,659 thousand in connection with this contract and met the conditions for success of key stage 1.

The repayment schedule is as follows: €2,055 thousand per year from 1 September 2023 to 1 September 2026 (four instalments).

As part of the implementation of the Project PIAVE ARTUS repayable advance, the Company will have to pay, in addition to the projected fixed repayment schedule, if applicable, an annual payment equal to:

- 45% (forty-five percent) of the proceeds, excluding taxes, of the concession of intellectual property rights resulting from the project, received during the previous calendar year,

- 45% (forty-five percent) of the proceeds generated by the sale of intellectual property rights arising from the project, as well as from the sale of prototypes, pre-series and models produced as part of the project.

The sums due to Bpifrance under the terms of this paragraph will be deducted as a priority and in accordance with the final instalment and, as appropriate, the preceding instalments.

The contract entered into between Bpifrance and MYOPOWERS provides for the payment of an additional payment once the Company has repaid in full the advances received. The Company undertakes, for a period of 4 (four) consecutive years after the date of termination of said repayment and once it has reached a cumulative amount of revenue excluding tax equal to or greater than €20,000,000 (twenty million euros), to pay 1% (one percent) of the annual revenue generated by the exploitation of the products developed thanks to the project.

- The amount of additional payments is capped at the sum of €4,000,000 (four million euros).
- The total period including fixed sum repayments and additional amounts is limited to 15 (fifteen) years.

As at 31 December 2020, based on revenue forecasts, the Company has made an estimate of the additional payments. The debt was recognised at amortised cost by recognising €326 thousand of accrued interest.

11.2 French Government Guarantee Loan (PGE loan)

Accounting principles

The Group benefits from French Government guaranteed loans (*Prêts Garantis par l'Etat*, or PGE).
These loans were initially recorded at fair value, which corresponds to the cash received, and subsequently recognised using the amortised cost method.
The effective interest rate was determined on the basis of the best estimate of the expected repayment date taking into account the extension option that the company intends to exercise.
During the year 2020, the Group took out four PGE to strengthen its cash position in the current context of the Covid-19 pandemic.
As of 31 December 2020, the PGE were classified as non-current financial liabilities.

Change in French Government Guarantee Loan

CHANGE IN PGE (Amounts in thousands of euros)	BNP Paribas State guaranteed loan Affluent Medical	Société Générale State guaranteed loan			Total
		Epygon	Kardiozis	Kephalios	
As at 31 December 2019	**-**	**-**	**-**	**-**	
(+) Collection	1,000	90	160	890	2,140
(-) Repayments	-	-	-	-	-
(+/-) Accrued interest	8	1	1	6	15
Financial expenses	-	-	-	-	-
As at 31 December 2020	**1,008**	**91**	**161**	**896**	**2,155**

Breakdown of PGE by maturity, in repayment value

MATURITIES OF PGE, IN REPAYMENT VALUE (Amounts in thousands of euros)	BNP Paribas State guaranteed loan	Société Générale State guaranteed loan			Total
	Affluent Medical	Epygon	Kardiozis	Kephalios	
As at 31 December 2020	**1,000**	**90**	**160**	**890**	**2,140**
Share at less than one year	-	-	-	-	**-**
Share between one and five years	915	79	48	870	**1,911**
Share at more than five years	85	11	112	20	**229**

11.2.1 French Government Guarantee Loan: BNP Paribas

On 6 April 2020, AFFLUENT MEDICAL contracted a loan guaranteed by the French Government with optional amortisation over five years, with BNP Paribas, under the following conditions:

- Amount of the financing: €1 million
- Term: 12 months
- Annual interest rate: 0%
- Repayment: an annual payment of the principal and interest in arrears after a deferred period of 12 months.

This loan benefits from a Government guarantee, under the "FDG Etat Coronavirus" guarantee fund, of up to 90%.

In February 2021, the Company negotiated an additional amortisation period of 12 months which will be followed by repayment over four years. The applicable annual interest rate is 1% with a guarantee cost of €21 thousand.

11.2.2 French Government Guarantee Loan: Société Générale

On 5 June 2020, EPYGON contracted a loan guaranteed by the French Government with optional amortisation over five years, with Société Générale, under the following conditions:

- Amount of financing: €90 thousand
- Term: 12 months
- Annual interest rate: 0.25%
- Repayment: an annual payment of the principal and interest in arrears after a deferred period of 12 months.

This loan benefits from a Government guarantee, under the "FDG Etat Coronavirus" guarantee fund, of up to 90%.

The Company intends to request an additional deferral of 12 months and repayment over 4 years.

On 5 June 2020, KARDIOZIS contracted a loan guaranteed by the French Government with optional amortisation over five years, with Société Générale, under the following conditions:

- Amount of financing: €160 thousand
- Term: 12 months
- Annual interest rate: 0.25%
- Repayment: an annual payment of the principal and interest in arrears after a deferred period of 12 months.

This loan benefits from a Government guarantee, under the "FDG Etat Coronavirus" guarantee fund, of up to 90%.

The Company intends to request an additional deferral of 12 months and repayment over 4 years.

On 5 June 2020, KEPHALIOS contracted a loan guaranteed by the French Government with optional amortisation over five years, with Société Générale, under the following conditions:

- Amount of financing: €890 thousand
- Term: 12 months
- Annual interest rate: 0.25%
- Repayment: an annual payment of the principal and interest in arrears after a deferred period of 12 months.

This loan benefits from a Government guarantee, under the "FDG Etat Coronavirus" guarantee fund, of up to 90%.
The Company intends to request an additional deferral of 12 months and repayment over 4 years.

11.3 Loans and convertible bonds

Change in loans

CHANGE IN LOANS (Amounts in thousands of euros)	KREOS bond	Financing CBs 2018	2018 CBs	2019 CBs	Total
At 1 January 2019	**3,704**	**2,448**	**2,524**	**-**	**8,677**
(+) Collection	3,872	-	-	4,000	7,872
(+) Security deposit	128	-	-	-	128
(-) Derivative liabilities	(144)	-	-	(399)	(543)
(+) Impact of amortised cost	217	102	102	4	424
Repayments	(516)	-	-	-	(516)
(+/-) Accrued interest	-	180	171	9	360
As at 31 December 2019	**7,262**	**2,730**	**2,797**	**3,614**	**16,403**
(+) Collection	-	-	-	4,000	4,000
(+) Security deposit	-	-	-	-	-
(-) Derivative liabilities	-	-	-	(1,364)	(1,364)
(+) Impact of amortised cost	174	63	62	39	338
Repayments	(1,952)	-	-	-	(1,952)
(+/-) Accrued interest	-	88	84	113	285
(+/-) Conversion	-	(2,882)	(2,943)	(3,718)	(9,543)
Of which nominal value and accrued interest	-	*(3,394)*	*(3,236)*	*(4,088)*	*(10,717)*
Of which discounts and unamortised costs	-	*511*	*292*	*370*	*1,174*
As at 31 December 2020	**5,483**	**-**	**-**	**(2,684)**	**8,167**

The CB for 2018, the Financing CB for 2018 and the first tranche of CB for 2019 were converted on 19 June 2020. Discounts and unamortised costs at the conversion date were recorded as a deduction from shareholders 'equity for €1,174 thousand (see table above). The fair value of the derivative liabilities recognised in respect of the conversion options of the 2018 Financing CB and the 2019 CB was recognised in equity at the conversion date for €680 thousand (€516 thousand for the derivative liability under the convertible option for the Financing CB in 2018 (see Note 11.3.2 "*Convertible Bond Loan – Financing CB 2018*") and €164 thousand in respect of the conversion option for the derivative liability of the 2019 CB (see Note 11.3.4 "*Convertible Bond 2019*"). The net impact on shareholders' equity as of 31 December 2020 amounted to a negative €493 thousand.

Breakdown of bonds by maturity date, in redemption value

MATURITIES OF BONDS, IN REDEMPTION VALUE (Amount in thousands of euros)	KREOS bond	Financing CBs	2018 CBs	2019 CBs	Total
At 31 December 2020	**5,532**	**-**	**-**	**4,034**	**9,566**
Share at less than one year	3,378	-	-	4,034	**7,411**
Share between one and five years	2,154	-	-	-	**2,154**
Share at more than five years	-	-	-	-	**-**

11.3.1 KREOS non-convertible bond

On 26 October 2018, the Company entered into a venture loan agreement with Kreos Capital in the form of a framework agreement organising the issue of a bond for an amount of up to €12 million through the issue of one tranche of €4 million and two tranches of up to €4 million each, and the issue of 196,722 share subscription warrants (BSA2018-KREOS).
The venture loan agreement provides for the pledge of the Company's assets (including a share of the Company's intellectual property) for the benefit of Kreos Capital.

Each tranche bears interest at 10% *per annum*. All tranches of non-convertible bonds issued are repayable in 36 monthly instalments with a repayment period of six months.

Under the terms of the agreement, the Company has the option at any time, subject to providing at least 30 days' prior notice to Kreos Capital, to redeem or repurchase the non-convertible bonds. The repayment will be equal to (1) the amount of the principal remaining due, increased by (2) the sum of the interest that the Company would have paid over the remaining term of the tranche in question, discounted at the rate of 4% *per annum*.

Tranche A was issued at the signing of the contract on 29 October 2018, and Tranche B on 1 June 2019. Tranche C will not be drawn down as the deadline of 30 September 2019 has been exceeded and the required conditions are not met.

A security deposit of €256 thousand (€128 thousand per tranche) was retained by Kreos Capital on the payments made. It will be deducted from the final monthly payment. It is presented in "Other non-current financial assets".

Each BSA2018-KREOS gives the right to subscribe to a number of shares N such that N = 6.10/SP with SP as defined below.
The Strike Price (SP) is set at the lower of i) the sum of €6.10 and ii) the lowest price used during the various capital increases that took place between the date of issue of the BSA2018-KREOS warrants and the date of exercise, less a discount of 20%.
The exercise period of each tranche begins on the issue date and ends on the earliest of i) the tenth anniversary of the issue date, ii) the date of transfer of ownership of more than 80% of the shares as described by the Shareholders' Agreement, or iii) the fifth anniversary of the Company's admission on the stock market.

Accounting treatment
In accordance with IFRS 9, non-convertible debt is measured using the amortised cost method.
As at 31 December 2019, the debt was valued at €7.2 million.

After analysis, the warrants attached to Tranche A (BSA2018-KREOS) were recognised as a derivative liability and measured at fair value with changes in this fair value recorded in profit or loss in accordance with IFRS 9.

The fair value has been determined by using the Black-Scholes pricing model with the following main assumptions:

BSA issued to the benefit of Kreos	Tranche A			
	Upon issue 26/10/2018	01/01/2019	31/12/2019	31/12/2020
Number of warrants	65,574	65,574	65,574	65,574
Strike price	€4.71	€4.71	€4.71	€4.71
Contractual term	7.55	7.37	6.37	5.37
Volatility	34.92%	35.75%	36.57%	45.98%
Risk-free rate	-0.19%	-0.26%	-0.51%	-0.75%
Value of the derivative (in thousands of euros)	**147**	**147**	**138**	**178**
Change in fair value over the period (in thousands of euros)		**N/A**	**(10)**	**40**

BSA issued to the benefit of Kreos	Tranche B		
	Upon issue (01/06/2019)	31/12/2019	31/12/2020
Number of warrants	65,574	65,574	65,574
Strike price	€4.71	€4.71	€4.71
Contractual term	6.96	6.37	5.37
Volatility	36.57%	36.57%	45.98%
Risk-free rate	-0.51%	-0.51%	-0.75%
Value of the derivative (in thousands of euros)	**144**	**138**	**178**
Change in fair value over the period (in thousands of euros)		**(6)**	**40**

During the financial year 2020, the KREOS loan was rescheduled for certain monthly maturities. The entire non-convertible bond (Tranches A and B) now matures in November 2022.

11.3.2 Convertible Bond Loan – Financing CB 2018

On 23 April 2018, the Company signed a bond loan agreement with TRUFFLE funds enabling the raising of €3 million over a period of 60 months from the date of issue.
At the end of this contract, the issuer issued 3 million convertible bonds for a total of €3 million.
On 19 June 2020, all of the convertible bonds were redeemed in new shares, generating the issue of 599,218 shares.

The convertible bonds have the following characteristics:

- 3 million CB with a nominal value of €1 each were issued at par with a maturity of 60 months, *i.e.* until 9 April 2023;
- The annual interest rate is set at 6%, interest payable on the date of conversion or redemption of the CB;
- The conversion ratio is set at five Financing CB for one share in the Company, except in specific cases detailed below;
- Holders of Financing CB may request the redemption or conversion of said Financing CB on their maturity date.

Furthermore, holders may request the early redemption or conversion of the Financing CB in the event of certain events (such as the sale of all Company shares or assets, in case of a fund raising of a minimum amount of €5 million or the admission to trading of the Company's shares on a regulated or organised market) or, if the holders prefer, after a two-year period following the issuance date of the Financing CB.
The issue price will then be determined according to the value of the share during an IPO or fund raising discounted by 10 or 15% depending on the date of issue of the new shares.

Accounting treatment

In accordance with IFRS 9, the debt component was measured using the amortised cost method.

The convertible bond conversion option has been separated, recognised as a derivative liability due to a variable conversion rate and measured at fair value with changes in fair value recognised in the income statement in accordance with IFRS 9.

The table below summarises the accounting treatment of the convertible option:

Convertible option – Financing CB 2018	**Upon issue 23/04/2018**	**01/01/2019**	**31/12/2019**	**19/06/2020**
Number of outstanding bonds	3,000,000	3,000,000	3,000,000	3,000,000
Number of shares that may be subscribed	3,000,000	3,000,000	3,000,000	3,000,000
Strike price	€5.00	€5.00	€5.00	€5.00
Expected term	3.50	2.80	1.80	1.34
Volatility	33.93%	36.97%	38.29%	38.29%
Risk-free rate	-0.38%	-0.54%	-0.62%	-0.62%
Value of the derivative (in thousands of euros)	**732**	**713**	**596**	**516**
Change in fair value over the period (in thousands of euros)		**N/A**	**(117)**	**(80)**

11.3.3 Convertible Bond Loan 2018

Convertible bonds were issued by the Company on 27 March 2018 for a total amount of €2,850 thousand, in order to remunerate the bonds convertible into shares to the Company following the contribution transaction. On 19 June 2020, all convertible bonds were redeemed in new shares, generating the issue of 604,834 shares.

The convertible bonds have the following characteristics:

- 2,850 thousand CBs with a nominal value of €1 each were issued at par with a maturity of 48 months, *i.e.* until 27 March 2022;
- The annual interest rate is set at 6%;
- The conversion ratio is based on the ratio set under the terms and conditions of the convertible bonds contributed under the Contribution.

Accounting treatment

Due to the presence of a fixed exchange rate, the 2018 CBs were classified as compound instruments with a debt component and an equity component.

The company first estimated the fair value of the debt component by discounting the contractual flows at the rate of 11.51%.

The value of the equity component corresponds to the difference between the cash received and the fair value of the debt component and was recognised as an equity instrument in accordance with IAS 32 for an amount of €519 thousand.

11.3.4 Convertible Bond 2019

On 10 December 2019, the Company signed a bond loan agreement with Head Leader Limited, Truffle Biomedtech Crossover Fund and Truffle Innov FRR France enabling €8 million to be raised over a period of 60 months from the date of issue.

At the end of this contract, the issuer issued 2,300 thousand CB for the benefit of TRUFFLE Biomedtech Crossover Fund, 1,700 thousand for the benefit of Truffle Innov FRR France and 4 million CB for the benefit of Head Leader Limited for a total of €8 million.

The Company was paid €4 million by the funds managed by Truffle Capital in December 2019.
On 19 June 2020, all of these convertible bonds were redeemed in new shares, generating the issue of 679,116 shares.
The payment of the €4 million from the Head Leader fund took place on 16 October 2020.

The agreement provides for the pledge of certain assets of the Company (the Chinese patent of KALIOS held by KEPHALIOS and 40% of the shares of Shanghai Epygon Medical Technology and Shanghai MyoPowers Medical Technology) for the benefit of the subscribers.

The convertible bonds have the following characteristics:

- 8 million CB with a nominal value of €1 each were issued at par with a maturity of 60 months, *i.e.* until 10/12/2024;
- The annual interest rate is set at 4%;
- The bond conversion price is equal to the subscription value of the share at the time of the most recent capital increase on the date of the conversion request.

Accounting treatment

In accordance with IFRS 9, the debt component of convertible bonds was measured using the amortised cost method.

The option to convert the convertible bonds has been separated, recognised in derivative liabilities due to a variable conversion rate and measured at fair value, and changes in this fair value were recorded in the income statement in accordance with IFRS 9.

The fair value has been determined by using the Black & Scholes pricing model with the following main assumptions:

Convertible option – 2019 CB – Truffle Biomedtech Crossover Fund and Truffle Innov FRR France	**Upon issue 10/12/2019**	**31/12/2019**	**19/06/2020**
Number of outstanding bonds	4,000,000	4,000,000	4,000,000
Number of shares that may be subscribed	4,000,000	4,000,000	4,000,000
Strike price	€5.00	€5.00	€5.00
Expected term	0.50	0.50	0.10
Volatility	35.95%	35.92%	35.92%
Risk-free rate	-0.66%	-0.68%	-0.68%
Value of the derivative (in thousands of euros)	**399**	**398**	**164**
Change in fair value over the period (in thousands of euros)		**(1)**	**(234)**

Conversion option – 2019 – Head Leader	Upon issue (16/10/2020)	31/12/2020
Number of outstanding bonds	4,000,000	4,000,000
Number of shares that may be subscribed	4,000,000	4,000,000
Strike price (1)	€5.00	€4.00
Expected term	5	0.42
Volatility	41.09%	0.00%
Risk-free rate	-0.81%	0.00%
Value of the derivative (in thousands of euros)	**1,364**	**1,000**
Change in fair value over the period (in thousands of euros)		**(364)**

(1) According to the contract, the strike price is reduced by 20% in the event of the securities being floated on a regulated market.

11.4 Debt related to lease liabilities

Change in lease liabilities

CHANGES IN LIABILITIES ON LEASE LIABILITIES (Amount in thousands of euros)	Lease liabilities
At 1 January 2019	**716**
(+) Increase	480
(-) Repayments	(184)
As at 31 December 2019	**1,013**
(+) Increase	167
(-) Repayments	(222)
As at 31 December 2020	**957**

During the financial year 2019, the lease liabilities increased by €480 thousand, corresponding to the following items:

- renewal of the commercial lease for the Aix-en-Provence premises in the amount of €307 thousand (lease over six years discounted at a rate of 3.26%);
- industrial and IT equipment leased to the tune of €98 thousand discounted at rates of 2.76% and 3.12%;
- various vehicles leased for an amount of €61 thousand, discounted at a rate of 3.00%;
- office equipment leased for an amount of €14 thousand, discounted at a rate of 3.15%.

Breakdown of financial debt by maturity, in redemption value

CURRENT AND NON-CURRENT LEASE LIABILITIES (amount in thousands of euros)	Lease liabilities
As at 31 December 2020	**1,075**
Share at less than one year	258
Share between one and five years	590
Share at more than five years	226

Accounting principles

The Group provides retirement, death and disability benefits to its employees according to local customs and requirements through pension payments by social security bodies, which are financed by contributions from the Group and the employees (defined contribution plan) in Italy and France, the two countries where the Group operates.

The Group also provides pension, death and disability benefits to its Italian and French employees through the following defined benefit plans:

- For Italian employees, the "Trattamento di Fine Rapporto" (TFR) scheme;
- Employees of the Group's French companies benefit from a retirement allowance in the form of the payment of a pension upon retirement.

Pension plans, similar compensation and other employee benefits that have the status of defined benefit plans (in which the Group guarantees a defined amount or level of benefits) are recognised in the statement of financial position on the basis an actuarial valuation of the obligations at the end of the period, less the fair value of the plan assets.

This valuation is determined using the projected unit credit method, taking into account the employee turnover rate and the probability of mortality. All actuarial gains and losses are recognised in equity under "Other comprehensive income".

The Group's contributions to defined contribution plans are recognised as expenses in the income statement during the period to which they relate. The pension expense (cost of services rendered and interest expense) is presented in operating income.

EMPLOYEE BENEFITS COMMITMENTS (Amounts in thousands of euros)	**31/12/2020**	**31/12/2019**	**01/01/2019**
Italian employees	58	45	24
French employees	59	41	22
Employee benefits commitments	**117**	**86**	**45**

12.1 Italian employees

The main actuarial assumptions used to assess retirement benefits are as follows:

ACTUARIAL ASSUMPTIONS FOR PENSION BENEFITS – Italy	**31/12/2020**	**31/12/2019**	**01/01/2019**
Retirement age		Age 67	
Discount rate (IBOXX Corporates AA)	0.33%	0.77%	1.57%
Mortality table	ISTAT table SIM/F 2019	ISTAT SIM/F table 2018	
Salary adjustment rate		3.60%	
Turnover		3.00%	

The provision for pension commitments has changed as follows:

EMPLOYEE BENEFITS COMMITMENTS IN ITALY (Amounts in thousands of euros)	31/12/2020	31/12/2019
Opening of the period	**45**	**24**
Cost of services rendered	20	11
Financial cost	0	0
Benefits paid	(7)	-
Actuarial difference	(0)	11
Close of the period	**58**	**45**

12.2 French employees

The main actuarial assumptions used to assess retirement benefits are as follows:

ACTUARIAL ASSUMPTIONS FOR PENSION BENEFITS – France		31/12/2020	31/12/2019	01/01/2019
Retirement age		Voluntary departure between the ages of 65 and 67		
Collective agreements	Kephalios	Chemical Industries 3108		
	Other French entities	Executive: Metallurgy Industries (management) 3025 Non-executive: Metallurgy Industries 3126		
Discount rate (IBOXX Corporates AA)		0.33%	0.77%	1.57%
Mortality table		INSEE 2019	INSEE 2018	INSEE 2017
Salary adjustment rate		2.00%		
Turnover	Kephalios	Medium		
	Other French entities	High		
Social security charges rate		45%		

The provision for pension commitments has changed as follows:

EMPLOYEE BENEFITS COMMITMENTS IN FRANCE (Amounts in thousands of euros)	31/12/2020	31/12/2019
Opening of the period	**41**	**22**
Cost of services rendered	15	9
Financial cost	0	0
Compensation paid	-	-
Actuarial difference	3	10
Changes in scope	-	-
Close of the period	**59**	**41**

Accounting principles

Provisions correspond to commitments resulting from litigation and various risks, the timing and amount of which are uncertain, to which the Company may be exposed in the course of its activities.

A provision is recorded when the Company has an obligation to a third party resulting from a past event that is probably result in an outflow of resources for the benefit of this third party, with no equivalent consideration expected, and for which future cash outflows may be estimated reliably. The amount recorded as a provision is the estimate of the expenditure necessary to settle the obligation, discounted where necessary at the year-end.

PROVISIONS (Amounts in thousands of euros)	31/12/2019				
	Amount at start of the period	Provisions	Reversals	Changes in scope	Amount at end of the period
Provisions for risks	-	-	-	-	-
Provisions for litigation	-	103	-	-	**103**
Provisions for risks and contingencies	**-**	**103**	**-**	**-**	**103**

The Group has set aside a provision of €103 thousand for industrial tribunal disputes that arose during the financial year 2019 and €125 thousand the financial year 2020.

PROVISIONS (Amounts in thousands of euros)	31/12/2020				
	Amount at start of the period	Provisions	Reversals	Changes in scope	Amount at end of the period
Provisions for risks	-	-	-	-	-
Provisions for litigation	103	125	-	-	**228**
Provisions for risks and contingencies	**103**	**125**	**-**	**-**	**228**

Note 14: Other current and non-current liabilities

Accounting principles

The fair value of current liabilities is assimilated to their balance sheet value, given the very short payment terms.

OTHER CURRENT AND NON-CURRENT LIABILITIES (Amounts in thousands of euros)	31/12/2020	31/12/2019	01/01/2019
Trade payables and related accounts	2,352	3,704	3,703
Tax and social security payable	1,441	1,201	950
Current deferred income	350	409	371
Current tax liability	32	18	-
Other debts	138	115	198
Non-Group current accounts	300	300	336
Total other current liabilities	**4,613**	**5,746**	**5,558**
Non-current deferred income	9	234	525
Total other non-current liabilities	**9**	**234**	**525**

Deferred income relates in particular to the spreading of grants received under the PIAVE ARTUS and MIVANA projects. They were classified as other current liabilities for the portion of grants to be received within one year and as other non-current liabilities for longer-term grants.

Accounting principles

The Company has distinguished three categories of financial instruments according to the consequences that their characteristics have on their valuation method and relies on this classification to present some of the information required by IFRS 7:

- Level 1 category: financial instruments listed on an active market;
- Level 2 category: financial instruments whose measurement involves the use of valuation techniques based on observable parameters;
- Level 3 category: financial instruments whose measurement involves the use of valuation techniques based in whole or in part on unobservable parameters; an unobservable parameter being defined as a parameter whose value results from assumptions or correlations that are not based on observable market prices, on the same instrument at the valuation date, or on available observable market data on the same date.

Financial instruments recognised at fair value through profit or loss under Level 3 are derivative liabilities recognised in respect of conversion options on certain convertible bonds (Financing CB 2018 and 2019 CB, (see Notes 11.3.2 "*Convertible Bond Loan – Financing CB 2018*" and 11.3.4 "*Convertible Bond 2019*") and in respect of warrants attached to the Kreos non-convertible bond issue (see Note 11.3.1 "*KREOS non-convertible bond*").

The Company's assets and liabilities are valued as follows at the end of the financial years presented:

(Amounts in thousands of euros)	31/12/2020		Value – statement of financial position under IFRS 9	
Balance sheet headings	**Book value**	**Market value**	**Fair value through profit or loss**	**Amortised cost**
Non-current financial assets	351	351	-	351
Other current receivables	2,261	2,261	-	2,261
Cash and cash equivalents	5,650	5,650	5,650	-
Total of balance sheet headings concerning an asset item	**8,262**	**8,262**	**5,650**	**2,612**
Current financial liabilities	3,575	3,575	-	3,575
Current lease liabilities	226	226	-	226
Non-current financial liabilities	16,248	16,248	-	16,248
Non-current lease liabilities	731	731	-	731
Trade payables	2,352	2,352	-	2,352
Other current liabilities	2,261	2,261	-	2,261
Derivative liabilities	1,351	1,351	1,351	-
Total of balance sheet headings concerning a liability item	**26,743**	**26,743**	**1,351**	**25,392**

(Amounts in thousands of euros)	31/12/2019		Value – statement of financial position under IFRS 9	
Balance sheet headings	**Book value**	**Market value**	**Fair value through profit or loss**	**Amortised cost**
Non-current financial assets	331	331	-	331
Other current receivables	3,989	3,989	-	3,989
Cash and cash equivalents	2,126	2,126	2,126	-

Total of balance sheet headings concerning an asset item	**6,446**	**6,446**	**2,126**	**4,320**
Current financial liabilities	3,290	3,290	-	3,290
Current lease liabilities	202	202	-	202
Non-current financial liabilities	19,882	19,882	-	19,882
Non-current lease liabilities	811	811	-	811
Trade payables	3,704	3,704	-	3,704
Other current liabilities	2,043	2,043	-	2,043
Derivative liabilities	1,264	1,264	1,264	-
Total of balance sheet headings concerning a liability item	**31,196**	**31,196**	**1,264**	**29,931**

(Amounts in thousands of euros)	**01/01/2019**		**Value – statement of financial position under IFRS 9**	
Balance sheet headings	**Book value**	**Market value**	**Fair value through profit or loss**	**Debt at amortised cost**
Non-current financial assets	140	140	-	140
Other current receivables	3,795	3,795	-	3,795
Cash and cash equivalents	3,339	3,339	3,339	-
Total of balance sheet headings concerning an asset item	**7,274**	**7,274**	**3,339**	**3,935**
Current financial liabilities	1,188	1,188	-	1,188
Current lease liabilities	119	119	-	119
Non-current financial liabilities	10,001	10,001	-	10,001
Non-current lease liabilities	597	597	-	597
Trade payables	3,703	3,703	-	3,703
Other current liabilities	1,854	1,854	-	1,854
Derivative liabilities	854	854	854	-
Total of balance sheet headings concerning a liability item	**18,317**	**18,317**	**854**	**17,463**

Note 16: Other operating income

OTHER OPERATING INCOME **(Amounts in thousands of euros)**	**31/12/2020**	**31/12/2019**
Research Tax Credit	380	1,087
Grants	444	342
Total other operating income	**824**	**1,429**

Other operating income includes:

- research tax credits for French companies amounting to €380 thousand in 2020 and €1,087 thousand in 2019. This decrease is explained by the financing of subsidies and repayable advances received from the BPI, which are deducted from the calculation basis of the research tax credit; and
- grants spread over the duration of the expenses incurred as part of the project with Bpifrance in the amount of €36 thousand (see Note 11.1.1 "*BPI Innovation loan*") and the MIVANA and PIAVE ARTUS development projects (see Notes 11.1.2 "*Project MIVANA repayable advance*" and 11.1.3 *"Project PIAVE ARTUS repayable advance"*) in the amount of €408 thousand in 2020 (of which €375 thousand for Project MIVANA, €33 thousand for Project PIAVE ARTUS) and €330 thousand in 2019.

Note 17: Operating expenses

17.1 External expenses

External expenses (Amounts in thousands of euros)	31/12/2020	31/12/2019
Fees	(2,969)	(3,117)
Missions and receptions	(128)	(414)
Maintenance and repairs	(152)	(86)
Advertising, publications, public relations	(21)	(38)
Rentals and rental expenses	(58)	(39)
Insurance premiums	(48)	(42)
Studies, research, documentation and seminars	(9)	(22)
Miscellaneous	(178)	(142)
Total external expenses	**(3,563)**	**(3,899)**

17.2 Personnel expenses

Personnel expenses (Amounts in thousands of euros)	31/12/2020	31/12/2019
Employee compensation	(2,782)	(2,165)
Social security charges	(976)	(985)
Pension commitments	(29)	(21)
Short-time working compensation	52	-
Share-based payments	(959)	(437)
Total personnel expenses	**(4,694)**	**(3,607)**

The Company's average headcount was 42 as at 31 December 2020 compared to 40 as at 31 December 2019.

17.3 Other current operating income and expenses

Other current operating income and expenses (Amounts in thousands of euros)	31/12/2020	31/12/2019
Net book value of assets sold	-	(17)
Income from assets sold	-	14
Other miscellaneous expenses and income	46	16
Other current operating income and expenses	**46**	**14**

Note 18: Other operating income and expenses

Accounting principles

Other operating income and expenses include significant items which, due to their type and unusual nature, cannot be considered inherent to the Group's day-to-day business.

They may include:

- costs related to the merger/acquisition of companies;
- certain restructuring charges;
- other operating income and expenses such as a provision relating to a very significant litigation;
- a capital gain or loss on the disposal or significant and unusual impairment of non-current assets.

Other non-recurring operating income and expenses

The Group did not recognise any other non-recurring operating income or expenses during the financial years 2019 and 2020.

Note 19: Net financial income

Accounting principles

The financial result includes all:

- Expenses related to the financing of the Company: interest paid, amortised costs of financial debts, accretion of repayable advances.
- Changes in the fair value of derivative liabilities.

Foreign exchange gains and losses are also recognised in financial income.

Breakdown of financial income and expenses

FINANCIAL INCOME AND EXPENSES (Amounts in thousands of euros)	31/12/2020	31/12/2019
Cost of net financial debt	**(2,165)**	**(1,901)**
Income from cash and cash equivalents	-	-
Interest expenses	(2,129)	(1,884)
Effect of accretion	(36)	(17)
Other financial income and expenses	**629**	**132**
Foreign exchange income	1	(3)
Change in fair value of derivative liabilities	597	132
Other	30	3
Net financial income	**(1,536)**	**(1,769)**

The interest expense under IFRS 16 amounted to €37 thousand in 2020 and €38 thousand in 2019.

The cost of bonds is set forth in Note 11.3 "*Loans and convertible bonds*".

The effect of accretion is set forth in Note 11.1 "*Repayable advances and innovation loan*".

Note 20: Income tax

Accounting principles

Current and previous tax assets and liabilities are measured at the amount that the Company expects to recover or pay to the tax authorities.
The tax rates and tax regulations used to determine these amounts are those enacted or substantially enacted at the balance sheet date.

Deferred taxes are recognised, using the liability method, for all temporary differences existing at the balance sheet date between the tax base of assets and liabilities and their carrying amount in the financial statements as well as on tax loss carried forwards.

The main temporary differences relate to tax losses carried forward and to technologies developed internally and recognised in the context of business combinations prior to the date of transition to IFRS.

Deferred tax assets are recognised for tax losses carried forward when it is more likely than not that the Company will have future taxable profits against which these unused tax losses can be offset. The determination of the amount of deferred tax assets that may be recognised requires management to make estimates both on the consumption period of the tax loss carried forwards, and on the level of future taxable profits, with regard to tax management strategies.

Tax rate and tax loss carried forwards

Affluent Medical had tax losses that can be carried forward indefinitely in France amounting to €68,487 thousand as at 31 December 2020.

The income tax rate applicable to Affluent Medical is the current rate in France, *i.e.* 28%. This rate will gradually decrease to 25% from 2022.

The deduction of tax losses carried forward in France in the following financial year is limited to €1 million *per annum*, plus 50% of the portion of the profit above this limit.

In accordance with the principles described above and the mechanism for capping tax losses carried forward, no deferred tax assets have been recognised in addition to deferred tax liabilities in the Group's consolidated financial statements as at 31 December 2020.

Deferred tax assets are recognised for tax losses carried forward when it is more likely than not that the Company will have future taxable profits against which these unused tax losses can be offset.

Deferred tax assets recognised in the amount of deferred tax liabilities are presented as a deduction from these in the consolidated statement of financial position.

Reconciliation between theoretical tax and effective tax

TAX PROOF **(amounts in thousands of euros)**	**31/12/2020**	**31/12/2019**
Net income (loss)	(14,319)	(16,589)
Neutralisation		
Share of companies accounted for under the equity method	(398)	(1,190)
Consolidated tax	209	210
Tax credits	380	1,087
Pre-tax income	**(14,509)**	**(16,697)**
Current tax rate	28.00%	28.00%
Theoretical tax at the current rate	**4,063**	**4,675**
Permanent differences	181	(31)
Share-based payments	(269)	(122)
Non-capitalised tax loss, adjusted for deferred taxation	(3,770)	(4,306)
Effect of tax rate differences	4	2
Other	(0)	(8)
Income taxes	**209**	**210**
Effective tax rate	1.5%	1.3%

Type of deferred taxes

NATURE OF DEFERRED TAXES (amounts in thousands of euros)	31/12/2020	31/12/2019
Other temporary differences	181	78
Deferred tax loss in France	19,176	15,416
Total items that are deferred tax assets	**19,357**	**15,495**
Valuation difference on technologies developed in-house	(6,001)	(6,459)
Other temporary differences	(1,515)	(1,341)
Total deferred tax liabilities	**(7,516)**	**(7,800)**
Total deferred tax items	**11,841**	**7,695**
Unrecognised deferred tax assets	(14,282)	(10,364)
Deferred tax assets (liabilities), net	**(2,440)**	**(2,669)**

Loss carried forwards

LOSS CARRIED FORWARDS (amounts in thousands of euros)	31/12/2020	31/12/2019
France	68,487	55,058
Italy	-	-
Total	**68,487**	**55,058**
Of which activated	17,481	17,843

Note 21: Earnings per share

Accounting principles

Basic earnings per share are calculated by dividing the income attributable to equity holders of the Company by the weighted average number of outstanding shares during the period.

Diluted earnings per share are determined by adjusting the income attributable to ordinary shareholders and the weighted average number of ordinary shares outstanding for the effects of all potentially dilutive ordinary shares.

If the inclusion in the calculation of diluted earnings per share of instruments giving deferred rights to capital (share subscription/founder's share warrants, convertible bonds) generates an anti-dilutive effect, these instruments are not taken into account.

As the Company’s net income for the two years presented is a loss, the diluted earnings per share are identical to the basic earnings per share.

BASIC EARNINGS PER SHARE	31/12/2020	31/12/2019
Net income for the year (in thousands of euros)	(14,319)	(16,589)
Weighted average number of shares outstanding	13,360,416	11,899,967
Weighted average number of shares for diluted earnings	13,360,416	11,899,967
Basic earnings per share (€/share)	(1.07)	(1.39)
Diluted earnings per share (€/share)	(1.07)	(1.39)

In accordance with IAS 33, the earnings per share on the diluted basis presented above is identical to the basic earnings per share because incorporating the effects of dilution would result in an improved earnings per share on a diluted basis compared to basic earnings per share.

As at 31 December 2020, the Company's dilutive instruments consisted of:

- BSAs attached to the KREOS non-convertible bonds, (see Note 11.3.1 "*KREOS non-convertible bond*");
- convertible bonds per share (2019 CB), (see Note 11.3.4 "*Convertible Bond 2019*");
- share subscription/founders' share warrants granted to employees, members of the Board of Directors, external service providers, (see Notes 10.1 "*Share subscription warrants (Bons de souscription d'actions, or BSA)"* and 10.2 "*Founders' share warrants (Bons de souscription de parts de créateur d'entreprise, or BSPCE)"*).

Note 22: Segment information

Accounting principles

In accordance with IFRS 8, segment information is prepared on the basis of internal management data used to analyse business performance and allocate resources.

Given the stage of development of the Company's products, the operation of the research and development activities of medical devices is closely linked. The Company has a cross-functional research management team and an operational and clinical development team whose costs and monitoring are not strictly allocated by medical device. As a result, the Group's performance is currently analysed at the consolidated level by the Company's management and its Board of Directors.

At this stage, the Company has concluded that its operations constitute a single operating segment: the conduct of research and development of medical devices with a view to their future marketing.

Operating assets, liabilities and losses as well as research and development costs are located in France and Italy, and in China through joint ventures.

The Group's non-current assets amounted to €56,915 thousand as at 31 December 2020 broken down geographically as follows: €55,899 thousand in France, €1,002 thousand in Italy and €14 thousand for China.

Note 23: Related parties

23.1 Compensation due to corporate officers

Executive compensation breaks down as follows:

Compensation of corporate officers (Amounts in thousands of euros)	31/12/2020	31/12/2019
Fixed compensation	253	281
Variable compensation paid	36	15
Consulting fees	2	-
Benefits in kind	11	7
Directors' fees	48	91
Share-based payments	540	504
TOTAL	**890**	**898**

Note 24: Commitments

24.1 Pledges

The venture loan agreement set up with Kreos Capital provides for the pledge of the Company's assets (including a share of the Company's intellectual property) for the benefit of Kreos Capital, (see Note 11.3.1 "*KREOS non-convertible bond*").

The 2019 convertible bond agreement provides for the pledge of certain assets of the Company (the Chinese patent of KALIOS held by KEPHALIOS and 40% of the shares of Shanghai Epygon Medical Technology and Shanghai MyoPowers Medical Technology) for the benefit of subscribers, (see Note 11.3.4 "*Convertible Bond 2019*").

Note 25: Management and assessment of financial risks

The Group's policy is not to subscribe to financial instruments for speculative purposes.
The principal risks to which the Company is exposed are liquidity risk and credit risk. The Company believes that it is not significantly exposed to interest rate and foreign currency exchange risk.

Interest rate risk

Interest rate risk represents the Company's exposure to changes in market interest rates.

Changes in interest rates could affect returns on cash and term deposits. However, this risk is not considered significant given the absence of term deposits held by the Company.

All the Company's debts, excluding repayable advances, have been subscribed at a fixed rate.

The repayable advances on the MIVANA and PIAVE projects (see Notes 11.1.2 "*Project MIVANA repayable advance*" and 11.1.3 *"Project PIAVE ARTUS repayable advance"*) include additional payments that depend on the success of the project and the level of revenue generated by the Company.

An increase of ten points in revenue assumptions would have the following impacts on accrued interest recognised as at 31 December 2020:

(Amounts in thousands of euros)	Project MIVANA EPYGON	Project MIVANA - KEPHALIOS	Project PIAVE ARTUS - MYOPOWERS
Effective interest rates used to calculate accrued interest	14.04%	15.51%	6.78%
Effective interest rates if revenue assumptions increased by 10 points	14.32%	16.23%	7.00%
Impact on accrued interest as at 31 December 2020	€54,000	€21,000	€20,000

Credit risk

Credit risk is associated with deposits with banks and financial institutions.

The Company seeks to minimise the risk associated with banks and financial institutions by placing term deposits with leading financial institutions. The maximum level of credit risk corresponds to the carrying amount of financial assets. As the current receivables mainly include research tax credits granted by the French State, the Company does not bear any significant credit risk.

Foreign currency risk

The main risks related to foreign exchange impacts are not considered significant due to the low level of activity of its subsidiaries abroad.

At this stage of its development, the Company has not made any hedging measures to protect its business against exchange rate fluctuations. However, the Company cannot rule out the possibility that a significant increase in its activity could result in greater exposure to foreign currency exchange risk. The Company will then consider adopting an appropriate hedging policy for these risks.

Equity risk

The Company does not hold any equity investments or marketable securities on a regulated market.

Liquidity risk

As at 31 December 2020, the Company's cash amounted to €5,650 thousand, compared to €2,126 thousand as at 31 December 2019. The Company has generated operating losses and negative cash flows since its inception. The cash flows related to the Company's operating activities amounted to a negative €8,936 thousand and €11,412 thousand respectively for the financial years ended 31 December 2020 and 2019. As at 31 December 2020, the Company's net loss amounted to €14,319 thousand.

Since its creation, the Company has financed its growth through successive capital increases, bond issues, repayable advances, loans guaranteed by the State and the repayment of receivables from Research Tax Credits. The Company does not generate any revenue and continues its research and development efforts for its medical devices.

The Company believes that it should continue to recognise losses in the medium-term and that its current resources will enable it to finance its activity until the end of May 2021.

The Company intends to proceed with an Initial Public Offering on the Euronext Paris market (see Note 27 "*Post-closing events*"). In the event that this transaction is postponed, the Company could finance its future cash requirements through a combination of public or private capital increases, bank or bond financing, collaboration agreements, licenses and development or other forms of non-dilutive financing.

At the date of closing of the financial statements, the Company's management believes that it has reasonable assurance that it will find adequate financing. However, the Company cannot guarantee that it will succeed in obtaining it.

The Company's financial statements as at 31 December 2020 were prepared on a going concern basis (see Note 2.1 *"Principles applied to the preparation of the financial statements"*). As such, they do not include any adjustments related to the amount or classification of assets and liabilities that may be necessary if the Company is not able to continue its activities on a going concern basis.

Note 26: Statutory Auditors' fees

STATUTORY AUDITORS' FEES	Financial year 2020 12 months		Financial year 2019 12 months
(Amounts excl. tax in thousands of euros)	**PwC**	**EXPERTEA**	**PwC**
Statutory audit assignment			
Affluent Medical	45	22	24
Fully consolidated subsidiaries	50	-	23
Services other than the certification of financial statements			
Sub-total	**95**	**22**	**47**
Other services rendered			
- Tax	-	-	-
- Other	-	-	-
Sub-total	**-**	**-**	**-**
Total	**95**	**22**	**47**

Note 27: Post-closing events

February 2021

- The Company has contracted a loan guaranteed by the French State in the amount of €395 thousand with CIC with an interest rate of 0% *per annum* and a maturity date of 5 February 2022. This loan benefits from a State guarantee under the "FDG Etat Coronavirus" guarantee fund of up to 90.00%. The Company has an option to extend the amortisation and repayment period of the loan up to five years after the initial maturity date provided for in the contract.
- Proposed Initial Public Offering of the Company's shares on Euronext Paris during the first half of 2021.

Note 28: Reconciliation of consolidated financial statements prepared in accordance with CRC 99-02 and those prepared in accordance with IFRS

In accordance with Section 28 of Regulation (EC) No. 1136/2009 of the European Commission of 25 November 2009, it should be noted that the Company has published consolidated financial statements in accordance with CRC 99-02 as of December 2018.

For the sole purpose of the financial information, the Company considered the transition date to be 1 January 2019 and produced its first set of financial statements under IFRS as of 31 December 2020 with a comparison as of 31 December 2019.

It has opted for some of the exemptions provided for by IFRS 1, presented in Note 2.1 "*Principles applied to the preparation of the financial statements*".

With regard to the income statement, the Group has chosen a presentation by type of operating income and expenses.

The Company's financial statements prepared in accordance with International Financial Reporting Standards (IFRS) differ in certain respects from those prepared in accordance with French accounting principles (CRC 99-02) used to prepare the consolidated financial statements as of 31 December 2018.

Opening balance sheet: transition from French standard CRC 99-02 to IFRS

Affluent Medical SA Statement of financial position	Consolidated financial statements CRC 99-02 31 December 2018	Consolidation of the EPYGON SRL subsidiary Note A	IAS 20 & Repayable advances Note B	IFRS 16 Leases Note C	Loans IFRS 9 Note D	Deferred taxes IAS 12 Note E	Equity-accounted companies Note F	IAS 19R Pension commitment Note G	Reclassifications Other	Consolidated financial statements IFRS January 2019
ASSETS										
Goodwill	32,203									32,203
Other intangible assets	26,209	110								26,318
Property, plant and equipment (including right-of-use assets)	362	407		699						1,468
Investments accounted for using the equity method	1,829						(249)			1,580
Other non-current financial assets	10	(10)			128				12	140
Other non-current assets	12								(12)	-
Deferred tax assets	-									-
Total non-current assets	**60,626**	**506**	**-**	**699**	**128**	**-**	**(249)**		**-**	**61,710**
Receivables	4	18							(21)	-
Other current receivables	8,041	271				(4,436)			(80)	3,795
Current tax asset	-									-
Cash and cash equivalents	3,224	115								3,339
Total current assets	**11,268**	**403**	**-**	**-**	**-**	**(4,436)**	**-**		**(101)**	**7,133**
TOTAL assets	**71,894**	**910**	**-**	**699**	**128**	**(4,436)**	**(249)**		**(101)**	**68,843**
Capital	11,900									11,900
Premiums	47,646									47,646
Currency translation	(40)						40			-
Other items in comprehensive income	-									-
Reserves and net income (Group share)	(10,998)	404	(1,407)	(17)	575	(880)	(289)	(5)	128	(12,489)
Total equity – attributable to owners of the parent company	**48,509**	**404**	**(1,407)**	**(17)**	**575**	**(880)**	**(249)**	**(5)**	**128**	**47,058**
Other equity	1,451								(1,451)	-
Non-current financial liabilities	9,722		570		(1,045)				755	10,001
Non-current lease liabilities	-			597						597
Employee benefits commitments	-							45		45
Non-current provisions	26							(26)		0
Deferred tax liabilities	6,454					(3,556)				2,899
Derivative liabilities	-				713					713
Other non-current liabilities	-		525							525
Non-current liabilities	**17,653**	**-**	**1,095**	**597**	**(332)**	**(3,556)**	**-**	**19**	**(696)**	**14,779**
Current financial liabilities	392				(255)				1,050	1,188
Current lease liabilities				119						119
Trade payables	3,573	239							(108)	3,703
Other current liabilities	1,766	266	312					(14)	(475)	1,854
Derivative liabilities					141					141
Current liabilities	**5,732**	**505**	**312**	**119**	**(114)**	**-**	**-**	**(14)**	**466**	**7,006**
Total liabilities and equity	**71,894**	**910**	**-**	**699**	**128**	**(4,436)**	**(249)**	**-**	**(101)**	**68,843**

Note A: EPYGON SRL is fully consolidated in the consolidated financial statements under IFRS, although it is considered as a non-significant subsidiary according to the French standard CRC 99-02.

Note B: According to IAS 20 "Accounting for public grants and information to be provided on public assistance", the fact that a repayable advance or a loan does not bear the payment of an annual interest or the payment of a reduced interest amounts to considering that the Company benefited from a rate more favourable than market conditions. The difference between the amount of the advance or loan at historical cost and that of the advance discounted at a marginal debt ratio is considered as a subsidy received from the Government.
Subsidies received as part of development projects are spread over the duration of the expenses incurred in connection with the said project.
When the repayable advances include additional payments that depend on the success of the project and the level of revenue generated by the Company, a restatement has been made to take into account the estimated future disbursements in respect of these additional payments in determining the effective interest rate of the financing.
Repayable advances are classified as "Other equity" according to the French standard CRC 99-02.

Note C: According to IFRS 16 "Leases", all leases (finance leases, operating leases, real estate leases) are restated and the Company has recognised a right-of-use and a liability relating to lease obligations. Only finance leases are restated in accordance with French accounting standard CRC 99-02.

Note D: According to IFRS 9 "Financial instruments" and IAS 32 "Financial instruments: presentation", financial debts are analysed. Debt components are recognised at amortised cost. Conversion options and warrants attached to financial debt are either recognised as derivatives in the absence of a fixed exchange rate, or as equity instruments. Please refer to Section 8.1.3 "*Financing by convertible and non-convertible bonds*" of the Registration Document.

Note E: Capitalised deferred tax assets in the amount of deferred tax liabilities are presented in the statement of financial position in net position.

Note F: The Company has taken into account the share of expenses incurred by joint ventures in the context of the equity method of accounting in the IFRS transition balance sheet at 1 January 2019.

Note G: The pension obligations in accordance with IAS 19R include the commitment relating to the defined benefits of the Italian TFR scheme not included in the consolidated financial statements prepared according to the French standard CRC 99-02 as at 31 December 2018.

Note H: The Company has applied IFRS 2 "Share -based payments" to all equity instruments granted to employees since its creation. An expense is recognised against an increase in reserves (see Note 10 "*Share-based payments*").

Balance sheet as at 31 December 2019: transition from French standard CRC 99-02 to IFRS

Affluent Medical SA Statement of financial position	Consolidated financial statements CRC 99-02 31 December 2019	Consolidation of the EPYGON SRL subsidiary Note A	IAS 20 & Repayable advances Note B	IFRS 16 Leases Note C	Loans IFRS 9 Note D	Deferred taxes IAS 12 Note E	Equity-accounted companies Note F	IAS 19R Pension commitment Note G	Share-based payments IFRS 2 Note H	Reclassifications Other	Consolidated financial statements IFRS 31 December 2019
Total equity attributable to owners of the parent company	**34,318**	**457**	**(1,511)**	**(30)**	**282**	**(1,110)**	**(1,427)**	**(0)**	**-**	**(16)**	**30,964**

Results as at 31 December 2019: transition from French standard CRC 99-02 to IFRS

Affluent Medical SA Income statement	Consolidated financial statements CRC 99-02 31 December 2019	Consolidation of the EPYGON SRL subsidiary Note A	IAS 20 & Repayable advances Note B	IFRS 16 Leases Note C	Loans IFRS 9 Note D	Deferred taxes IAS 12 Note E	Equity-accounted companies Note F	IAS 19R Pension commitment Note G	Share-based payments IFRS 2 Note H	Reclassifications Other	Consolidated financial statements IFRS 31 December 2019
TOTAL NET INCOME	**(14,258)**	**53**	**(104)**	**(13)**	**(293)**	**(233)**	**(1,190)**	**(9)**	**(437)**	**(543)**	**(16,589)**

18.1.1.2. Notes to the consolidated financial statements under IFRS for the financial years 31 December 2019 and 2020

Clarification on the going concern principle

For the periods ending 31 December 2019 and 31 December 2020, the Company has obtained a financial support letter from the primary shareholders of the Company managed by Truffle Capital for the financial years 2020 and 2021 respectively.

Annual impairment test of goodwill at 31 December 2019 and at 31 December 2020

The Group carried out annual impairment tests on goodwill (€32,203 thousand at 31 December 2020 unchanged compared to 31 December 2019 and at 1 January 2019 see section 18.1.1.1 note 3 of the Registration Document) at the end of the financial years presented.

For the purposes of goodwill impairment tests, the Group is divided at the end of the financial years into four cash-generating units ("CGUs") or groups of CGUs, which generally correspond to a company.

The key assumptions used by the Company at 31 December 2020 and at 31 December 2019 are based on:

- Estimates of clinical trial development cycles, medical device release dates and market penetration. To this end:
    - The Company relied on external studies and publications to determine the various operational assumptions,
    - The Company took into account the possibility of the arrival of new entrants during the period in question to determine the flows generated by the medical devices;
- Establishing partnerships: the Company is studying different scenarios in its search for partnerships to license the Kardiozis technology. As at 31 December 2020, the IFRS 5 criteria were not met;
- Discount rates (WACC) applied to forecasts of around 12% for all CGUs;
- Perpetual growth rates of the operating normative flow beyond the ten-year projection of around 2%.

As at 31 December 2020 and 31 December 2019, based on internal valuations, the Group concluded that the recoverable amounts of the CGUs tested exceeded their carrying amounts. The Group's management believes that no reasonable change in the key assumptions mentioned above would result in the recoverable amounts of the CGUs being significantly lower than their carrying amounts.

In particular:

- an increase in the discount rate of 100 basis points would not give rise to a risk of impairment;
- a decrease in long-term growth rates of 100 basis points would not give rise to a risk of impairment;
- a one-year delay in the market launch date and a decrease in revenue or market penetration estimates by 10% would not generate any risk of impairment.

Impairment test of depreciable assets at 31 December 2019 and at 31 December 2020

Depreciable fixed assets are mainly made up of technologies contributed by the Subsidiaries at the time of the creation of the Company, the net book value of which amounted to €22,497 thousand at 31 December 2020 and €24,354 thousand at 31 December 2019 (see section 18.1.1.1 note 4.1 of the Registration Document).

The minor delays in the implementation of the Company's clinical programs in 2020 due to the Covid-19 health crisis (see section 18.1.1.1 note 2.6 of the Registration Document) were not considered to be a significant indication of impairment.

The Company did not identify any indications of impairment as at 31 December 2019.

Provision for disputes

As indicated in section 18.6 of the Registration Document, the Company is the subject of legal proceedings with Implantica Marketing Limited.

As of 31 December 2019 and 31 December 2020, the Company did not record any provisions for risks and charges in respect of this dispute.

Repayable advances for "MIVANA project" and "PIAVE Artus project"

The valuation of additional payments did not change significantly between 1 January 2019, 31 December 2019 and 31 December 2020. At this stage, the delays observed in the conduct of clinical trials had negligible effects on the calculation of accrued interest.

18.1.1.3. Consolidated historical financial information under French standards for the year ended 31 December 2018

Consolidated balance sheet

In thousands of euros

Asset	Note	31/12/2018
Goodwill	*4.1*	32,203
Intangible assets	*4.2*	26,209
Property, plant and equipment	*4.3*	362
Financial assets	*4.4*	22
Investments in equity affiliates	*4.4*	1,829
Total fixed assets		**60,626**
Inventories and work in progress		0
Trade receivables and related accounts	*4.5*	4
Other receivables and accruals	*4.6*	8,041
Cash and marketable securities	*4.8*	3,224
Total current assets		**11,268**
Total assets		**71,894**

Liabilities	Note	31/12/2018
Capital	*4.9*	11,900
Premiums		47,646
Consolidated retained earnings		251
Consolidated result		-11,248
Other (translation differences)		-40
Equity (Group share)		**48,509**
Minority interests		0
Total equity:		**48,509**
Other equity		**1,451**
Provisions for risks and contingencies	***4.10***	**26**
Deferred tax provisions for cons	***4.10***	**6,454**
Loans and financial liabilities	*4.11*	10,114
Trade payables and related accounts	*4.12*	3,573
Other operating liabilities	*4.12*	850
Other debts and accruals	*4.12*	916
Total debts		**15,454**
Total liabilities		**71,894**

Consolidated income statement

In thousands of euros

INCOME STATEMENT	Note	31/12/2018
Revenue	*5.1*	1,902
Other operating income	*5.2*	127
Total operating income		**2,029**
Purchases consumed raw materials and goods		0
Other purchases and external expenses		-11,213
Personnel expenses	*5.3*	-1,795
Taxes and duties		-28
Amortisation, depreciation and provisions	*5.4*	-1,988
Other operating expenses		-217
Total operating expenses		**-15,241**
Operating income (loss)		**-13,212**
Financial expenses		-487
Financial income		63
Financial income (loss)	***5.5***	**-424**
Current result of consolidated companies		**-13,636**
Exceptional income and expenses	*5.6*	91
Income taxes	*6.3*	2,297
Net income of consolidated companies		**-11,248**
Share of net income of equity affiliates		0
Amortisation of goodwill		0
Net income of all consolidated accounts		**-11,248**
Minority interests		2
Net income (Group share)		**-11,248**
Earnings per share		-0.95 €
Diluted earnings per share		-1.92 €

Cash flow statement

In thousands of euros

	CASH FLOW STATEMENT	31/12/2018
OPERATING ACTIVITIES	***OPERATING ACTIVITIES***	
	NET INCOME OF ALL CONSOLIDATED ACCOUNTS	**-11,248**
	Dividends received from equity affiliates	
	Other restatements with no impact on cash flow	
	Deterioration in earnings + Dilution effect	
	Amortisation, depreciation and provisions	1,610
	Reversals of depreciation and provisions	-65
	Capital gains and losses on disposals	
	Deferred taxes	-347
	Grants transferred to profit or loss	
	FREE CASH FLOW	**-10,050**
CHANGE IN WORKING CAPITAL REQUIREMENT	**Change in accrued interest**	**307**
	Inventory changes	
	Change in operating receivables	-517
	Change in other receivables	1,111
	Changes in operating liabilities	1,871
	Changes in other liabilities	-2,435
	Deferred expenses transfers	
	Liaison accounts	
	Prepaid income and deferred charges	379
	Foreign exchange gains & losses	
	CHANGE IN WORKING CAPITAL REQUIREMENT	**409**
	Net cash flow from operating activities	**-9,334**
INVESTMENT ACTIVITIES	***INVESTMENT ACTIVITIES***	
	Payments / acquisitions of intangible assets (1)	-14
	Payments / acquisitions of tangible assets (1)	-181
	Collection / disposal of tangible and intangible assets.	3
	Investment grants received	
	Financial property disbursements / acquisitions	-1,869
	Receipts / disposals of financial assets	
	Net cash on acquisition/disposal of subsidiaries	
	Net cash flow from investing activities	**-2,061**
FINANCING ACTIVITIES	***FINANCING ACTIVITIES***	
	Capital increases or contributions	3,243
	Dividends paid to shareholders of the parent	
	Dividends paid to minority shareholders	
	Changes in other equity	-500
	Loan subscriptions (1)	7,000
	Loan repayment	
	Net cash flow from financing activities	**9,743**
CHANGE IN CASH POSITION		**-1,653**
	Impact of exchange rate fluctuations	
	OPENING CASH POSITION (*)	**4,874**
	CLOSING CASH POSITION (*)	**3,221**

(1) Excluding acquisitions/finance leases

(*) Cash expressed here corresponds to its restrictive definition:

	31/12/2018
+ Liquidity	3,224
- Bank overdrafts	-2
Net cash position	3,221

Change in consolidated equity

In thousands of euros

Closing position	Share capital	Premiums	Consolidated retained earnings	Income for the financial year	Translation differences	Total equity (Group share)	Minority interests
Solde au 27/03/2018	**11,900**	**47,544**				**59,444**	
Appropriation of income							
Income for the financial year				**(11,248)**		**(11,248)**	
Dividends distributed							
Changes in share capital		103	251			354	
Acquisitions or disposals of treasury shares							
Change in translation differences					(40)	(40)	
Other							
Balance at 31/12/2018	**11,900**	**47,646**	**251**	**(11,248)**	**(40)**	**48,509**	

All amounts are expressed in thousands of euros.

1. Significant events

1.1. Highlights of the year

In early 2018, given the obvious potential synergies, the companies EPYGON SAS, KARDIOZIS SAS, KEPHALIOS SAS and MYOPOWERS MEDICAL TECHNOLOGIES FRANCE SAS were combined to create the Affluent Medical group. Transfers of all shares and convertible bonds issued by EPYGON, KEPHALIOS, KARDIOZIS and MYOPOWERS took place in favour of Affluent Medical. Affluent Medical was also transformed into a French Public Limited Company with a Board of Directors on 27 March 2018.

The Company announced on 25 April 2018 that it had obtained the "Innovative Company" qualification awarded by Bpifrance. This qualification, which recognises the innovative nature of the technologies developed by Affluent Medical and the dynamism of its R&D, enabled the company to open its capital to FCPI investments.

On 7 June 2018, the French Financial Markets Authority (AMF) affixed visa number 18-231 to the prospectus relating to the proposed IPO of the shares of Affluent Medical on the Euronext Growth market, consisting of the offering circular, registered under the number I.18-045, dated 28 May 2018, and an operation note. For the reasons mentioned above, the Group has decided to postpone its IPO.

On 4 September 2018, Affluent Medical announced that it had successfully completed its first OPTIMISE clinical trial for KALIOS, its fully adjustable mitral valve repair device. KALIOS was implanted in five patients between January and May 2018 by Professor Martin Andreas, Principal Investigator of this feasibility study, at the Vienna General Hospital (AKH). The initial results of the study show that the primary endpoint was met, thus confirming the surgical safety of KALIOS.

On 5 November 2018, Affluent Medical announced that it had successfully achieved the objectives of its first clinical trial conducted in women for ARTUS, its new artificial urinary sphincter for the treatment of stress urinary incontinence. This first step made it possible to successfully validate the surgical technique of implantation of the device by celioscopy and by open approach, and to verify its intraoperative safety.

On 14 November 2018, Affluent Medical announced that it had successfully completed the placement of its bond issue for a maximum amount of €12 million with Kreos Capital in three tranches of ordinary bonds of €4 million. The first tranche was mobilised upon signing. The second tranche is conditional upon achieving objectives and the third tranche depends on a deadline clause and must be used before 31 October 2019.

1.2. Significant events

No event likely to have a significant influence on the Group's assets and financial position occurred after the end of the financial year.

2. Activity(ies) and scope

2.1. Activity

Affluent Medical is a medical device (medtech) company that designs, develops, manufactures and plans to market advanced implantable prostheses with high medical potential.

The products developed by Affluent Medical are extremely innovative implantable prostheses. They are intended to care for critical pathologies in cardiovascular and urological care. The purpose of these technologies is to prolong life and improve the quality of life of patients.

The Company is currently developing four implants that can be implanted by minimally invasive interventional medicine, which offer innovative and effective solutions in each of their therapeutic areas. These implants should allow cardiac, aortic or urethral flows to be regulated by re-establishing patients' natural physiology, while simplifying the surgical procedure and reducing the total cost of short and long-term care. The products developed by Affluent Medical are intended to allow surgeons and physicians to insert implants precisely, rapidly and with an optimum level of safety.

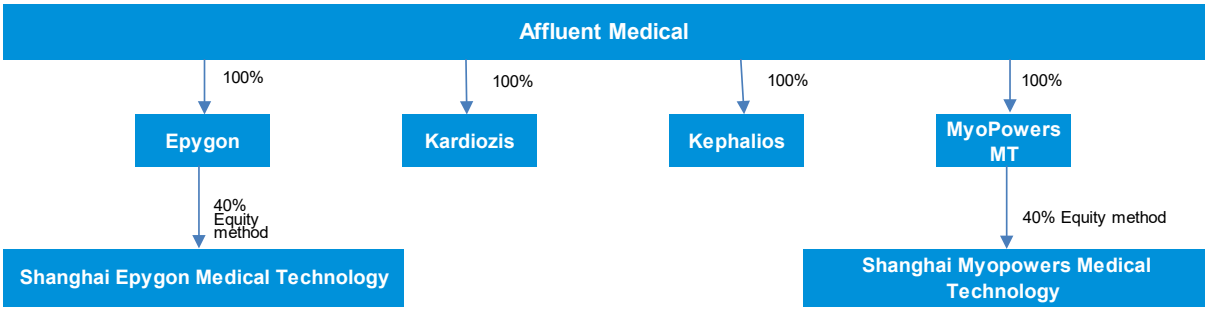
The creation of Affluent Medical follows the merger of four technologies from the Truffle Capital portfolio: KARDIOZIS, KALIOS, EPYGON and ARTUS:

- KARDIOZIS: The first endovascular prosthesis to prevent endoleaks in the aneurysm of the abdominal aorta, which affects 5 to 10% of men between the ages of 65 and 80;
- KALIOS: The first fully adjustable mitral valve repair medical device designed to effectively meet the needs of patients with mitral regurgitation, representing 1% of the global population;
- EPYGON: The first transcatheter mitral valve to restore natural blood flow and protect the ventricle. Currently, four million patients in Europe, the United States and Asia suffer from severe mitral valve regurgitation without being able to benefit from optimal therapies;
- ARTUS: The first electronically activated artificial sphincter to treat urinary incontinence. One in four adults suffers from stress urinary incontinence, with a high prevalence in women.

Affluent Medical is continuing pre-clinical and clinical trials for these devices, which will significantly improve the lives of patients and the actions of healthcare staff. They each meet a medical need that is currently unmet.

Affluent Medical intends to launch its first medical device in Europe in 2021, once it has obtained the CE marking. The other medical devices will be marketed in Europe between 2021 and 2022.

2.2. Organisational structure as at 31 December 2018



2.3. Entities

The entities included in the scope of the consolidated financial statements are presented below:

Companies	Legal form	SIREN No.	Headquarters	Method of consolidation 31/12/2018	% control 31/12/2018	% interest 31/12/2018
Epygon	SASU	539 455 238	5, rue de la Baume, 75008 Paris	Full consolidation	100%	100%
Kardiozis	SAS	532 628 336	5, rue de la Baume, 75008 Paris	Full consolidation	100%	100%
Kephalios	SAS	531 557 650	5, rue de la Baume, 75008 Paris	Full consolidation	100%	100%
MyoPowers MT	SAS	799 927 355	18, rue Alain Savary, 25000 Besançon	Full consolidation	100%	100%
Shanghai Myopowers Medical Technology				Equity method	40%	40%
Shanghai Myopowers Medical Technology				Equity method	40%	40%

On 28 October 2017, Epygon and MyoPowers entered into joint-venture agreements with Shanghai Zuquan Investment Management Company Limited under the terms of which the parties agreed to form Shanghai Epygon Medical Technology Co., Ltd, and Shanghai MyoPowers Medical Technology Co., Ltd (the "Joint Ventures"), for the purpose of researching, developing, and manufacturing and marketing in China (including continental China, Hong Kong, Macao and Taiwan) of medical devices developed or being developed by the subsidiaries Epygon and MyoPowers respectively, and which will be selected jointly by the parties.

In 2018, the Company created the two Joint Ventures in which it holds 40% of the share capital, and they have been consolidated by the equity method.

Investments in equity affiliates:

- Shanghai EPYGON Medical Technology (40%): €914 thousand
- Shanghai MYOPOWERS Medical Technology (40%): €914 thousand

2.4. Non-consolidated entities

The non-consolidated entities are as follows:

In thousands of euros

Companies	Legal form	SIREN No.	Head office	% interest 31/12/2018	VNC Equity interests	Amounts of shareholder equity	result last year ended
Epygon Italy	SRL		5, Via Ribes 10010 Colloretto Giacosa	100.00%	10	N/C	N/C

N/C - Information not known

This entity is not consolidated in accordance with Article L. 233-19 II 2° of the French Commercial Code. A subsidiary or an investment may be left outside the scope of consolidation when it is only, alone or with others, of marginal interest in relation to the objective of providing a true and fair view of the consolidated financial statements.

3. Accounting standards, consolidation methods, valuation methods and rules

3.1. Accounting standards

The consolidated financial statements of the Affluent Medical Group are prepared in accordance with the accounting rules and principles in force in France. The provisions of Regulation No. 99.02 of the French Accounting Regulation Committee.

3.2. Consolidation methods

3.2.1. Consolidation methods

The consolidated financial statements are based on the financial statements closed on 31 December 2018, over a period of twelve months. There is no comparison as this is the first year of the Company's creation.

Affluent Medical, Epygon and Kardiozis MyoPowers were fully consolidated. Shanghai MyoPowers Medical Technology and Shanghai Epygon Medical Technology have been consolidated using the equity method.

All major transactions between consolidated companies are eliminated.

Full consolidation consists of:

- including in the accounts of the consolidating company the items of the accounts of the consolidated companies, after any restatements;
- allocating equity and income between the interests of the consolidating company and the interests of other shareholders or partners known as "minority interests";
- eliminating book-entry transactions between the fully consolidated company and the other consolidated companies.

3.2.2. Elimination of intra-group transactions

In accordance with regulations, transactions between consolidated companies as well as internal results between these companies have been eliminated in the consolidated financial statements.

3.2.3. Goodwill

3.2.3.1. Concept of Goodwill:

In accordance with regulatory provisions, goodwill represents the difference between:

- the acquisition costs of the equity investments;
- the acquiring company's share of the total valuation of the assets and liabilities identified at the acquisition date.

Positive goodwill is recorded as a fixed asset.

Negative goodwill is recorded under provisions for risks and charges and is reversed over a period measured in the same way as positive goodwill.

In accordance with Regulation No. 99-02, Section 2110, the consolidating company has a period that ends upon the closing date of the first financial year following the acquisition, during which it may carry out the analyses and expert reports necessary for said valuation.

3.2.3.2. Amortisation or impairment of positive goodwill

The Group determines the useful life of goodwill, whether limited or not.

When there is no foreseeable limit to the period during which the goodwill will provide economic benefits to the Group, it is not amortised. In this case, an impairment test is performed each year.

When there is a foreseeable limit to its useful life at the time of acquisition, the goodwill is amortised on a straight-line basis over this period, or, if it cannot be determined reliably, over ten years.

3.2.4. Translation methods for foreign companies

As Affluent Medical subsidiaries are independent foreign companies, their financial statements have been translated using the closing rate method:

- balance sheet items are converted into euros at the closing rate;

- income statement items are translated at the average rate for the year;
- the resulting translation adjustment is included in the consolidated shareholders' equity under "Translation adjustments" and does not affect the result.

3.2.5. Year-end dates of consolidated companies

Companies are consolidated on the basis of their balance sheet as at 31 December 2018.

Valuation methods and rules

The principles and methods applied by the Affluent Medical Group are as follows:

3.2.6. Application of preferential methods

The application of the preferential methods of CRC 99-02 is as follows:

Application of preferential methods	YES NO-N/A	Note
Accounting for finance leases	N/A	N/A
Provisioning of retirement and similar benefits	YES	N/A
Spreading of bond issue costs and redemption premiums over the life of the bond	N/A	N/A
Recognition in profit or loss of asset/liability translation adjustments	YES	N/A
Recognition according to the percentage of completion of partially completed operations at year-end	N/A	N/A

3.2.7. Intangible assets

3.2.7.1. Valuation of intangible assets

Intangible assets are valued at their acquisition cost, after deduction of rebates, discounts and payment discounts, or at their production cost.

Impairment is recognised when the current value of an asset is lower than the net book value.

3.2.7.2. Amortisation periods for intangible assets

The methods and depreciation periods used are as follows:

Intangible assets	Method	Term
Concessions, patents, licenses	Straight-line	15 years
Software and software packages	Straight-line	15 years

3.2.8. Property, plant and equipment

Property, plant and equipment are valued at their acquisition cost, after deduction of rebates, discounts and payment discounts, or at their production cost.

Impairment is recognised when the current value of an asset is lower than the net book value.

The main depreciation methods and useful lives used are as follows:

Property, plant and equipment	Method	Term
Plant and equipment	Straight-line	5 to 10 years
Office equipment	Straight-line	5 to 10 years
IT equipment	Straight-line	3 years
Office furniture	Straight-line	10 years

3.2.9. Financial assets

This item consists mainly of deposits and guarantees paid, which do not need to be written down.

It also includes equity interests in an unconsolidated company. These are shown on the balance sheet at their acquisition cost.

3.2.10. Receivables and payables

Receivables and payables are valued at their nominal value.

An impairment of receivables is recognised by name when the inventory value is lower than the book value.

3.2.11. Provisions for retirement

Pension obligations were calculated using a discount rate of 1.57% and a salary increase rate of 2%. The social security tax rate used is 45%.

3.2.12. Cash and marketable securities

Marketable securities are valued at their purchase or subscription cost, excluding ancillary costs.

An impairment loss is recognised when the market price or the probable realisable value is lower than the purchase price.

3.2.13. Income tax expense

In accordance with the provisions of

CRC 99-02, the Group recognises deferred taxes in the event of:

- temporary differences between the tax and book values of assets and liabilities in the consolidated balance sheet;
- tax credits and tax loss carried forwards.

Deferred taxes are calculated using the liability method, applying the latest tax rate in force for each company.

In accordance with CRC 99-02, the amounts of deferred tax assets and liabilities are offset for the same tax entity.

Deferred tax assets are only taken into account if:

- their recovery does not depend on future results;
- or if their recovery is probable due to the existence of a taxable profit expected in the near future.

3.2.14. Provisions for risks and contingencies

Given the Group's business, the purpose of the provisions recorded is to cover risks or litigation of a one-off or latent nature. These items mainly relate to one-off disputes or deferred taxes.

3.2.15. Distinction between exceptional income and recurring income

Current income is income from activities in which the Company is engaged in the course of its business as well as ancillary activities that it undertakes on an ancillary basis or as a continuation of its normal activities.

Extraordinary income is the result of unusual events or operations that are not expected to occur frequently and regularly.

3.2.16. Earnings per share

Earnings per share correspond to the consolidated net income (Group share), based on the weighted average number of shares of the parent company outstanding during the financial year.

4. Notes on balance sheet items

The tables below are an integral part of the consolidated financial statements.

4.1. Positive goodwill

Affected companies	Changes in scope	EA appropriation	31/12/2018
Gross values			
EPYGON	20 322	9 600	10 722
KARDIOZIS	7 561	2 200	5 361
KEPHALIOS	16 519	8 100	8 419
MYOPOWERS	13 678	7 805	5 873
Total	**58 080**	**27 705**	**30 375**
amortisations			
EPYGON			
KARDIOZIS	61	61	
KEPHALIOS	278	278	
MYOPOWERS	1 488	1 488	
Total	**1 827**	**1 827**	
Net values			
EPYGON	20 322	9 600	10 722
KARDIOZIS	7 500	2 139	5 422
KEPHALIOS	16 241	7 822	8 697
MYOPOWERS	12 190	6 317	7 361
Total	**58 080**	**25 878**	**32 202**

A study was carried out for the allocation of goodwill. When the Group was created, internally developed technologies were recognised for an amount of €27,700 thousand in gross value and €25,878 thousand in net value.

	Kephalios	Kardiozis	Myopowers	Epygon	Total
Rémunération remise aux vendeurs	15 995	7 478	16 472	19 555	59 500
Capitaux propres retraités acquis	190	112	3 371	110	3 783
Ecarts d'acquisition avant Affectation	15 805	7 366	13 101	19 445	55 717
Affectation EA immobilisations incorporelles					
Approche méthode des revenus excédentaires	9 000	3 500	7 800	16 600	36 900
Approche méthode par les coûts	6 200	1 500	7 800	6 100	21 600
Immobilisations incoporelles affectées retenues	**8 100**	**2 200**	**7 800**	**9 600**	**27 700**
Ammortissement immobilisations incoporelles ouverture	278	61	1 488		1 827
Immobilisations incoporelles affectées	7 822	2 139	6 317	9 600	25 878
Impôts différés	(715)	(195)	(577)	(877)	(2 364)
Total	**8 698**	**5 422**	**7 361**	**10 722**	**32 203**

FR	EN
Kephalios	Kephalios
Kardiozis	Kardiozis
Myopowers	MyoPowers
Epygon	Epygon
Total	Total
Rémunération remise aux vendeurs	Compensation paid to sellers
Capitaux propres retraités acquis	Acquired adjusted equity capital
Ecarts d'acquisition avant Affectation	Goodwill before Allocation
Affectation EA immobilisations incorporelles	Allocation of EA intangible assets
Approche méthode des revenus excédentaires	Surplus revenue method approach
Approche méthode par les coûts	Cost-based approach
Immobilisations incorporelles affectées retenues	Allocated intangible assets retained
Amortissement immobilisations incorporelles ouverture	Amortisation of opening intangible assets
Immobilisations incorporelles affectées	Allocated intangible assets
Impôts différés	Deferred taxes

4.2. Intangible assets

Intangible assets are valued at their acquisition or production value.

Amounts in thousands of euros	Changes in scope	Increases	Decreases	31/12/2018
Gross values				
Goodwill	2 612	25 892		28 505
Intangible assets				
Business capital				
Advances and prepayments				
Total	**2 612**	**25 892**		**28 505**
amortisations				
Goodwill				
Intangible assets	791	1 505		2 295
Business capital				
Advances and prepayments				
Total	**791**	**1 505**		**2 295**
Net values				
Goodwill				
Intangible assets	1 822	24 387		26 209
Business capital				
Advances and prepayments				
Total	**1 822**	**24 387**		**26 209**

Technologies developed internally were recognised for an amount of €25,892 thousand following the allocation of goodwill. These internally developed technologies were valued using the discounted cash flow method, taking into account the estimated lifetime of the technologies concerned. Depreciation charges for this intangible asset will be recognised in profit or loss under the item “Depreciation, amortisation and provisions”.

The method used to determine goodwill and allocated intangible assets corresponds to the difference between the acquisition cost of the securities and the total valuation of the assets and liabilities identified at the acquisition date.

4.3. Property, plant and equipment

Property, plant and equipment are recorded on the balance sheet at their acquisition or production cost, excluding any financial expenses.

Amounts in thousands of euros	Changes in scope	Increases	Decreases	31/12/2018
Gross values				
Land				
Buildings				
Plant and equipment	291	130	4	418
Other tangible assets	57	51		108
Other leased tangible assets				
Property, plant and equipment in progress				
Advances and prepayments				
Total	**349**	**181**	**4**	**526**
amortisations				
Land				
Buildings				
Plant and equipment	65	61	1	125
Other tangible assets	21	18		39
Other leased tangible assets				
Property, plant and equipment in progress				
Advances and prepayments				
Total	**86**	**79**	**1**	**164**
Net values				
Land				
Buildings				
Plant and equipment	227	69	3	293
Other tangible assets	36	33		69
Other leased tangible assets				
Property, plant and equipment in progress				
Advances and prepayments				
Total	**263**	**102**	**3**	**362**

4.4. Financial assets

Amounts in thousands of euros	Changes in scope	Increases	Decreases	31/12/2018
Gross values				
Equity interests	10			10
Receivables from equity interests				
Loans				
Other financial assets	12			12
Investments in equity affiliates		1,829		1,829
Total	**22**	**1,829**		**1,851**
Depreciation				
Equity interests				
Receivables from equity interests				
Loans				
Other financial assets				
Total				
Net values				
Equity interests	10			10
Receivables from equity interests				
Loans				
Other financial assets	12			12
Total	**22**	**1,829**		**1,851**

Financial assets include equity interests in the non-consolidated company Epygon Italie. These are shown on the balance sheet at their acquisition cost (see Note 2.4 "*Conversion method*").

An impairment loss may be recognised when the inventory value of the investments, including the share of net assets, falls below their acquisition cost.

On 28 October 2017, Epygon and MyoPowers entered into joint-venture agreements with Shanghai Zuquan Investment Management Company Limited under the terms of which the parties agreed to form Shanghai Epygon Medical Technology Co., Ltd, and Shanghai MyoPowers Medical Technology Co., Ltd (the "Joint Ventures"), for the purpose of researching, developing, manufacturing and marketing in China (including continental China, Hong Kong, Macao and Taiwan) of medical devices developed or being developed by the subsidiaries Epygon and MyoPowers respectively, and which will be selected jointly by the parties.

In 2018, the Company created the two Joint Ventures in which it holds 40% of the share capital, and they have been consolidated by the equity method.

Investments in equity affiliates:

- Shanghai EPYGON Medical Technology (40%): €914 thousand
- Shanghai MYOPOWERS Medical Technology (40%): €914 thousand

4.5. Trade receivables and related accounts

Receivables breakdown by maturity as follows:

Amounts in thousands of euros	Gross total	Maturities			Depreciation	Net total
		Less than 1 year	More than 1 year	More than 5 years		
Trade receivables and related accounts	4	4				4
Total	**4**	**4**				**4**

Receivables and payables are valued at their nominal value.

4.6. Other receivables and accruals

Amounts in thousands of euros	Changes in scope	Provisions	Reversals	31/12/2018
Depreciation of other operating receivables	404			404
Total	**404**			**404**

Nature	Gross total	Maturities			Depreciation	Net total
		Less than 1 year	More than 1 year	More than 5 years		31/12/2018
Receivables related to equity investments						
Other financial assets	12	7		5		12
Total non-current receivables	**12**	**7**				**12**
Advances and prepayments on orders						
Deferred tax assets	4,437	4,437				4,437
Other receivables	3,658	3,658			404	3,254
Prepaid expenses	350	350				350
Total other operating receivables	**8,445**	**8,445**			**404**	**8,041**

Impairment method for receivables: a provision for impairment of receivables is made by name when the inventory value is lower than the book value.

Other receivables amounting to €3,658 thousand consist of the following items:

- VAT receivables: €1,057 thousand
- Tax receivables on corporate tax: €1,967 thousand, mainly the RTC for the financial year 2018 for a total amount of €1,951 thousand.
- Grant to be received as part of the PSPC MIVANA project: €404 thousand.
- Miscellaneous: €230 thousand

Following the allocation of goodwill, deferred tax assets on tax loss carried forwards were taken into account for an amount of €4,430 thousand since their recovery does not depend on future results, but they are retained in the amount of the deferred taxes already recognised and capped in accordance with tax rules, to the maximum of tax loss carried forwards that can be used each year to determine taxable income.

4.7. Impairments on current assets

Impairment of current assets breaks down according to:

Amounts in thousands of euros	Changes in scope	Provisions	Reversals	31/12/2018
Depreciation of other operating receivables	404			404
Total	**404**			**404**

The receivable relating to grants to be received recognised in previous years in the PSPC MIVANA project was written down at full value over the course of the year 2018 pending the achievement of the contractual objectives.

4.8. Cash and cash equivalents

Cash and cash equivalents	Gross book value	Depreciation	Net values 31/12/2018
Marketable securities - cash equivalent			
Treasury shares			
Cash assets	3,224		3,224
Financial instruments			
Total	**3,224**		**3,224**

4.9. Composition of share capital

Affluent Medical was incorporated on 23 February 2018 under the legal form of a single-member simplified joint stock company (SASU). By a decision of the sole shareholder of 27 March 2018, it was decided to change the legal form of the company into a French *Société Anonyme* (SA) as well as the contribution of the shares of the various subsidiaries.

The share capital of Affluent Medical SA after the contribution of subsidiaries' securities is made up of 11,899,967 shares (4,049,423 ordinary shares and 7,850,544 preferred shares) with a par value of €1).

The main terms and conditions of the A shares are as follows:

- Pre-emptive distribution right in the event of a distribution of any kind whatsoever and right of preferential distribution of the sale price, enabling their holders to receive the subscription price of the Contributed A Shares or of the A Shares issued as a priority after the Contribution they hold;
- Right of permanent representation on the Board of Directors;
- Right to convene meetings of the Board of Directors;
- Specific law relating to quorum and majority rules for the Board of Directors;
- Enhanced right to information and audit rights.

As at 31 December 2018, the total amount of shareholders' equity (income included) was **€48,508,590**

4.10. Provisions for risks and contingencies

Provisions for risks and charges break down as follows:

Cash and cash equivalents	Gross book value	Depreciation	Net values 31/12/2018
Marketable securities - cash equivalent			
Treasury shares			
Cash assets	3,224		3,224
Financial instruments			
Total	**3,224**		**3,224**

MYOPOWERS had been the subject of a tax audit covering the years 2014 to 2016. The company had provisioned for 50% of the RTC in the 2017 financial statements. This provision was fully reversed in the 2018 financial year. The final amount of the tax adjustment was €829 and only concerned 2014.

4.10.1. Deferred tax liabilities

Deferred tax liabilities of €6,793 thousand arise from the temporary difference between the carrying amount of the taxable assets. Intangible assets allocated as part of the allocation of goodwill will only give rise to tax deductions lower than their carrying amount, resulting in a deduction either at the time of the sale of the asset or at the time of its use at the rate of depreciation ("tax value" of the asset less than its "book value").

4.11. Loans and financial liabilities

4.11.1. Type and maturity of borrowings and financial debt

Financial debts can be broken down by maturity as follows:

Amounts in thousands of euros	31/12/2018	Less than 1 year	1 to 5 years
Convertible bond loans	5,850		5,850
Other bond loans			
Loans and other borrowings from financial institutions	3,872	687	3,185
Profit sharing liabilities			
Borrowings arising from finance leases			
Total bank and finance lease borrowings	**9,722**	**687**	**9,035**
Other financial liabilities			
Total borrowings and other financial liabilities			
Bank overdrafts	2	2	
Accrued interest not yet due	390	390	
Total bank overdrafts and accured interest	**392**	**392**	
Total borrowings and financial liabilities	**10,114**	**1,079**	**9,035**

Pursuant to its decisions dated 27 March 2018, the Company's sole partner decided to:

(i) issue a total of 2,850 thousand bonds convertible into shares with a par value of €1 to remunerate the bonds convertible into shares that were contributed to the Company under the Contribution (the **2018 CB** issue comprising 750 thousand CB 2018-1, 400 thousand CB 2018-2, 1,200 thousand CB 2018-3, and 500 thousand CB 2018-4). The term of the convertible bonds is four (4) years (as from the date of issue of the convertible bonds contributed to the Company and in remuneration of which the CB 2018-1, CB 2018-2, CB 2018-3 and CB 2018-4 were issued) and they earn annual interest of six percent (6%). Interest will be paid at the Company's choosing, either (i) on each anniversary of the bonds' issue date or (ii) on the date on which the bonds will be redeemed or converted. Except in the event of early redemption, the 2018 CB are convertible, if their holders so wish, in the event of specific events (such as the sale of all Company shares or assets, the raising of funds or the admission to trading of the Company's shares on a regulated or organised market) or, if the holders prefer, after a two-year period following the issue date of the convertible bonds that were the subject of the Contribution. The conversion ratio of the 2018 CB is based on the ratio set under the terms and conditions of the convertible bonds contributed under the Contribution. As and when the Company's shares are admitted for trading on the Euronext Growth market, the 2018 CB will be converted into common shares based on a ratio previously agreed between the subscribers and the Company, resulting in the issuance of 742,457 new common shares.

(ii) delegate to the Board of Directors, for an eighteen-month period, the authority to issue a bond in a maximum nominal amount of €5 million through the issuance of 5 million bonds convertible into common shares with a par value of €1 (the "**Financing CB**"). The Board of Directors implemented this authority pursuant to its decisions dated 9 April 2018 and issued a bond in an amount of €3 million through the issue of 3 million Financing CB with a par value of €1. The bond's term was set at 5 years as from the date of issuance and the Financing CB bear interest at an annual rate of 6%. Holders of Financing CB may request the redemption or conversion of said Financing CB on their maturity date. Furthermore, holders may request the early redemption or conversion of the Financing CB if certain events occur (such as the sale of all Company shares or assets, the raising of funds in a maximum amount of €5 million or the admission to trading of the Company's shares on a regulated or organised market) or, if the holders prefer, after a two-year period following the issuance date of the Financing CB. The conversion ratio is set at 5 Financing CB to 1 Company share, with the exception of conversions resulting from the raising of funds or admission to trading of the Company's shares on a regulated or organised market, for which the conversion ratio will be based on the share price used for the raising of funds or the admission to trading of the Company's shares on a regulated or organised market, less a discount.

On 2 November 2018, Affluent Medical completed the placement of its bond issue for a maximum amount of €12 million with Kreos Capital comprising three tranches of ordinary bonds of €4 million each. The first tranche was mobilised at signature for €4 million. The second tranche is conditional upon achieving objectives and the third tranche depends on a deadline clause and must be used before 31 October 2019. The bond's term was set at 42 years as from the date of issue and the Financing CB bear interest at an annual rate of 10%.

4.11.2. Change in borrowings and financial debt

Amounts in thousands of euros	Changes in scope	Increase	Decrease	31/12/2018
Convertible bond loans	2 850	3 000		5 850
Other bond loans				
Loans and other borrowings from financial institutions		4 000	128	3 872
Profit sharing liabilities				
Borrowings arising from finance leases				
Total bank and finance lease borrowings	**2 850**	**7 000**	**128**	**9 722**
Other financial liabilities	336		336	1
Total borrowings and other financial liabilities	**336**		**336**	**1**
Bank overdrafts	1	1		2
Accrued interest not yet due	67	323		390
Total bank overdrafts and accrued interest	**68**	**324**		**392**
Total borrowings and financial liabilities	**3 255**	**7 324**	**464**	**10 115**

4.12. Trade and other payables

Other current liabilities include the following items:

Amounts in thousands of euros	31/12/2018	Less than 1 year	1 to 5 years
Convertible bond loans	5,850		5,850
Other bond loans			
Loans and other borrowings from financial institutions	3,872	687	3,185
Profit sharing liabilities			
Borrowings arising from finance leases			
Total bank and finance lease borrowings	**9,722**	**687**	**9,035**
Other financial liabilities			
Total borrowings and other financial liabilities			
Bank overdrafts	2	2	
Accrued interest not yet due	390	390	
Total bank overdrafts and accured interest	**392**	**392**	
Total borrowings and financial liabilities	**10,114**	**1,079**	**9,035**

Other debts of €907 thousand consist mainly of:

- RTC pre-financing for €445 thousand
- Shareholder current account (including interest) for €436 thousand

5. Income statement items

5.1. Revenue breakdown

Revenue	31/12/2018	%
Miscellaneous services	7	0.37%
Revenue from licence agreement	1,895	99.63%
Total	**1,902**	

The revenue recorded of €1,895 thousand relates to the licensing agreements signed with the Chinese partner Shanghai Zuquan Investment Management Company Limited for the joint ventures Shanghai Epygon Medical Technology Co., Ltd, and Shanghai MyoPowers Medical Technology Co., Ltd. For the performance of these contracts, the subsidiaries grant the Joint Ventures the exclusive right to use their patents and know-how to develop, manufacture and market the selected products only in China.

5.2. Other operating income

Amounts in thousands of euros	31/12/2018
Stored production	0
Operating grants	68
Amortisation reversals and operating provisions	0
Other operating income	57
Transfer of operating expenses	1
Total	**127**

5.3. Personnel expenses

Amounts in thousands of euros	31/12/2018
Gross wages	1,381
Social security charges	414
Employee participation	0
Total	**1,795**

5.4. Amortisation, depreciation and provisions

The amount of amortisation, depreciation and provisions included in operating income can be broken down as follows:

Amounts in thousands of euros	31/12/2018
Operating depreciation charges	1,583
Depreciation on finance leases	
Provisions and operating depreciation	404
Total	**1,988**

Allocation of €1,294 thousand following the allocation of EA to intangible assets. Affected assets are depreciated over nine months over the year, the date of creation of the Group.
€404 thousand were recognised for the impairment of grants receivable recognised in previous years for Project MIVANA (see Section 4.6).

5.5. Financial income (loss)

Financial income breaks down as follows:

Amounts in thousands of euros	31/12/2018
Financial income	
Other investment income	
Revenue from receivables and marketable securities	
Currency gains	3
Reversals of provisions and expense transfers	
Net income on the sale of marketable securities	
Other financial income	61
Total	**63**
Financial expenses	
Provisions	
Interest and similar expenses	424
Currency losses	63
Net expenses on sale of marketable securities	
Other financial expenses	
Total	**487**
Financial income (loss)	**(424)**

The interest of €424 thousand breaks down as follows:

- Interest on bonds -€302 thousand
- Interest on Kreos Capital loan -€67 thousand
- Interest on shareholders' current accounts -€29 thousand
- Interest on RTC pre-financing -€20 thousand
- Miscellaneous interest -€6 thousand

5.6. Exceptional income/expenses

Non-recurring income breaks down as follows:

Amounts in thousands of euros	31/12/2018
Exceptional income	
Non-recurring income from operations	53
Exceptional income from previous years	
Exceptional income on equity transactions	
-On disposal of intangible assets	3
-On disposal of tangible assets	
-On disposal of other financial assets	
Other exceptional income	
Reversal of exceptional provisions	65
Exceptional expense transfers	
Deterioration in earnings N-1	
Total	**121**
Exceptional expenses	
Non-recurring expenses on operations	
Exceptional expenses from previous years	1
Exceptional expenses on capital transactions	
-On disposal of intangible assets	3
-On disposal of tangible assets	
- On disposal of consolidated shares	
-On disposal of other financial assets	
Extraordinary depreciation and provisions	26
Total	**30**
Exceptional income/expenses	**91**

MYOPOWERS had been the subject of a tax audit covering the years 2014 to 2016. The Company had provisioned for 50% of the 2014 RTC in the 2017 financial statements for €65 thousand. This provision was fully reversed in the 2018 financial year. The final amount of the tax adjustment was €829 and only concerned 2014.

6. Corporate tax

6.1. Breakdown of balance sheet items

Amounts in thousands of euros

Deferred tax assets	Changes in scope	Effect on reserves	Effect on income	Other changes	31/12/2018
Organic & effort construction					
Profit sharing					
Retirement benefits			7		7
Inventory margins					
Application for patent approval following GW allocation					
Deferred tax assets capitalised on tax loss carryforwards	4,430				4,430
Deferred tax assets					
Other					
Offsetting of deferred tax assets and liabilities					
Total	**4,430**		**7**		**4,437**

Deferred tax liabilities	Changes in scope	Effect on reserves	Effect on income	Other changes	31/12/2018
Deductible intra-group provisions					
Regulated provisions					
Valuation difference					
Application for patent approval			340		340
Deferred tax liabilities capitalised on intangible assets	(6,794)				(6,794)
Offsetting of deferred tax assets and liabilities					
Total	**(6,794)**		**340**		**(6,454)**

Impact on consolidated reserves					
Impact on consolidated income			**347**		**10,891**

6.2. Non-capitalised tax losses

Deferred tax assets are only taken into account if:

- their recovery does not depend on future results;
- or if their recovery is probable due to the existence of a taxable profit expected in the near future.

Deferred tax loss carried forwards tax assets may well be recorded up to the amount of deferred tax liabilities as long as the reversal schedule is compatible.

Ordinary losses can be carried forward indefinitely but are only attributable each year to up to 50% of the profit realised after taking into account an annual ceiling of €1.25 million. Losses on activities amounted to €16,875 thousand, applying an average tax rate of 26% over 15 years.

6.3. Breakdown of corporate income tax

Amounts in thousands of euros	31/12/2018
Corporate tax	(1,951)
Deferred taxes	(347)
Income taxes	**(2,297)**

The tax income of €1,951 thousand relates to receivables related to the various research tax credits for the Group.

6.4. Tax proof

Tax rationalisation	31/12/2018
Net income of all consolidated accounts	(11,248)
Reversal of amortisation charges Depreciation on EA	*0*
Net income of consolidated companies	**(11,248)**
Income taxes **(1)**	(2,297)
Net income before tax	*(13,546)*
<Theoretical tax at current rate, 26%> **(2)**	*(3,556)*
Tax difference (1) - (2)	**1,259**

Explanations	Expenses	Income
Permanent differences - social	27	
Permanent differences - consolidation		
Tax credit		1,950
Deferred tax not capitalised / losses for the y	3,182	
Difference in social tax rate		
Total	**3,209**	**1,950**
Net difference	**1 59**	

7. Other information

7.1. Off-balance sheet commitments

7.1.1. Commitments given

The Group has not identified any significant off-balance sheet commitment.

7.1.2. Commitments received

The Group has not identified any significant off-balance sheet commitment.

7.2. Average number of employees

The average number of employees in fully consolidated companies is 34 employees.

7.3. Statutory Auditors' fees

The Statutory Auditors' fees for the financial year 2018 break down as follows:

- PwC: €108,995
- LCA AUDIT: €8,791
- Total: €117,786

7.4. Executives

7.4.1. Compensation allocated to members of the administrative and management bodies

This information would result in an individual amount being disclosed.

18.1.2. Change of accounting reference date

N/A

18.1.3. Accounting standards

The Group's consolidated financial statements have been prepared in accordance with IFRS for the financial years ended 31 December 2019 and 2020.

The Group's consolidated financial statements have been prepared in accordance with French accounting standards for the financial years ended 31 December 2018.

18.1.4. Change in accounting standards

The Group's consolidated financial statements have been prepared in accordance with international accounting standards (IFRS) for the financial years ended 31 December 2019 and 2020 with a view to the proposed admission of the Company's shares on the Euronext Paris regulated market.

18.1.5. Financial information prepared in accordance with national accounting standards

The Group's consolidated financial statements have been prepared in accordance with French accounting standards for the financial year ended 31 December 2018.

18.1.6. Consolidated financial statements

Please refer to Section 18.1.1 "*Consolidated historical financial information for the financial years ended 31 December 2018, 2019 and 2020*".

18.1.7. Date of latest financial information

Financial year ended 31 December 2020

18.2. Interim and other financial information

N/A

18.3. Audit of historical annual information

18.3.1. Statutory Auditors' audit report on the Group's consolidated financial statements prepared in accordance with IFRS for the financial years ended 31 December 2019 and 2020

This is a translation into English of the statutory auditors' report on the consolidated financial statements of the Company issued in French and it is provided solely for the convenience of English speaking users.
This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

Statutory Auditors' report on the "consolidated financial statements" prepared in accordance with IFRS for the years ended 31 December 2019 and 2020

PricewaterhouseCoopers Audit
63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

Expertea Audit
60, boulevard Jean Labro
13016 Marseille

Statutory Auditors' report on the consolidated financial statements

Financial years ended 31 December 2019 and 2020

To the members of the Board of Directors
Affluent Medical
Les Pleiades III, Building B
320, avenue Archimède
13100 AIX EN PROVENCE

In our capacity as Statutory Auditors of Affluent Medical and in accordance with the Delegated Regulation (EU) 2019/980 supplementing Regulation (EU) 2017/1129 in the context of the proposed public offering and the admission of capital securities to be traded on the regulated market of Euronext Paris, we have audited the accompanying consolidated financial statements of Affluent Medical for the financial years ended 31 December 2019 and 31 December 2020, prepared for the purposes of the prospectus and presented in accordance with the IFRS as adopted by the European Union.

Due to the global crisis related to the Covid-19 pandemic, the "consolidated financial statements" have been prepared and audited under specific conditions. Indeed, this crisis and the exceptional measures taken in the context of the state of sanitary emergency have had numerous consequences for companies, particularly on their operations and their financing, and have led to greater uncertainties on their future prospects. Those measures, such as travel restrictions and remote working, have also had an impact on the companies' internal organization and the performance of the audits.

It is in this complex and evolving context that these consolidated financial statements were prepared under the responsibility of the Board of Directors. Our role is to express an opinion on these "consolidated financial statements" based on our audit.

We conducted our audit in accordance with professional standards applicable in France and the professional guidance issued by the French Institute of statutory auditors (Compagnie nationale des commissaires aux comptes) relating to this engagement. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the "consolidated financial statements" are free from material misstatement. An audit involves performing procedures, on a test basis or by selection, to obtain audit evidence about the amounts and disclosures in the "consolidated financial statements". An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as the overall presentation of the "consolidated financial statements". We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

In our opinion, the "consolidated financial statements" prepared for the purposes of the prospectus give a true and fair view of the financial position and assets and liabilities of the as at 31 December 2019 and 31 December 2020 and of the results of its operations for the years then ended 31 December 2019 and 31 December 2020 in accordance with the International Financial Reporting Standards as adopted in the European Union.

Without qualifying the opinion expressed above, we draw your attention to the matter set out in Note 2.1 "Principles applied to the preparation of the financial statements" in the notes to the consolidated financial statements, which specifies the assumptions underlying the application of the going concern principle for the closing of the consolidated financial statements and the measures implemented by the management to ensure the financing of the company.

Neuilly-sur-Seine and Marseille, on 9 April 2021

PricewaterhouseCoopers Audit	Expertea Audit
Thierry Charron	Jérôme Magnan

18.3.2. Statutory Auditors' audit report on the Group's consolidated financial statements prepared in accordance with French standards for the financial year ended 31 December 2018

This is a translation into English of the statutory auditors' report on the consolidated financial statements of the Company issued in French and it is provided solely for the convenience of English speaking users.
This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

Statutory Auditors' audit report on the "consolidated financial statements" prepared in accordance with accounting rules and principles applicable in France for the financial year ended 31 December 2018

Statutory Auditors' report on the consolidated financial statements

Year ended 31 December 2018

To the Annual General Meeting
Affluent Medical
5, rue de la Baume
75008 Paris

Opinion

In compliance with the engagement entrusted to us by your General Meeting, we audited the accompanying consolidated financial statements of AFFLUENT MEDICAL ("The Group") for the year ended 31 December 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 31 december 2018 and of the results of its operations for the year then ended in accordance with French accounting principles.

Basis of opinion

Audit Framework

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the *Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements* section of our report.

Independence

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from 1 January 2018 to the date of our report and specifically we did not provide any prohibited non-audit services referred to in the French Code of ethics (code de déontologie) for statutory auditors.

Justification of assessments

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 following assessments that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period.

These assessments were addressed in the context of our audit of the consolidated financial statements as a whole, approved in the context described above, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the consolidated financial statements.

Accounting estimates:

Goodwill and intangible assets are tested for impairment as soon as there is an indication of loss in value and at least once every twelve months as described in Notes 3.2.3.1 "*Concept of Goodwill*", 3.2.3.2 "*Amortization or impairment of positive goodwill*" and 3.2.7.1 "*Valuation of intangible assets*".

We assessed the approaches used by the Affluent Medical Group, described in the notes, on the basis of the information available to date, and performed our procedures to verify the application of these approaches.

As part of our assessments, we verified the reasonable nature of these estimates.

Specific verifications

We have also performed, in accordance with professional standards applicable in France, the specific verification required by laws and regulations of the Group's information given in the 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.

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 French accounting principles 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 consolidated financial statements were approved by the Board of Directors.

Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements

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.

Prepared in Neuilly-sur-Seine, 24 May 2019

PricewaterhouseCoopers Audit

Thierry Charron

18.3.3. Other information contained in the Registration Document verified by the Statutory Auditors

N/A

18.3.4. Financial information included in the Registration Document not taken from the Group's audited financial statements

N/A

18.4. Pro forma financial information

N/A

18.5. Dividend policy

18.5.1. Dividend policy

The Company is positioned as a growth stock and does not intend, as at the date of approval of the Registration Document, to adopt a regular dividend payment policy.

18.5.2. Dividends paid over the last three financial years

In respect of the last three financial years, the Company has not distributed any dividends.

18.6. Legal and arbitration proceedings

In a summons of 12 June 2019, the company Implantica Marketing Limited brought an action for patent infringement before the Paris Court of Justice against the Company and MyoPowers. The company claims that the development of the Artus medical device reproduces certain claims made by the French part of a European patent belonging to it, and seeks compensation for the damage it claims to have suffered. It therefore seeks an order that the Company and MyoPowers be ordered to pay the sum of €2 million in provisional damages and €500 thousand in respect of its alleged moral damage. The Company and MyoPowers have made several claims, notably to demonstrate the invalidity of the patent invoked by Implantica Marketing Limited and, consequently, the absence of infringement. In this regard, in a decision of 4 June 2020 ruling on an application for a provisional ban by Implantica Marketing Limited, the court admitted that there were serious doubts about the validity of the patent invoked, which also expired on 8 February 2021. Consequently, in its decision dated 4 June 2020, the court rejected Implantica Marketing Limited's application seeking an interim ban on the development of the Artus medical device pending a decision on the merits in the patent infringement case. Implantica was ordered to pay €50 thousand which has been paid. Since the decision of 4 June 2020, the proceedings on the merits have resumed: Implantica Marketing Limited reiterated its claims for damages mentioned above in submissions dated 11 January 2021; the Company and Myopowers responded *via* submissions dated 10 March 2021. The closing arguments are expected to be scheduled for June 2021.

In view of the above, no provision for the dispute was recorded in the financial statements.

The Group is also involved in other labour disputes that are not very significant.

To the best of the Group’s knowledge, at the date of approval of the Registration Document, there are no other administrative, criminal, judicial or arbitration proceedings pending or in which the Company and/or its Subsidiaries might be threatened, likely to have or having had a significant impact on the Group’s financial position or profitability over the last twelve months.

18.7. Significant change in financial position of the Group

N/A

19. ADDITIONAL INFORMATION

19.1. Share capital

19.1.1. Share capital amount

As at the date of this Registration Document, the share capital amounts to €15,256,824, divided into 15,256,824 fully paid-up shares with a par value of €1, comprised of 4,049,423 ordinary shares and 11,207,401 category A preferred shares.

All the category A preferred shares will be fully converted into ordinary shares, by decision of the General Meeting of 6 April 2021, with a ratio of one ordinary share for one A preferred shares, subject to the condition precedent of the admission of the Company's shares to trading on the Euronext Paris regulated market.

19.1.2. Non-equity securities

Refer to section 19.1.4 "Convertible securities, exchangeable securities or securities with warrants" of the Registration Document.

19.1.3. Number, book value and par value of shares held by or on behalf of the Company

As at the date of approval of this Registration Document, the Company held no treasury shares and no Company shares were held by a third party on its behalf.

The General Meeting of 6 April 2021 decided to grant the Board of Directors the authority – for a period of 18 months as from the date of the meeting and subject to the condition precedent of the admission of the Company's shares to trading on the Euronext Paris regulated market – to implement a share buyback program pursuant to the provisions of Article L. 22-10-62 of the French Commercial Code and EU Regulation No. 596/2014 of 16 April 2014 on market abuse and in accordance with the AMF General Regulations, under the following conditions:

Maximum number of shares that may be purchased: 10% of the total number of shares comprising the Company's share capital at the share buyback date. When shares are purchased in order to encourage trading and boost their liquidity, the number of shares included when calculating this 10% limit shall be equal to the number of shares purchased, less the number of shares resold over the term of the authorisation.

Purpose of share buybacks:

- to encourage the trading and liquidity of the Company's shares as part of a liquidity agreement to be entered into with an independent investment services provider, in accordance with an ethics charter recognised by the AMF; and/or to honour the obligations under share option plans, bonus share plans, employee savings plans or other share grants to employees of the Company or an associated business. This includes (i) the implementation of any Company stock option plan pursuant to the provisions of Articles L. 225-177 *et seq.* of the French Commercial Code, (ii) the grant of existing shares to employees under their employee profit-sharing plan and the implementation of any company savings plans as provided by law, including Articles L. 3332-1 to L. 3332-8 *et seq.* of the French Labour Code, and (iii) the grant of existing bonus shares as provided for under Articles L. 225-197-1 *et seq.* of the French Commercial Code; and/or

- to deliver shares following the exercise of rights attached to transferable securities giving rights to share capital through redemption, conversion, exchange, presentation of a warrant or any other means, in compliance with current regulations; and/or

- to cancel all or some of the shares thus purchased, subject to a specific resolution; and/or

- more generally, to carry out any transaction in accordance with current regulations.

Maximum purchase price: 300% (excluding acquisition costs) of the price per new share approved as part of the admission of the Company's shares to trading on the Euronext Paris regulated market, subject to adjustments to account the impact on the Company's capital of new transactions, particularly changes in the share's par value, capital increases through the capitalisation of reserves, the allocation of bonus shares, stock splits or reverse stock splits, distribution of reserves or any other assets, capital depreciation, or any other transaction relating to equity capital.

Maximum amount of funds that may be allocated to the buyback: €3 million**.**

Shares bought back in this way may be cancelled.

Note that the development and implementation of the share buyback program will be communicated in accordance with legal and regulatory provisions.

19.1.4. Convertible securities, exchangeable securities or securities with warrants

As at the date of this Registration Document, securities giving access to the Company's capital are as described in the tables below:

19.1.4.1. Share subscription warrants (BSAs)

	BSA-2018-1	BSA-2018-2	BSA-2018-4	BSA-2018-5	BSA-2020-1	BSA-2018 Kreos
Dates of the decisions of the General Meeting	27 March 2018				18 June 2020	26 October 2018
Date of the decisions of the Board of Directors	9 April 2018		23 October 2018		8 July 2020	26 October 2018
Total number of BSAs authorised	4,441,932 (common ceiling with the BSPCEs issued under the delegations put in place at the General Meeting of 27 March 2018)				850,000	400,000
Total number of BSAs granted	106,860	131,520	65,760	65,000	32,080	196,722
Number of BSAs subscribed	106,860	131,520	65,760	65,000	32,080	196,722
Total number of shares that may be issued when the BSAs are exercised, including the number that may be subscribed by:	106,860	131,520	65,760	65,000	32,080	(*Note 6*)
Corporate officers	1,644 ***(Note 1)***	131,520 ***(Note 2)***	32,880 ***(Note 3)***	-	32,080 ***(Note 5)***	0
Non-corporate officers	105,216	-	32,880	65,000	0	(*Note 6*)
Start date for exercising the BSAs	9 April 2018	9 April 2019	9 April 2019	According to the objective achievement schedule (*Note 4*)	8 July 2021	26 October 2018
Expiry date	10 years from the Board of Directors' issuance decision (i.e. midnight Paris time on 8 April 2028)	10 years from the Board of Directors' issuance decision (i.e. midnight Paris time on 8 April 2028)	10 years from the Board of Directors' issuance decision (i.e. midnight Paris time on 22 October 2028)	10 years from the Board of Directors' issuance decision (i.e. midnight Paris time on 22 October 2028)	10 years from the Board of Directors' issuance decision (i.e. midnight Paris time on 7 July 2030)	(*Note 6*)
Subscription price of the BSAs	€0.35 per BSA	€0.35 per BSA	€0.42 per BSA	€0.42 per BSA	€0.35 per BSA	€1 for all BSA 2018 Kreos share subscription warrants
Exercise price of the BSAs	€5	€5	€6.10	€6.10	€5.89	(*Note 6*)
Exercise conditions	All exercisable on their issue date *(Note 1)*	Exercisable based on a vesting schedule *(Note 2)*	Exercisable based on a vesting schedule *(Note 3)*	Exercisable based on the achievement of objectives (*Note 4*)	Exercisable based on a vesting schedule *(Note 5)*	(*Note 6*)
Number of BSAs cancelled or null and void	105,216	46,971	8,905	32,500	0	65.574 (*Note 6*)
Number of BSAs outstanding	1,644	84,549	56,855	32,500	32,080	131,148 (*Note 6*)

	BSA-2018-1	BSA-2018-2	BSA-2018-4	BSA-2018-5	BSA-2020-1	BSA-2018 Kreos
Total number of shares that may be subscribed when the BSAs are exercised	1,644	84,549	56,855	32,500	32,080	169,779 (*Note 6*)

At the date of approval of the Registration Document, the total number of BSAs amounts to 338,776 giving entitlement to 377,407 new shares of the Company.

Note 1: Each BSA-2018-1 share subscription warrant gives the right to subscribe (1) ordinary share. As the terms and conditions of the BSA-2018-1 do not provide for vesting conditions, all such BSAs shall be exercisable on their issuance date by the Board of Directors. The BSA-2018-1 exercisable on a given date will become null and void in the following scenarios:

- the failure to exercise the BSA-2018-1 share subscription warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSA-2018-1 holder is party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

The corporate officer as of the date of awarding of the BSA-2018-1 is Mr Christian Latrémouille who is no longer a corporate officer of the Company as of the date of approval of the Registration Document.

Note 2: Each BSA-2018-2 share subscription warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSA-2018-2 provide for the following vesting schedule:

- 1/4 of the issued BSA-2018-2 shall become exercisable on the last day of the calendar month in which the date of the first anniversary of the vesting starting date falls (i.e. 30 April 2019);
- 1/48th of the issued BSA-2018-2 shall become exercisable on the last day of each calendar month following the date mentioned in the above paragraph (i.e. the last day of each month as of 30 April 2019).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSA-2018-2 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.
The BSA-2018-2 share subscription warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to exercise the BSA-2018-2 share subscription warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSA-2018-2 holder is party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

The corporate officers who have subscribed for BSA-2018-2 are: Christian Latrémouille, José Da Gloria, Thierry Hebreteau and Reinhard Ambros who are no longer corporate officers of the Company as of the date of approval of the Registration Document.

Note 3: Each BSA-2018-4 share subscription warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSA-2018-4 share subscription warrants provide for the following vesting schedule:

- 1/4 of the issued BSA-2018-4 share subscription warrants shall become exercisable on the last day of the calendar month in which the date of the first anniversary of the vesting starting date falls (i.e. 30 October 2019);
- 1/48th of the issued BSA-2018-4 share subscription warrants shall become exercisable on the last day of each calendar month following the date mentioned in the above paragraph (i.e. the last day of each month as of 30 October 2019).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSA-2018-4 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.
The BSA-2018-4 share subscription warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to exercise the BSA-2018-4 share subscription warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSA-2018-4 holder is party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

The corporate officer who subscribed for the BSA-2018-4 is Jean-Michel Malbrancq who is no longer a corporate officer of the Company as of the date of approval of the Registration Document.

Note 4: Each BSA-2018-5 share subscription warrants gives the right to subscribe (1) ordinary share. The terms and conditions of the BSA-2018-5 share subscription warrants provide that the BSA 2018-5 will become exercisable, provided that no departure has occurred prior to the achievement of clinical objectives (as part of clinical studies on the Artus medical device) and regulatory objectives (obtaining CE marking for the Artus medical device). The Board of Directors has sole authority to assess whether or not the objectives have been

achieved. If an objective is not achieved before its deadline, the BSA-2018-5 share subscription warrants will automatically lapse. The Board of Directors may unilaterally decide to modify the definition of each of the objectives or the conditions for their achievement.
The BSA-2018-5 share subscription warrants exercisable on a given date will become null and void in the following scenarios:
- the failure to exercise the BSA-2018-5 share subscription warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSA-2018-5 holder is party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 5: Each BSA-2020-1 share subscription warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSA-2020-1 share subscription warrants provide for the following vesting schedule:
- 1/4 of the issued BSA-2020-1 share subscription warrants shall become exercisable on the last day of the calendar month in which the date of the first anniversary of the vesting starting date falls (i.e. 31 July 2021);
- 1/48th of the issued BSA-2020-1 share subscription warrants shall become exercisable on the last day of each calendar month following the date mentioned in the above paragraph (i.e. the last day of each month as of 31 July 2021).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSA-2020-1 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.
The BSA-2020-1 share subscription warrants exercisable on a given date will become null and void in the following scenarios:
- the failure to exercise the BSA-2020-1 share subscription warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSA-2020-1 holder is party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

The corporate officer having subscribed for the BSA-2020-1 is Dominique Carouge.

Note 6: The BSA-2018 Kreos share subscription warrants may be exercised until the first of the following three events occurs:
- the expiry of a period of ten years from the date of issue;
- the completion of one or more disposals of Company shares resulting in any person holding more than 80% of Affluent Medical's share capital and voting rights;
- the expiry of a period of five years from the date of the Company's IPO.

The number of exercisable BSA-2018 Kreos share subscription warrants is determined based on the number of bonds with a maximum unit amount of €4 million issued. Two of the three tranches were issued. The last tranche will not be issued; the number of exercisable BSA-2018 Kreos share subscription warrants is therefore 131,148 (refer to section 8.1.3 of the Registration Document).

In the event of a capital increase of the Company with a subscription price of less than €6.10 per share, the number of new shares issued by exercise of the BSA-2018 Kreos share subscription warrants may be adjusted upwards, within a maximum limit of 400 thousand new shares, by determining an allocation ratio R, such that R = 6.10/RP. RP corresponds to a minimum of between €6.10 and the lowest price per share used to carry out a capital increase between the date of issue and exercise of the BSA-2018 Kreos share subscription warrants, minus a 20% discount.

As at the date of approval of the Registration Document, since the allocation of the BSA-2018 Kreos share subscription warrants, the lowest subscription price per share used in the Company's capital increase is €5.89 per share, RP would then be equal to €4,712.

In the event of an IPO, a minimum share allocation ratio R_{MIN} will be determined such that R_{MIN} = 6.10/(MV-RP) with MV corresponding to the price set in the IPO.

The other BSA share subscription warrants will not give rise to adjustments in the context of the admission of the Company's shares to trading on the Euronext Paris regulated securities market.

Only a portion of the BSAs of the various plans presented above are exercisable on the date of the Registration Document. These are:

- 1,644 BSAs under the BSA 2018-1 plan granting the right to the same number of Company shares;
- 61,650 BSAs under the BSA 2018-2 plan granting the right to the same number of Company shares;
- 47,950 BSAs under the BSA 2018-4 plan granting the right to the same number of Company shares;
- 131,148 BSAs under the BSAKreos plan granting the right to 169,779 Company shares.

This corresponds to a total of 242,372 warrants which, in the event of their exercise, would grant entitlement to 281,023 Company shares.

19.1.4.2. Company founders' share warrants plan

	BSPCE-2018-1	BSPCE-2018-2	BSPCE-2018-3	BSPCE-2019-1	BSPCE-2019-2	BSPCE-2019-3
Dates of the decisions of the General Meeting	27 March 2018					18 September 2019
Date of the decisions of the Board of Directors	9 April 2018			10 July 2019		1 October 2019
Total number of BSPCEs authorised	4,441,932 (common ceiling with the BSA share subscription warrants issued under the delegations put in place at the General Meeting of 27 March 2018)					700,000
Total number of BSPCEs granted	1,364,526	1,035,721	1,159,025	150,000	300,600	200,400
Number of BSPCEs subscribed	1,364,526	1,035,721	1,159,025	150,000	300,600	200,400
Total number of shares that may be issued when the BSPCEs are exercised, including the number that may be subscribed by:	1,364,526	1,035,721	1,159,025	150,000	300,600	200,400
Corporate officers	59,184	427,441	295,921	0	300,600	200,400
Non-corporate officers	1,305,342	608,280	863,104	150,000	0	0
Start date for the exercise of the BSPCEs	9 April 2018	9 April 2018	Date on which the Board of Directors notes the achievement of the objectives set under the terms and conditions of the founders' share warrants (BSPCEs)	For 50%:10 July 2020 For 50%: on the date the Board of Directors determines that the objectives set in the terms and conditions of the founders' share warrants (BSPCEs) have been achieved	Date on which the Board of Directors notes the achievement of the objectives set under the terms and conditions of the founders' share warrants (BSPCEs)	1 October 2020
Expiry date	10 years from the Board of Directors' grant decision (i.e. midnight Paris time on 8 April 2028)			10 years from the Board of Directors' grant decision (i.e. midnight on 9 July 2029)		10 years from the Board of Directors' grant decision (i.e. midnight on 30 September 2029)
Exercise price of the BSPCEs	€5			€6.10		
Exercise conditions	(*Note 1*)	*(Note 2)*	(*Note 3*)	(*Note 4*)	(*Note 5*)	(*Note 6*)
Number of BSPCEs cancelled or null and void	83,844	600,067	830,223	12,500	0	0
Number of BSPCEs outstanding	1,280,682	435,654	328,802	137,500	300,600	200,400
Total number of shares that may be subscribed when the BSPCEs are exercised	1,280,682	435,654	328,802	137,500	300,600	200,400

	BSPCE-2020-2	BSPCE-2020-3	BSPCE-2020-4	BSPCE-2020-5
Dates of the decisions of the General Meeting	18 June 2020			
Date of the decisions of the Board of Directors	8 December 2020			
Total number of BSPCEs authorised	850,000			
Total number of BSPCEs granted	226,300	75,000	134,935	75,000
Number of BSPCEs subscribed	226,300	75,000	134,935	75,000
Total number of shares that may be issued when the BSPCEs are exercised, including the number that may be subscribed by:	226,300	75,000	134,935	75,000
Corporate officers	0	0	87,675	0
Non-corporate officers	226,300	75,000	47,260	75,000
Start date for the exercise of the BSPCEs	At the end of the first anniversary of the date of the Board of Directors' grant decision	Date on which the Board of Directors notes the achievement of the objectives set under the terms and conditions of the founders' share warrants (BSPCEs)		
Expiry date	10 years from the Board of Directors' grant decision (i.e. midnight on 7 December 2030)			
Exercise price of the BSPCEs	€5.89			
Exercise conditions	(*Note 7*)	(*Note 8*)	(*Note 9*)	(*Note 10*)
Number of BSPCEs cancelled or null and void	0	0	0	0
Number of BSPCEs outstanding	226,300	75,000	134,935	75,000
Total number of shares that may be subscribed when the BSPCEs are exercised	226,300	75,000	134,935	75,000

As of the date of approval of the Registration Document, the total number of BSPCEs is 3,194,873 granting entitlement to 3,194,873 new Company shares.

Note 1: Each BSPCE-2018-1 founders' share warrant gives the right to subscribe (1) ordinary share. As the terms and conditions of the BSPCE-2018-1 founders' share warrants do not provide for any vesting condition, all BSPCEs shall be exercisable on the date of their issue by the Board of Directors. The BSPCE-2018-1 founders' share warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to exercise BSPCE-2018-1 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2018-1 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 2: Each BSPCE-2018-2 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2018-2 founders' share warrants provide for the following vesting schedule:

- 1/4 of the issued BSPCE-2018-2 founders' share warrants shall become exercisable on the last day of the calendar month in which the date of the first anniversary of the vesting starting date falls (i.e. 30 April 2019);
- 1/48th of the issued BSPCE-2018-2 shall become exercisable on the last day of each calendar month following the date mentioned in the above paragraph (i.e. the last day of each month as of 30 April 2019).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSA-2018-2 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.

The BSPCE-2018-2 founders' share warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to exercise BSPCE-2018-2 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2018-2 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 3: Each BSPCE-2018-3 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2018-3 founders' share warrants stipulate that the BSPCE-2018-3 will only be exercisable in the event of the achievement of objectives set by the Board of Directors, particularly in terms of regulations (obtaining a CE marking or FDA approval for the Group's medical devices) and transactions (approved disposal of Group securities or assets or the Company's IPO).

The BSPCE-2018-3 founders' share warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to achieve an objective before the achievement deadline (or, in the absence of such a date, prior to the expiry of the term of validity of the BSPCE-2018-3 founders' share warrants);
- the failure to exercise BSPCE-2018-3 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2018-3 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 4: Each BSPCE-2019-1 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of BSPCE-2019-1 founders' share warrants provide the following vesting schedule for 50% of the BSPCE-2019-1 founders' share warrants:

- 1/4 of the issued BSPCE-2019-1 founders' share warrants shall become exercisable on the last day of the calendar month in which the date of the first anniversary of the vesting starting date falls (i.e. 30 April 2019);
- 1/48th of the issued BSPCE-2019-1 founders' share warrants shall become exercisable on the last day of each calendar month following the date mentioned in the above paragraph (i.e. the last day of each month as of 30 April 2019).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSA-2019-1 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.

The terms and conditions of the BSPCE-2019-1 founders' share warrants stipulate that 50% of the BSPCE-2019-1 founders' share warrants will only be exercisable in the event of the achievement of objectives set by the Board of Directors, in particular on the regulatory or clinical level (CE marking; ISO 13,495 certification; successful clinical trial).

The BSPCE-2019-1 founder's share warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to achieve an objective before the achievement deadline (or, in the absence of such a date, prior to the expiry of the term of validity of the BSPCE-2019-1 founders' share warrants);
- the failure to exercise the BSPCE-2019-1 in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2019-1 holder is party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 5: Each BSPCE-2019-2 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2019-2 founders' share warrants stipulate that the BSPCE-2019-2 founders' share warrants shall only be exercisable in the event of the achievement of objectives set by the Board of Directors, particularly at the regulatory or clinical (obtaining a CE marking; successful clinical study) or transactional level (financing).
The BSPCE-2019-2 founders' share warrants exercisable on a given date will become null and void in the following scenarios:
- the failure to achieve an objective before the achievement deadline (or, in the absence of such a date, prior to the expiry of the term of validity of the BSPCE-2019-2 founders' share warrants);
- the failure to exercise BSPCE-2019-2 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2019-2 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 6: Each BSPCE-2019-3 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2019-3 founders' share warrants provide for the following vesting schedule:
- 1/3 of the issued BSPCE-2019-3 founders' share warrants become exercisable on the last day of the calendar month in which the date of the first anniversary of the vesting starting date falls (i.e. on the first);
- 1/36th of the issued BSPCE-2019-3 founders' share warrants shall become exercisable on the last day of each calendar month following the date mentioned in the above paragraph (i.e. the last day of each month as of 1 November 2020).

As an exception to the above vesting schedule, the Board of Directors may decide that all or some of the BSA-2019-3 share subscription warrants shall become exercisable early, it being specified that this decision may unilaterally come with conditions.
The BSPCE-2019-3 exercisable on a given date will become null and void in the following scenarios:
- the failure to exercise BSPCE-2019-3 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2019-3 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 7: Each BSPCE-2020-2 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2020-2 founders' share warrants provide for the following vesting schedule:
- 1/4 of the issued BSPCE-2020-2 founders' share warrants shall become exercisable on the last day of the calendar month in which the date of the first anniversary of the vesting starting date falls (i.e. 31 December 2021);
- 1/48th of the issued BSPCE-2020-2 shall become exercisable on the last day of each calendar month following the date mentioned in the above paragraph (i.e. the last day of each month as of 31 December 2021).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSA-2020-2 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.
The BSPCE-2020-2 founders' share warrants exercisable on a given date will become null and void in the following scenarios:
- the failure to exercise BSPCE-2020-2 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2020-2 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 8: Each BSPCE-2020-3 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2020-3 founders' share warrants provide that the BSPCE-2020-3 founders' share warrants

will only be exercisable in the event of the achievement of objectives set by the Board of Directors, particularly in terms of transactions (completion of an IPO).
The BSPCE-2020-3 founders' share warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to achieve an objective before the achievement deadline (or, in the absence of such a date, prior to the expiry of the term of validity of the BSPCE-2020-3 founders' share warrants);
- the failure to exercise BSPCE-2020-3 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2020-3 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 9: Each BSPCE-2020-4 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2020-4 founders' share warrants provide that the BSPCE-2020-4 founders' share warrants will only be exercisable in the event of the achievement of objectives set by the Board of Directors, in particular at the regulatory, clinical and industrial level (successful clinical study, obtaining CE marking, production of implants) or transactional level (completion of an IPO).
The BSPCE-2020-4 founders' share warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to achieve an objective before the achievement deadline (or, in the absence of such a date, prior to the expiry of the term of validity of the BSPCE-2020-4 founders' share warrants);
- the failure to exercise the BSPCE-2020-4 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2020-4 holder is party;
- in the event of a departure from the Company (in particular due to the termination of the service agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Note 10: Each BSPCE-2020-5 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2020-5 founders' share warrants provide that the BSPCE-2020-5 founders' share warrants will only be exercisable in the event of the achievement of objectives set by the Board of Directors, in particular on the regulatory and clinical level (successful completion of a clinical study, obtaining a CE marking) or transaction level (completion of an IPO).
The BSPCE-2020-5 founders' share warrants exercisable on a given date will become null and void in the following scenarios:

- the failure to achieve an objective before the achievement deadline (or, in the absence of such a date, prior to the expiry of the term of validity of the BSPCE-2020-5 founders' share warrants);
- the failure to exercise BSPCE-2020-5 founders' share warrants in the context of the implementation of the drag along provision under the terms of any extra-statutory commitment to which the BSPCE-2020-5 holder will be party;
- in the event of a departure from the Company (in particular due to the termination of the service provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

Only a portion of the BSPCEs of the various plans presented above are exercisable on the date of the Registration Document. These are:

- 1,280,682 BSPCEs under the BSPCE 2018-1 plan granting the right to the same number of Company shares;
- 317,664 BSPCEs under the BSPCE 2018-2 plan granting the right to the same number of Company shares;
- 31,250 BSPCEs under the BSPCE 2019-1 plan granting the right to the same number of Company shares;
- 100,200 BSPCEs under the BSPCE 2019-3 plan granting entitlement to the same number of Company shares.

i.e. a total of 1,729,796 BSPCEs which, if exercised, grant entitlement to the same number of Company shares.

19.1.4.3. Convertible bonds

On 6 December 2019, the Board of Directors of Affluent Medical issued a total of 4 million convertible bonds with a par value of one (1) euro each to Head Leader Limited (the "**CBs**"). Head Leader Limited is a Hong Kong company linked to the Chinese group Gaoze (see section 5.3.6), shareholder through Shanghai Zuquan Investment Management Company Limited in the Group's joint ventures in China.

The CBs mature on 10 December 2024 and earn four percent (4%) annual interest.

The CBsare guaranteed by pledges of:
- Kalios patents covering China;
- the 40% stake held by Epygon in the capital of Shanghai Epygon Medical Technology Co. Ltd. (joint venture created with Shanghai Zuquan Investment Management Company Limited); and
- the 40% stake held by MyoPowers in the capital of Shanghai MyoPowers Medical Technology Co. Ltd. (joint venture created with Shanghai Zuquan Investment Management Company Limited).

In the event of the Company's IPO, convertible bond holders may request, at the latest 30 days before the completion of the IPO, the repayment of their convertible bonds. The Company must then repay the convertible bonds as well as the accrued interest within 60 days of the IPO's completion date.

On 25 February 2021, Head Leader Limited notified the Company of its request for the redemption of convertible bonds in the event of the admission of the Company's shares to trading on the Euronext Paris regulated market. This reimbursement totalling approximately €4.1 million will be made within 60 business days of the completion of the admission of the Company's shares to trading on the regulated Euronext Paris market.

The aforementioned pledges will be released as part of this repayment.

19.1.4.4. Summary of dilutive instruments

The table below presents a summary of dilutive instruments as at the date of approval of the Registration Document:

	BSAs	BSPCEs	Convertible bonds	Total
Total number of shares that may be subscribed upon exercise of BSPCE founders' share warrants/BSA share subscription warrants or conversion of convertible bonds	**377,407**	**3,194,873**	**0***	**3,572,280**

* Taking into account the expected redemption of convertible bonds following the admission of the Company's shares to trading on the Euronext Paris regulated market.

As at the date of approval of the Registration Document, the potential dilution that may result from the exercise or the definitive allocation of all dilutive instruments is 18.97% of the share capital on a fully diluted basis.

19.1.5. Vesting rights and/or obligations attached to capital issued but not paid up and capital-increase undertaking

The financial authorisation resolutions approved by the General Meeting of 6 April 2021 are summarised below:

Transaction	Cap (nominal amount)	Methods for determining the issue price/exercise price	Term	Common cap
Delegation of authority to the Board of Directors to increase the share capital in one or more instalments, with the cancellation of preferential subscription rights, by public offering (23rd resolution)	Capital increase: €10,000,000 Debt securities: €60,000,000 (1) (2)	The price will be determined in accordance with normal market practices.	26 months	N/A
Authorisation to be given to the Board of Directors to reduce the share capital by cancelling treasury shares, subject to a condition precedent (24th resolution)	Up to a limit of 10% of the share capital per 24-month period		18 months	N/A
Delegation of authority to the Board of Directors to increase the share capital through the issuance of shares, securities giving rights to other equity securities or giving right to debt securities and/or securities giving rights to equity securities, with preferential subscription rights, subject to a condition precedent (25th resolution)	Capital increase: €6,100,000 Debt securities: €60,000,000	(3)	26 months	Number of shares: 6,100,000 Common cap to the 25th to the 28th resolutions, and the 31st to the 33rd resolutions
Delegation of authority to the Board of Directors to increase capital through the issuance of shares, securities giving rights to other equity securities or giving right to debt securities and/or securities giving rights to equity securities, with the cancellation of preferential subscription rights, by means of a public offering and with the ability to grant priority subscription rights, subject to a condition precedent (26th resolution)	Capital increase: €6,100,000 Debt securities: €60,000,000 (1) (2)	(4)	26 months	Number of shares: 6,100,000 Common cap to the 25th to the 28th resolutions, and the 31st to the 33rd resolutions
Delegation of authority to the Board of Directors to increase capital through the issuance of shares, securities giving rights to other equity securities or giving right to debt securities and/or securities giving rights to equity securities, with the cancellation of preferential subscription rights reserved to a category of persons (listed below), subject to a condition precedent: - to natural persons or legal entities or UCITS, or other French or foreign funds investing, primarily, or having invested more than one million Euros over the 24 months preceding	Capital increase: €6,100,000 Debt securities: €60,000,000	(5)	18 months	Number of shares: 6,100,000 Common cap to the 25th to the 28th resolutions, and the 31st to the 33rd resolutions

Transaction	Cap (nominal amount)	Methods for determining the issue price/exercise price	Term	Common cap
the share capital increase in question, (a) in the Company's sector of activity or (b) in growth securities listed on a regulated market or a multilateral trading facility (such as Euronext Growth) considered to be "Community SMEs" as defined in Appendix I to Regulation (EC) No. 651/2014 of the European Commission of 17 June 2014; and/or - to groups of business angels and family offices, whether French or foreign; and/or - to one or more strategic partners of the Company, located in France or abroad, that have entered into or are expected to enter into one or more partnership (development, co-development, distribution, manufacturing, etc.) or commercial agreements with the Company (or a subsidiary) and/or the companies that they control, which control them or which are under joint control with them, directly or indirectly, within the meaning of Article L. 233-3 of the French Commercial Code; and/or to any credit institution or investment services provider authorised to provide the investment service referred to in point 6 of Article L. 321-1 of the French Monetary and Financial Code, acting within the framework of share capital increase programme through the exercise of options or a similar operation. (27th resolution)				
Delegation of authority to the Board of Directors to increase capital, up to a limit of 20% of the share capital per year and per issue, through the issuance of shares, securities giving rights to other equity securities or giving right to debt securities and/or securities giving rights to equity securities, with the cancellation of preferential subscription rights, by means of an offering to qualified investors or a restricted group of investors within the meaning of Article L. 411-2 of the French Monetary and Financial Code, subject to a condition precedent (28th resolution)	Capital increase: 20% of the share capital per year Debt securities: €60,000,000	(4)	26 months	Number of shares: 6,100,000 Common cap to the 25th to the 28th resolutions, and the 31st to the 33rd resolutions
Authorisation to be granted to the Board of Directors in accordance with Articles L. 22-10-52 1° paragraph 2 and R. 22-10-32 of the French Commercial Code to set the issue price of shares, securities giving rights to other equity securities or giving right to debt securities	Within the limit of 10% of the share capital	(6)	26 months	

Transaction	Cap (nominal amount)	Methods for determining the issue price/exercise price	Term	Common cap
and/or securities giving rights to equity securities, with the cancellation of preferential subscription rights under the authorisation, subject to the 27th and 29th resolutions, subject to a condition precedent (29th resolution)				
Delegation of authority to the Board of Directors to increase the number of shares to be issued in the event of a capital increase with or without preferential subscription rights (30th resolution)	15% of the initial issue (5)	Same price as the initial issue	26 months	N/A
Delegation of authority to the Board of Directors to increase the share capital through the capitalisation of additional paid-in capital, reserves, earnings or other accounting items, subject to a condition precedent (31st resolution)	Capital increase: €6,100,000	N/A	26 months	N/A
Delegation of authority to the Board of Directors to issue shares and securities in consideration for contributions in kind, subject to a condition precedent. (32nd resolution)	Within the limit of 10% of the share capital		26 months	Common cap to the 25th to the 28th resolutions, and the 31st to the 33rd resolutions
Delegation of authority granted to the Board of Directors to issue shares and securities in the event of a public exchange offer initiated by the Company, subject to a condition precedent (33rd resolution)	Capital increase: €6,100,000 Debt securities: €60,000,000		26 months	Common cap to the 25th to the 28th resolutions, and the 31st to the 33rd resolutions
Authorisation to the Board of Directors to grant share subscription and/or purchase options, with the cancellation of shareholders' preferential subscription rights in favour of a category of persons, subject to a condition precedent (35th resolution)	Within the limit of 10% of the share capital on an undiluted basis on the grant date (8)	(9)	38 months	Common cap to the 35th to the 38th resolutions
Delegation of authority for the Board of Directors to issue share subscription warrants with the cancellation of preferential subscription rights in favour of a category of persons (listed below), subject to a condition precedent: - strategic partners of the Company, persons bound by a service or consultancy agreement with the Company or one of its subsidiaries; - shareholders, managers or employees of these entities in the case of legal entities; - executives, corporate officers or employees of the Company or its subsidiaries;	Within the limit of 10% of the share capital on an undiluted basis on the issue date (8)	(10)	18 months	Common cap to the 35th to the 38th resolutions

Transaction	Cap (nominal amount)	Methods for determining the issue price/exercise price	Term	Common cap
(36th resolution)				
Authorisation to the Board of Directors to allocate free shares, existing or to be issued, with the cancellation of shareholders' preferential subscription rights reserved to a category of persons, subject to a condition precedent (37th resolution)	Within the limit of 10% of the share capital on an undiluted basis on the grant date (8)		38 months	Common cap to the 35th to the 38th resolutions
Delegation of authority to the Board of Directors to grant founders' share warrants with the cancellation of preferential subscription rights reserved to a category of persons, subject to a condition precedent (38th resolution)	Within the limit of 10% of the share capital on an undiluted basis on the grant date (8) (11)		38 months	Common cap to the 35th to the 38th resolutions
Delegation to the Board of Directors to carry out a capital increase by issuing shares or securities giving access to the share capital, reserved for members of a company savings plan with the cancellation of preferential subscription rights in favour of the latter (40th resolution)	€152,568	(12)	18 months	N/A

(1) These amounts are not cumulative. The maximum cumulative cap authorised by the General Meeting for capital increases is set at a nominal value of €10 million. The total nominal amount of issues of the Company's debt securities (such as convertible or redeemable warrants) giving access to the Company's share capital may not exceed €60 million.

(2) The Board of Directors may decide, where applicable, to increase the number of new shares by an additional maximum of 15% of the number of shares initially set as part of a capital increase carried out on the basis of this resolution, for the purposes of responding to excess demand expressed as part of a public offering, under an "Extension Clause" in accordance with market practices.

(3) The Board of Directors has full powers to set the issue price within the legal or regulatory limits in force.

(4) The issue price of the securities that may be issued under this delegation must be set in accordance with the regulations applicable on the date of issue, to date, the volume-weighted average of the share prices of the last three (3) trading days preceding the start of the public offering, possibly reduced by a maximum discount of 10%.

(5) The issue price of the securities that may be issued under this delegation is set by the Board of Directors, based on the share price, it being specified that:

- the share subscription price may not be less than 85% of the volume-weighted average of the last fifteen (15) trading sessions preceding the day on which the issue price is set; and
- the issue price of the securities giving access to the share capital is such that the amount received immediately by the Company at the time of this issue, increased, where applicable, by the amount that may be received subsequently by it for each share issued as a result of this issue of these securities may not be less than 85% of the volume-weighted average of the last fifteen (15) trading sessions preceding the day on which the issue price is set.

(6) At least 80% of the weighted average of the last twenty (20) trading sessions preceding its determination.

(7) Within the time frames and limits stipulated by the regulations applicable on the date of the issue (to date, within thirty days of the closing of the subscription, up to a limit of 15% of the initial issue and at the same price as that used for the initial issue).

(8) These amounts are not cumulative. The maximum cumulative ceiling authorised by the General Meeting may not exceed 10% of the share capital on an undiluted basis recorded at the date of the grant or issue decision.

(9) The purchase or subscription price of the shares will be determined by the Board of Directors, and in any event, will be at least equal to 95% of the volume-weighted average of the share prices of the twenty (20) trading sessions preceding the day on which the Option is granted.

(10) As long as the Company's shares are admitted to trading on a regulated market, the exercise price will be at least equal to 90% of the volume-weighted average of the twenty (20) trading sessions preceding the day on which the Board decides on the allocation of said warrant. If the Company issues warrants to one of its directors, it must ensure that these are issued at market conditions, in accordance with the AMF communication dated 5 June 2018.

(11) The implementation of this delegation is subject to the Company's eligibility for all of the conditions required for the allocation of founders' share subscription warrants in application of the regulations in force and, in particular, Article 163 bis G of the French General Tax Code.

(12) The share subscription price will be set in accordance with the provisions of Article L. 3332-19 or Article L. 3332-20 of the French Labour Code, depending on whether or not the shares are listed for trading on a regulated market at the date of the capital increase, namely:

- if the capital increase is concomitant with the admission of the Company's shares to trading on the regulated market: the subscription price will be determined by reference to the IPO price, provided that the decision of the Board of Directors is made no later than ten (10) trading sessions after the date of the first listing, this price being possibly reduced by a maximum discount of 30% or, where applicable, 40% if the period of unavailability provided for by the plan, in application of Articles L. 3332-25 and L. 3332-26 of the French Labour Code, is greater than or equal to ten years;
- after the admission of the Company's shares to trading on a regulated market: the issue price will be set under the conditions set out in Article L. 3332-19 of the French Labour Code, it being understood that the discount set, pursuant to the aforementioned Article L. 3332-19, in relation to an average of listed prices of the Company's share on the corresponding regulated market during the twenty (20) trading sessions preceding the date of the decision of the Board of Directors, or its delegatee, setting the opening date for subscriptions, may not exceed 30% or, where applicable, 40% if the period of unavailability provided for by the plan, pursuant to Articles L. 3332-25 and L. 3332-26 of the French Labour Code, is greater than or equal to ten years;

if the securities are not admitted to trading on a regulated market, the price will be determined in accordance with the objective methods used for the valuation of shares, taking into account, according to an appropriate weighting in each case of the Company's net financial position, profitability and business outlook. These criteria are assessed, where applicable, on a consolidated basis or, failing that, taking into account the financial information from significant subsidiaries. It is thus determined each financial year under the control of the Statutory Auditors. The subscription price may not be higher than the sale price thus determined, nor lower than it by more than 30% or, where applicable, by 40% if the period of unavailability provided for by the plan, in application of the provisions of Articles L. 3332-25 and L. 3332-26 of the French Labour Code, is greater than or equal to ten (10) years.

No financial delegation presented above has been used as at the date of approval of the Registration Document.

19.1.6. Information about the Company's capital that is under option or agreed conditionally or unconditionally to be put under option

Not applicable.

19.1.7. Changes in share capital

19.1.7.1. Table of changes in share capital in the past two financial years

Date	Transaction type	Capital movement in €	Issue/ contribution premium in €	Number of shares created	Number of shares comprising the capital	Par value in €	Share capital in €
23 February 2018	Formation of the Company	€1	€0	1	1	€1	€1
27 March 2018	Contribution in kind of the entire capital of Epygon, Kephalios, Kardiozis and MyoPowers by their partners	€11,899,966	€47,599,864.00	11,899,966	11,899,967	€1	€11,899,967
14 May 2020	Share capital increase in cash	€390,490	€1,909,496.10	390,490	12,290,457	€1	€12,290,457
20 June 2020	Capital increase by conversion of Conversion bonds[60]	€1,883,168	€7,966,787.96	1,883,168	14,173,625	€1	€14,173,625
29 September 2020	Share capital increase in cash	€215,618	€1,054,372.02	215,618	14,389,243	€1	€14,389,243
29 September 2020	Capital increase through the conversion of debt	€171,486	€636,213.06	171,486	14,560,729	€1	€14,560,729
8 December 2020	Share capital increase in cash	€696,095	€3,403,904.55	696,095	15,256,824	€1	€15,256,824

19.1.7.2. Changes of the allocation of the share capital in the past three financial years

Shareholders	Situation at 31 December 2020		Situation at 31 December 2019		Situation at 31 December 2018	
	Number of shares	% of share capital	Number of shares	% of share capital	Number of shares	% of share capital
Funds and companies managed by Truffle Capital	10,674,399	69.96%	7,735,621	65.01%	7,735,621	65.01%
Other financial investors	4,361,344	28.59%	3,953,876	33.23%	3,953,876	33.23%
Founders, executives and members of the Board of Directors and committees	220,611	1.45%	210,000	1.76%	210,000	1.76%
Employees	470	0.00%	470	0.00%	470	0.00%
TOTAL	**15,256,824**	**100.00%**	**11,899,967**	**100.00%**	**11,899,967**	**100.00%**

[60] Several categories of convertible bonds issued in the past have been converted - the CB-2018-1, CB-2018-2, OC-2018-3 and OC-2018-4 issued at the time of the creation of the Company had a conversion price of €4.71, the Financing CBs had a conversion price of €5 and the OCA-2019 had a conversion price of €5.89.

19.2. Memorandum of association and bylaws

19.2.1. Corporate purpose (Article 2 of the bylaws)

The Company's direct and indirect purpose in France or abroad, either in its own name and on its own behalf or on behalf of, or in agreement with, third parties, is to:

- perform any activity related to medical devices, particularly technologies, processes and products in the field of therapeutics and minimally invasive surgery;

- acquire, subscribe for, hold, manage or sell, in any form, any stock or transferable security in any company or legal entity, whether formed or to be formed, French or foreign, and, in broader terms, perform any activity that a holding company may perform to manage its equity interests;

- provide any administrative, financial, accounting, commercial, IT, legal, HR or management services to the Company's subsidiaries or any other company in which it has an equity interest;

- the granting of sureties, endorsements and guarantees for the benefit of any company in its group and in the normal course of business of any company in its group; and

- in general, perform any personal property, real estate, industrial, commercial or financial transactions directly or indirectly related to the corporate purpose or to any similar or related purposes, or that may be useful to that purpose or likely to facilitate its achievement.

19.2.2. Provisions of the bylaws or other provisions related to members of corporate governance and management bodies

The Company is governed by a Board of Directors.

19.2.2.1. Board of Directors (Articles 12 and 13 of the bylaws)

Article 12. Board of Directors

12.1. Composition of the Board of Directors

The Company is governed by a board of directors (the "Board of Directors") whose minimum and maximum numbers of directors are determined by laws and regulations.

Directors shall be appointed and reappointed in their roles by the Ordinary General Meeting which may remove them at any time. However, in the event of a merger or spinoff, the appointment of directors may be made by the Extraordinary General Meeting.

Directors may be individuals or legal entities, whether or not Company shareholders. Directors that are legal entities are required, upon appointment, to designate a permanent representative who shall be bound by the same conditions and obligations and exposed to the same civil and criminal liabilities as if he/she were a director in his/her own right, and this without prejudice to the joint and several liability of the legal entity that he/she represents. The term of office of the permanent representative shall be the same as the term of office of the legal entity that he/she represents; he/she must be reappointed whenever the legal entity's term of office is up for renewal.

When the legal entity removes its representative, it must notify the Company of this removal, immediately and by registered letter, and appoint a new permanent representative according to the same terms and conditions. The foregoing shall also apply in the event of the death or resignation of the permanent representative.

12.2 Term of office – Age limit

Directors shall be appointed for a term of three (3) years and may always be reappointed. The duties of a director shall end at the close of the Ordinary General Meeting held to approve the financial statements for the financial year just ended and taking place during the year in which the term of office of said director expires.

No director may be appointed if they are over the age of eighty-five (85), and if their appointment would result in the number of directors over the age of 85 exceeding one third of the members of the Board.

The number of directors over the age of 85 may not exceed one third of the members of the Board of Directors. If this limit is reached, the oldest director shall be deemed to have resigned.

12.3 Vacancy of seats – Co-optation

In the event that one or more seats on the Board become vacant due to death or resignation, the Board of Directors may, in the interval between two General Meetings, temporarily fill the vacancy, which will be subject to ratification at the next Ordinary General Meeting.

In the event of failure of ratification, previous decisions and actions taken by the Board of Directors shall nevertheless remain valid.

The director appointed to replace another whose term has not expired shall only remain in office for the remainder of the term of office of his/her predecessor.

If the number of directors falls below the legal minimum, the remaining directors shall immediately call an Ordinary General Meeting in order to make up the number of Board members.

12.4 Compensation of directors

The Annual General Meeting may allocate a fixed annual amount to the directors in respect of their compensation for their duties on the Board of Directors. The Board of Directors distributes this compensation among its members as it sees fit.

Directors may not receive any compensation from the Company, whether permanent or not, in respect of their office as director, other than those provided for by law. Exceptional compensation for the assignments or offices entrusted to directors may be allocated by the Board of Directors.

The Chairman of the Board of Directors may receive compensation for his/her duties as Chairman. This compensation is then set in accordance with the law.

12.5 Directors' shares

Directors are not required to hold Shares of the Company.

12.6 Observers

The Company has an Advisory Board composed of a maximum of five (5) observers who may be appointed upon a decision of the Ordinary General Meeting or of the Board of Directors, for a term of three (3) years. Their term of appointment ends at the end of the Ordinary General Meeting called to approve the financial statements for the previous financial year and held in the year in which their term expires.

Observers may be individuals or legal entities and may or may not be Company shareholders. When a legal entity is appointed as an observer, it shall perform its duties through its legal representative or a permanent representative that it designates for that purpose.

They may be removed by the Ordinary General Meeting or the Board of Directors at any time, at will, and without notice.

They are invited to all the meetings of the Company's Board of Directors in the same way the directors are invited. They have the same right to information as the directors. They do not have any voting rights.

They participate in the meetings of the Company's Board of Directors in an advisory capacity with no say in the decision-making process.

Observers shall be bound to keep secret the Board of Directors' decisions and other information received as part of their role.

Observers may receive compensation for their role, as determined by decision of the Board of Directors. In any event, observer may be reimbursed for reasonable expenses incurred as part of their assignment as members of the Board of Directors, subject to providing receipts.

12.7 Ad hoc committees

The Board of Directors may decide to set up committees, such as an audit, appointment or compensation committee, responsible for studying and forming opinions on specific issues. The composition, powers and operating procedures shall be determined by the Board of Directors, if applicable within its internal regulations.

Article 13. Chairman of the Board of Directors

The Board of Directors shall elect a Chairman from among its physical members who shall hold office for a term determined by the Board but not to exceed his/her term of office as a director and who may be removed at any time. The Chairman may be re-elected.

In accordance with the legal provisions in force, the Board of Directors determines the compensation of the Chairman, which may be fixed and/or variable.

In the event of temporary incapacity or death of the Chairman of the Board of Directors, the Board may delegate a director to act as Chairman of the Board of Directors. In the event of temporary incapacity, the delegation shall be given for a specified period and may be renewed. In the event of death, the delegation shall be valid until the new Chairman of the Board of Directors is elected.

The Chairman of the Board of Directors shall organise and direct the Board's work on which he/she shall report to the General Meeting of Shareholders and executes its decisions. He/she shall oversee the effectiveness of the Company's governance structure and in particular ensure that the directors in a position to carry out their duties.

The Board of Directors may remove the Chairman at any time. Any provision to the contrary is deemed unwritten. The termination of the Chairman's duties shall not *de facto* entail the termination of his/her term of office as Director, but the termination of his/her term of office as Director shall automatically entail the termination of his/her duties as Chairman of the Board of Directors.

Article 14 Deliberations of the Board of Directors

14.1 Meetings of the Board of Directors

The Board of Directors shall meet at least four (4) times a year and as often as required by the best interests of the Company.

The Board of Directors may be convened at any time by its Chairman or at least two (2) directors. If the Board of Directors has not held a meeting for over two months, at least one third of its members may ask the Chairman to call a meeting of the Board to discuss a specific agenda. In the event the positions are separated, the Chief Executive Officer may also ask the Chairman to convene the Board of Directors to discuss a specific agenda.

The notice period for calling meetings of the Board of Directors shall be at least five business days prior to the meeting of the Board on the first call and at least two business days before the meeting of the Board on the second call, with the exception, where all directors are present (if necessary by videoconference or telecommunication) or represented or have waived the notice periods (it being specified that a director's presence – if necessary by videoconference or telecommunication – or representation at the meeting shall be deemed to have waived the aforementioned notice formalities).

Meeting notices may be made by any means of written communication, including regular mail or email, and must include, in addition to the agenda, all documents that will provide directors with information relating to the decisions on which the Board of Directors is being called upon to vote. Except in cases where all directors are present (if necessary by videoconference or telecommunication) or represented or have consented thereto in writing, the Board of Directors may not vote on any issue that is not on the agenda of the meeting notice.

Meetings shall be held at the registered office or any other place mentioned in the meeting notice in France or abroad. They shall be chaired by the Chairman of the Board of Directors (or the director delegated to act as chairman), or failing that, by a director chosen by the Board of Directors.

Any director may authorise another director, in writing (by letter, fax or email) to represent him/her and vote on decisions on his/her behalf at a given meeting of the Board of Directors. However, a director may not hold more than one proxy at any given meeting.

An internal rule that may be adopted by the Board of Directors may provide, in particular, within the limits established by law, for directors participating in meetings by videoconference or telecommunication to be deemed present for the purposes of calculating the quorum and voting majority, in accordance with prevailing regulations.

Persons outside the Board of Directors may be invited to participate in any Board meeting.

One or more secretaries may be designated and selected by the Board of Directors, even outside its members or shareholders.

The Board of Directors may also make, by written consultation, certain decisions within its own powers, in accordance with the laws and regulations in force.

In the event of a written consultation, the Chairman of the Board must send, by any means, including by electronic transmission, to each of the directors as well as, where applicable, the Observers and any representatives of the Social and Economic Committee, all the information required for decisions on the consultation agenda.

The directors have a timeframe specified in the documents to vote and communicate their observations to the Chairman in written by any means, including by electronic transmission.

Any director who does not respond within the timeframe (if not specified in the documents, this period will be five (5) days from the date of dispatch of the documents) shall be deemed to have abstained.

Minutes will be drawn up for the written consultation and signed by the Chairman to which each response from the directors is attached and which is sent to the Company to be kept under the same conditions as the minutes of the Board's deliberations.

14.2 Quorum and majority rules

The presence (if applicable by videoconference or telecommunication) of at least half of the directors in office shall be required for the Board of Directors validly deliberate.

All decisions of the Board of Directors are validly adopted by simple majority of directors present (if applicable by videoconference or telecommunication) or represented, it being specified that in the event of a tie, the Chairman of the meeting does not have the casting vote.

14.3 Attendance register and minutes

An attendance register is kept and signed by all the members of the Board of Directors attending the meeting.

The Board's decisions shall be recorded in minutes drawn up in a special register kept at the Company's registered office or on loose sheets as provided by prevailing regulations.

The minutes are drawn up and copies or extracts are issued and certified in accordance with the law.

Articles 15. Powers of the Board of Directors

The Board of Directors determines the Company's overall business strategy and oversees the implementation thereof in the best interests of the Company, taking into consideration the environmental and social aspects of its activity.

In dealings with third parties, the Company is committed even by the acts of the Board of Directors which do not fall within the scope of the corporate purpose, unless it proves that the third party was aware that the act exceeded such purpose, or that it could fail to be aware of it given the circumstances, it being excluded that only the publication of the bylaws is sufficient to constitute this proof.

The Board of Directors shall conduct checks and controls as it deems appropriate.

Each director must receive the information required to perform his/her duties and may ask Executive Management for all documents that he/she deems useful.

The Chairman shall organise and direct the Board of Directors' work and report thereon to the shareholders at General Meetings and execute its decisions.

He/she ensures the proper functioning of the Board of Directors and ensures that the directors are in a position to carry out their duties.

Sureties, endorsements and guarantees given by the Company must be authorised by the Board of Directors.

The Board of Directors has the capacity to decide on the issuance of bonds.

The provisions of Articles L. 225-38 of the French Commercial Code apply to agreements entered into, directly or via intermediaries, between the Company and one of its directors or Chief Executive Officers.

The Board may make the necessary changes to these bylaws to bring them into compliance with the laws and regulations in force, subject to ratification of this decision by the next Extraordinary General Meeting.

19.2.2.2. Executive Management (Article 16 of the bylaws)

16.1 Choice between the two methods of exercising Executive Management

Responsibility for the Company's Executive Management shall be assumed either by the Chairman of the Board of Directors or by any other physical person, whether or not a director, appointed by the Board of Directors and bearing the title of Chief Executive Officer.

The Board of Directors, voting with the quorum of members present or represented, shall choose between the two methods of executive management.

If the Company's Executive Management is assumed by the Chairman of the Board of Directors, the provisions hereafter regarding the Chief Executive Officer shall apply thereto.

16.2 Chief Executive Officer

The Chief Executive Officer, who may be a director or not, shall be appointed by the Board of Directors which sets the duration of his/her term of office. Failing that, the Chief Executive Officer shall be appointed for an indefinite period. The Board of Directors determines, under the conditions laid down by law and regulations, where applicable, his/her compensation and, where applicable, the limitations of his/her powers.

The Chief Executive Officer must be less than seventy-five years old. If the current Chief Executive Officer reaches this age, he/she is deemed to have resigned.

The duties of the Chief Executive Officer are terminated by death, dismissal or resignation.

The Chief Executive Officer may be removed at any time by the Board of Directors. If the Chief Executive Officer does not assume the role of Chairman of the Board of Directors, his/her removal may give rise to damages, if that removal is considered without due cause.

The Chief Executive Officer shall be vested with the broadest powers to act in the Company's name in all circumstances. He/she shall exercise his/her powers within the scope of the Company's corporate purpose, subject to the powers expressly attributed by the bylaws to General Meetings of Shareholders and to the Board of Directors.

The Chief Executive Officer shall represent the Company in its dealings with third parties. The Company shall be bound even by acts of the Chief Executive Officer that are not within the scope of the corporate purpose, unless the Company proves that the third party was aware that the act exceeded such purpose, or that it could fail to be aware of it given the circumstances. The publication of the bylaws alone not constituting sufficient proof.

Decisions of the Board of Directors limiting the powers of the Chief Executive Officer are not enforceable against third parties.

The Board of Directors shall determine his/her compensation, which may be fixed and/or variable.

The legal limitations relating to all offices shall be applicable to the Chief Executive Officer, as provided by law.

16.3 Deputy Chief Operating Officers

On the proposal of the Chief Executive Officer, the Board of Directors may appoint one or more Chief Operating Officers as provided by law. The Chief Operating Officers must be natural persons. They may be chosen from among the directors or from outside the Board. The number of Chief Operating Officers may not exceed five.

In agreement with the Chief Executive Officer, the Board shall determine the scope and duration of the powers granted to the Chief Operating Officers. With regard to third parties the Deputy Chief Executive Officer(s) have the same powers as the Chief Executive Officer subject, where applicable, to the specific limitations on powers that may be imposed on them by the Board of Directors. The Board shall determine their compensation, which may be fixed and/or variable.

No Chief Operating Officer may be older than seventy-five years of age. If a Chief Operating Officer in office reaches that age, he/she will be deemed to have resigned.

The Chief Operating Officers may be removed at any time by the Board of Directors on the proposal of the Chief Executive Officer; in the event of the Chief Executive Officer's death, resignation or removal, the Chief Operating Officers shall keep their offices and allocations until a new Chief Executive Officer is appointed, unless otherwise decided by the Board.

16.4 Delegations of authority

The Board of Directors may assign permanent or temporary assignments to its corporate officers, whether directors or not, delegate authority to them and set the compensation it deems appropriate.

19.2.3. Rights, entitlements and restrictions attached to the Company's shares

19.2.3.1. Forms of shares (Article 9.1 of the bylaws)

Shares may be held in registered or bearer form, as the shareholder so chooses, and can be traded freely, subject to prevailing laws and regulations. Shares that are not fully paid-up must be in registered form.

They give rise to registration in their owner's account and are transferred to the Company and third parties by transfer from one account to another, in accordance with the terms and conditions defined by applicable laws and regulations.

19.2.3.2. Voting rights (Articles 10 and 11 of the bylaws)

Article 10. Rights and obligations attached to shares

Each share entitles its holder to a proportionate share of the share capital that it represents in the ownership of corporate assets, in the sharing of profits and in the liquidation surplus.

Any person owning one or more shares is bound by these bylaws and by all decisions taken at Ordinary or Extraordinary General Meetings of shareholders.

The shares and the rights and obligations attached to these shares are indivisible. The co-owners of an undivided share are required to be represented vis-à-vis the Company by a single representative.

The heirs, creditors, beneficiaries or other representatives of a shareholder may not, under any pretext whatsoever, request the affixing of seals to the Company's property or securities, nor request the division or the auction, nor interfere in any way in the actions of its administration; they must, in order to exercise their rights, refer to the Company inventories and to the decisions of the shareholders' meetings.

The shareholders only bear losses up to the amount of their contributions.

The rights and obligations attached to the share follow the title in whatever hand it passes. Ownership of a share automatically entails acceptance of the bylaws and the decisions of the General Meeting.

Whenever it is necessary to own several shares in order to exercise any right, in the event of an exchange, consolidation, allocation of shares, capital increase or reduction, merger or any corporate transaction,

the owners of individual securities, or in a smaller number than that required, may exercise this right on the sole condition that they make it their personal business to consolidate and, if necessary, purchase or sell the necessary number of securities.

Article 11. Double voting rights

The voting right attached to capital shares and dividend shares shall be proportional to the amount of capital that they represent. Each share shall entitle the holder to one vote.

However, a double voting right of that conferred on the other shares in view of the portion of the capital they represent is allocated to all fully paid-up shares for which registration has been recorded for at least two (2) years on behalf of and in the name of the same shareholder.

In accordance with Article L. 225-123 paragraph 2 of the French Commercial Code, this double voting right is also conferred upon their issue in the event of a capital increase by incorporation of reserves, profits or issue premiums, to registered shares allotted free of charge to a shareholder on the basis of old shares for which he or she will benefit from this right.

The transfer of shares as a result of inheritance, liquidation of joint property between spouses or *inter vivos* donation to a spouse or relative to the degree of inheritance does not result in the loss of the acquired right and does not interrupt the deadlines provided above.

The same applies in the event of a transfer of shares following a merger or demerger of a shareholder company.

In addition, the merger or demerger of the Company has no effect on the double voting rights that may be exercised within the beneficiary company(ies) if the Company's bylaws so provide.

This double voting right may be exercised at any meeting.

Double voting rights cease automatically when the share is converted to bearer form or transferred into ownership.

19.2.3.3. Rights to dividends and profits

Each share confers a right to the Company’s profits and capital in proportion to the percentage of capital that it represents.

19.2.3.4. Preferential subscription rights

Shareholders have preferential subscription rights in proportion to the number of shares they own to subscribe for cash shares issued for the purpose of a capital increase.

19.2.3.5. Restrictions on voting rights

Not applicable.

19.2.3.6. Identifiable bearer shares (Article 9.2 of the bylaws)

The Company keeps itself informed of the composition of its shareholders under the conditions provided for by law.

As such, the Company may make use of all legal provisions relating to the identification of holders of securities conferring immediate or future voting rights at its shareholders' meetings.

19.2.3.7. Information rights (Article 25 of bylaws)

All shareholders have the right to obtain, under the conditions and at the times set by law, the documents necessary to enable them to make an informed decision and to pass judgment on the management and control of the Company. The nature of these documents and the conditions under which they are sent or made available are determined by law and regulations.

19.2.3.8. Buyback by the Company of its own shares

Please refer to section 19.1.3 of this Registration Document.

19.2.4. Procedures for amending shareholders' rights

Shareholders' rights as described in the Company's bylaws may only be amended by the shareholders at the Company's extraordinary general meeting.

19.2.5. Shareholders' meetings (Articles 19 to 25 of the bylaws)

Article 19. Shareholders' meetings

Shareholders' decisions are made during General Meetings.

Ordinary General Meetings are those called to make all decisions that do not modify the bylaws.

Extraordinary General Meetings are those called to decide or authorise amendments to the bylaws.

The decisions of the General Meetings are binding on all shareholders, even those absent, dissenting or incapable.

Article 20. Meeting notices

General Meetings shall be convened in accordance with the conditions and in the form provided for by current laws and regulations.

General Meetings shall be held at the registered office or at any other location indicated in the meeting notices and notice letters.

The meeting notice is made fifteen (15) days before the date of the meeting either by ordinary or registered letter addressed to each shareholder, or by electronic means under the conditions set by law, or by a notice inserted in an official gazette of legal announcements of the administrative department in which the registered office is located. If the meeting has been convened by notice in an official gazette, each shareholder must also receive the meeting notice by regular mail or, if they so request, by registered mail at their expense.

If a General Meeting is unable to duly vote on a decision due to a lack of the required quorum, a second meeting and, if applicable, a second extended meeting, shall be convened in the same manner as the first meeting and the meeting notice shall make reference to the date of the first meeting and reproduce its agenda. The procedures for convening the second General Meeting and, if applicable, the second extended General Meeting shall be governed by the legal provisions in force.

Article 21. Agenda

The agenda shall be drawn up in accordance with the legal and regulatory provisions in force.

Article 22. Participation in meetings – Powers

Regardless of the number of shares they hold, all shareholders have the right to attend General Meetings and participate in decisions either personally or by proxy, in accordance with the legal and regulatory provisions in force, subject to proof of identity, once their shares are fully paid up and registered in an account in their name within the legal deadline.

Any shareholder unable to attend the General Meeting in person may:

(i) be represented by giving their proxy to the individual or legal entity of their choosing, in accordance with the laws and regulations, or

(ii) send a proxy to the Company without stating any name, in accordance with the conditions provided by the laws or regulations; or

(iii) cast a ballot by mail using a form that may be obtained under the conditions indicated in the meeting notice.

Legal entities may participate in General Meetings through their legal representatives or by any other person that they have duly authorised to do so.

Shareholders may cast a ballot by mail in accordance with legal and regulatory provisions. On the decision of the Board of Directors mentioned in the meeting notice, the shareholders may, under the conditions and within the time limits set by the laws and regulations, send their proxy and voting forms by post by any means of telecommunication (i.e. including by electronic means) allowing for their identification and whose nature and conditions are determined by the regulations in force.

Article 23 – Holding of meetings

General Meetings shall be chaired by the Chairman of the Board of Directors or, failing that, by a director specifically appointed for that purpose by the Board of Directors. If the meeting is convened by a statutory auditor or court officer, the General Meeting shall be chaired by the person who convened the meeting. Failing that, the General Meeting shall elect its own Chairman.

When they so agree, the two shareholders present who hold the largest number of votes in their own names and/or through proxies, shall act as the tellers. The meeting office designates a secretary who does not have to be a shareholder.

Any shareholder may, if the Board of Directors so permits in the meeting notice convening a General Meeting, participate in this General Meeting by videoconference or by electronic means of telecommunication or transmission under the conditions set by current legislation or regulations.

Meeting decisions shall be recorded in minutes signed by meeting officers and entered in a special register as provided by law. Copies and extracts of the minutes shall be duly certified as provided by law.

Article 24. Quorum – Voting

24.1 General rules

Ordinary and Extraordinary Shareholders' Meetings are convened for the first time and, where applicable, held on second call under the quorum conditions provided for by law.

Decisions of General Meetings are made under the majority conditions provided for by law.

In the event of the use of videoconferencing or other means of telecommunication permitted by law, shareholders who participate in meetings by videoconference or other means of telecommunication shall be deemed present for the calculation of the quorum and majority.

24.2 Ordinary General Meetings

The Ordinary General Meeting votes on any items that do not directly or indirectly amend the bylaws and which do not fall within the exclusive competence of the Extraordinary General Meeting.

The Ordinary General Meeting is held at least once a year, within six months of the end of the financial year, to approve the financial statements and any consolidated financial statements for the year, unless this timeline is extended by court decision.

The meeting may not adopt any resolutions on first call unless the shareholders present, represented or casting ballots by mail hold at least one-fifth of the voting shares. There shall be no quorum requirement for meetings held on second call.

It rules by a majority of the votes cast by shareholders present or represented or voting by mail under the conditions provided for by law.

24.3 Extraordinary General Meetings

The Extraordinary General Meeting may amend any of the provisions of the bylaws just as it may decide to change the Company into another type of company. Under no circumstances may it increase the commitments of the shareholders or undermine the equality of their rights unless the shareholders unanimously approve such a decision.

The Extraordinary General Meeting may adopt resolutions provided that the shareholders present, represented or casting a ballot by mail hold at least one-quarter of the voting shares on first call and one-fifth on second call. If the latter quorum is not met, the second meeting may be postponed for up to two months before being called again.

The Extraordinary General Meeting rules by a two-thirds majority of the votes cast by the shareholders present or represented, or voting by mail, under the conditions provided for by law.

As an exception, the Extraordinary General Meeting may vote under the conditions for quorum and majority applicable to Ordinary General Meetings when it authorises an increase in share capital through the capitalisation of reserves, profits or additional paid-in capital.

19.3. Provisions having an effect of delaying, deferring or preventing a change in control

The Company's Bylaws contain no provisions of a nature to delay, defer, or prevent a change of control.

19.3.1. Crossing of statutory thresholds (Article 9.3 of the bylaws)

In addition to the declarations of crossing of thresholds expressly provided for by the legislative and regulatory provisions in force, any natural or legal person, acting alone or in concert, who comes to hold, directly or indirectly, in any way whatsoever within the meaning of Articles L. 233-7 *et seq.* of the French Commercial Code, a fraction equal to more than 2.5% of the share capital or voting rights, or any multiple of this percentage, including above the thresholds provided for by legal provisions and regulations, must inform the Company of the total number of shares and voting rights it holds, directly or indirectly, alone or in concert (or that it may be required to own in accordance with the Article L. 233-7 of the French Commercial Code), before and after the transaction that led to the crossing of the said threshold, as well as the nature of this transaction. This disclosure shall be made by means of registered letter with acknowledgment of receipt (or by any equivalent means for individuals residing

outside France), sent to the registered office no later than by the end of the fourth trading day following the day on which the threshold is exceeded.

This requirement shall apply under the same conditions as those stipulated in the previous paragraph each time the percentage of capital or voting rights held falls below one of the thresholds specified in the above paragraph.

In the event of non-compliance with the above provisions, a shareholder who fails to make the declaration regularly is deprived of the voting rights attached to the shares exceeding the fraction that has not been regularly declared for any General Meeting of shareholders that would be held until the expiry of the period provided for by law and the regulations in force following the date of regularisation of the notification. This penalty shall only be applied at the request, which shall be recorded in the minutes of the General Meeting, of one or several shareholders holding at least two and a half percent (2.5%) of the Company's capital.

19.3.2. Special

19.3.3. conditions governing changes in capital

There is no special stipulation in the Company's bylaws governing changes in its capital and that would be stricter than the legal provisions.

20. MATERIAL AGREEMENTS

20.1. Joint venture agreements entered into between Epygon, MyoPowers and Shanghai Zuquan Investment Management Company Limited

On 28 October 2017, Epygon and MyoPowers entered into a joint-venture agreement with Shanghai Zuquan Investment Management Company Limited under the terms of which the parties agreed to form, respectively, Shanghai Epygon Medical Technology Co., Ltd, and Shanghai MyoPowers Medical Technology Co., Ltd (the "**Joint Ventures**"), the purpose of which is the research and development, and manufacturing and marketing in China (including continental China, Hong Kong, Macau and Taiwan) of medical devices developed or being developed by the subsidiaries Epygon and MyoPowers, respectively, and which will be selected jointly by the parties. The production of the Epygon and MyoPowers medical devices will be carried out locally by the joint ventures that will market its two products directly in the territories indicated above.

Under these agreements, the newly created Joint Ventures shall make every effort to conduct the necessary clinical trials, submit registration applications for the products selected and obtain the government approvals required to market said products in China. It should be noted that the Joint Ventures will not have the right to export know-how or developed products outside China. Epygon and MyoPowers have respectively pledged to provide the technical assistance required in respect of the above, with their staff's travel costs to China being borne by each Joint Venture concerned.

In terms of ownership of the Joint Ventures, 60% of the capital is owned by Shanghai Zuquan Investment Management Company Limited and 40% by each of the Subsidiaries concerned at 31 December 2020.

The Joint Ventures' governance and management bodies are appointed by the two parties. Accordingly, the two parties are represented on the Joint Venture's Board of Directors: three Board members including the Chairman are appointed by Shanghai Zuquan Investment Management Company Limited, and two members including the Vice-Chairman are appointed by the Subsidiary concerned. Shanghai Zuquan Investment Management Company Limited is in charge of appointing the Joint Venture's Chief Executive Officer and the Subsidiary concerned will be in charge of appointing the Joint Venture's Chief Financial Officer. In addition, the parties plan to set up a joint research and development committee composed of staff from the Joint Venture and the Subsidiary concerned in order to coordinate and supervise clinical studies, regulatory issues and research and development. Two observers will be appointed by the two parties respectively.

In accordance with the agreements entered into as part of these joint ventures, in April 2018 Epygon and MyoPowers respectively granted a licence to their exclusive rights to use their patents and their know-how to develop, manufacture and market Epygon and Artus implants at Shanghai Epygon Medical Technology Co., Ltd and Shanghai MyoPowers Medical Technology Co., Ltd in China (including mainland China, Hong Kong, Macau and Taiwan). The license agreements expire on 26 April 2033 for the patent rights for the Epygon implant and on 21 December 2032 for the patent rights for the MyoPowers implant.

Under these patent agreements, Epygon and MyoPowers each received, from an affiliate of the company Shanghai Zuquan Investment Management Company Limited, the sum of RMB 7.2 million. These amounts were paid to Shanghai Epygon Medical Technology Co., Ltd and Shanghai MyoPowers Medical Technology Co., Ltd. in the form of contributions in cash for the purposes of their incorporation.

Epygon and MyoPowers reserve the exclusive right to use and exploit their patents and know-how (including licensing them) (i) in China for products other than the selected products, with the unanimous prior consent of all Board members, and (ii) outside China. Lastly, upon termination or expiration of the agreement, Epygon and MyoPowers may ask the Joint Ventures to grant them an exclusive right to exploit all intellectual property rights or know-how developed or held by a Joint Venture outside China and at no charge.

Before each Joint Venture reaches its break-even point, its expenditure related to the development and marketing programme for the Epygon and MyoPowers devices will be entirely financed on the basis of the following cash contributions:

- RMB 10.8 million (*i.e.* approximately €1.4 million[61])by Shanghai Zuquan Investment Management Company Limited;
- RMB 7.2 million (*i.e.* around €0.9 million[61]) by the relevant Subsidiary (Epygon or MyoPowers);

it being specified that any additional expenditure shall be borne by Shanghai Zuquan Investment Management Company Limited.

20.2. Agreements related to research and development for the MIVANA Project

20.2.1. Consortium agreement for the MIVANA Project

The Group's subsidiaries, Kephalios and Epygon, entered into a consortium agreement with MDB Texinov and the *Institut Français du Textile et de l'Habillement* (the French Institute of Textiles and Clothing – IFTH) dated 27 August 2015 in respect of the project known as "Innovative Medical Devices and Techniques Derived from the Textile Industry for the Creation of a National Cardiovascular Sector" (the "**MIVANA Project**"). The project aims to develop two ranges of cardiovascular implantable medical devices for (i) the repair of mitral valves to reduce post-surgical residual leakage or late regurgitation, and (ii) the percutaneous replacement of damaged mitral valves using a catheter. The goal of the MIVANA Project research and development program is to design and manufacture innovative textiles for use in cardiovascular implantable medical devices and to engineer the manufacturing process of such medical devices by developing robotic, automated textile assembly processes that will set a new standard in terms of quality, safety and cost.

Under the terms of this agreement, the parties agreed to contribute to the project's research and development program based on their respective specialties, it being specified that the subsidiaries Kephalios and Epygon are primarily tasked with the validation/product testing phase, animal testing and clinical trials. MDB Texinov and IFTH, the academic partner, are mainly involved in designing the textile structures and processes and developing automated textile assembly processes.

This agreement provides that each party to the contract receives directly from Bpifrance Financement grants and repayable advances corresponding to its share in the context of the MIVANA project depending on the achievement of key milestones, it being specified, however, that the parties bear the additional costs individually required to carry out their share of the programme. The project is worth a total of almost €27.4 million, of which €8.6 million is being provided under the Bpifrance Investments for the Future Programme.

Under the agreement, the parties agree that any prior knowledge or any proprietary new knowledge generated by one of the parties alone shall be the exclusive property of that party. Any new knowledge that is generated jointly by the parties shall be the joint property of the parties in proportion to their inventive contribution, unless the parties agree otherwise. The parties furthermore agree to make the protection of their new joint knowledge a priority in the event that it can be patented, by filing one or more new patents in their name and at their expense.

Prior knowledge and new knowledge – proprietary or joint – as well as any item, product, process or new patent may be used at no cost by the parties solely during the research and development program and are intended for industrial and/or commercial use by Kephalios, Epygon and MDB Texinov within the scope of their collaboration during the program's execution and/or after the end of the project.

[61] Based on the RMB/EUR exchange rate prevailing on the date of the signing of the *joint ventures.*

With regard to the use of knowledge for research purposes:

- each party may freely use, exploit, access and/or have exploited its prior knowledge;

- each party may use its proprietary new knowledge freely and without cost for its own research purposes, in any field if conducting the research alone, but only within the field of the project if conducting research in collaboration with a third party;

- each party must obtain the prior consent of the other joint-owners to use the knowledge for its own research purposes, in any field if conducting research alone, but only in the field of the project if conducting research in collaboration with a third party.

With regard to using the knowledge for the purposes of the program:

- each party grants the others, subject to third-party rights, a non-exclusive, free license to use its prior knowledge, its new proprietary knowledge and/or its new joint knowledge if the use of the knowledge is required for the program.

With regard to using the knowledge for industrial and/or commercial purposes:

- subject to third-party rights, each party agrees to grant Kephalios, Epygon or MDB Texinov a non-exclusive license to use their prior knowledge and/or proprietary new knowledge, limited to their respective field, if such knowledge is required for the industrial and/or commercial exploitation of the new proprietary or joint knowledge of Kephalios, Epygon or MDB Texinov (with financial terms and conditions being determined in a license agreement);

- each party shall benefit from exclusive industrial and/or commercial exploitation rights on its new joint knowledge in its own field, based on the understanding that the parties exploiting the new joint knowledge must remunerate the other co-owners who are parties to the agreement.

In the context of their collaboration, the parties have jointly designated Kephalios as lead partner to take charge of the overall coordination of the MIVANA Project and oversee its execution. The parties have also set up a strategy committee and a steering committee, chaired by the lead partner's representative and composed of a representative from each of the other parties. The role of the strategy committee is to manage the strategic aspects of the project, with decisions being made unanimously, with some exceptions. The steering committee is in charge of monitoring and periodically assessing the work, technological advances, budgets and scheduling of the project; its decisions shall be made by a majority of three-quarters of the members present or represented.

In the event of a serious breach by one of the parties in respect of one of its obligations under the consortium agreement, the other parties may decide at a strategy committee meeting on the automatic termination of the agreement in respect of the party in default, subject to the absence of an amicable solution and lack of compliance within a period of 30 days from the notification given to the defaulting party by the lead partner.

In the event of a change of control of one of the parties in favour of a competing entity of another party, or in the event of the sale of business assets of one of the parties to a third party to the consortium agreement, the lead partner may also put the continued involvement in the project of the party concerned by aforementioned transaction to the vote at a meeting of the strategy committee.

20.2.2. Bpifrance Financement public funding agreement for the MIVANA Project

To finance the MIVANA Project, Kephalios, Epygon, MDB Texinov and IFTH have entered into a public funding framework agreement with Bpifrance Financement dated 28 September 2015 for a cumulative total of €5,457,595 in repayable advances and €3,122,022 in grants.

In exchange, the parties have pledged to Bpifrance Financement that this funding will only be used for the MIVANA Project and to fund expenditures in industrial research and experimental development.

The contract provides for a maximum amount of recoverable grants and advances of €6,469,477 for Kephalios and Epygon, respectively up to the amount of €2,014,870 and €4,454,607, broken down as follows:

- a maximum overall amount of €1,957,391 in grants for Kephalios and Epygon, or €965,382 and €992,009 respectively;

- a maximum overall amount of €4,512,086 in repayable advances for Kephalios and Epygon, or €1,049,488 and €3,462,598 respectively.

As at the date of approval of the Registration Document, three of the four key stages of the MIVANA Project had been completed:

- Kephalios and Epygon received respectively €820 thousand and €753,537 in grants, *i.e.* a total of €1,573,537;
- Kephalios and Epygon received respectively €892 thousand and €1,655 thousand in repayable advances, *i.e.* a total of €2,547 thousand.

The completion of the fourth key stage of the MIVANA Project is scheduled for 31 December 2022, and the payment of grants and repayable advances related to the completion of this fourth key stage should take place in 2023.

Repayments of the advances received by Kephalios and Epygon in connection with the MIVANA Project should therefore begin as from the financial year 2024 and extend until 2027 (refer to section 3.4.4. of the Registration Document).

In the event of termination of the MIVANA consortium agreement referred to in section 20.2.1, Bpifrance Financement may request the repayment of the repayable aid paid (i) to the beneficiary that caused the termination of the project or (ii) to all beneficiaries in the event of a joint decision by the latter to discontinue the project (including through the termination of the consortium agreement).

20.3. Bpifrance agreement to provide funding for the Artus "Industrial Project for the Future" PIAVE initiative under the Investments for the Future Program

On 21 July 2016, the subsidiary MyoPowers and Bpifrance entered into an agreement, subject to two amendments dated 23 March 2017 and 22 February 2019, to fund the Artus Investments for the Future Action Programme "Industrial projects for the future" (the "**Artus PIAVE Project**") for the development of an artificial urinary sphincter for the treatment of severe stress urinary incontinence.

The agreement provides for a total amount of €7,996,149, of which €200,589 in grants and €7,795,560 in repayable advances, out of a total funding amount for the Artus PIAVE Project of €23.0 million.

In exchange, MyoPowers has pledged to Bpifrance Financement that this funding will only be used for the Artus PIAVE Project and to fund expenditures in industrial research, experimental development and investment.

As at the date of approval of the Registration Document, the first of the four key stages of the Artus PIAVE Project had been completed. On this occasion, MyoPowers received €117 thousand in grants and €3,659 thousand in repayable advances.

The completion of the next three key milestones of the Artus PIAVE Project are planned between the financial year 2021 and 2022.

Repayments of the advances received by MyoPowers as part of the Artus PIAVE Project are expected to start from the financial year 2023 and extend until 2026 (refer to section 3.4.4. of the Registration Document).

Bpifrance Financement may request the repayment of the repayable aid paid to MyoPowers in the event of the termination of the PIAVE Artus Project and termination of the aid contract as a result.

20.4. Venture Loan Agreement with Kreos Capital

On 29 October 2018, the Company entered into a venture loan agreement with Kreos Capital V (UK) Limited ("**Kreos**"), intended to enable the Company to benefit from a bond financing in the form of non-convertible bonds representing a maximum amount of €8 million to which Kreos has undertaken to subscribe in two tranches, in order to finance the Company's projects (the "**Venture Loan**"), as follows:

- €4,000,000 (*i.e.* 4 million bonds) ("**Tranche A**") issued on 29 October 2018 and fully subscribed;

- €4,000,000 (*i.e.* 4 million bonds) ("**Tranche B**") issued on 1 June 2019 and fully subscribed.

The parties also agreed that the amount of the Venture Loan could have been increased to €12,000,000 by payment of a third tranche of €4,000,000 in the event of mutual agreement between the Company and Kreos. This third tranche has not been issued and will not be.

Each tranche is repayable monthly over a period of 36 months. At 31 December 2020, non-convertible bonds issued to Kreos totalled €5,483 thousand (of which €3,573 thousand in current financial debt) (see also section 8.1.3).

Under the terms of the Venture Loan, the Company also issued to Kreos' subsidiary, Kreos Capital V (Expert Fund) Limited, 196,722 share subscription warrants, which were issued in full at the time of the issue of the Tranche A (see section 19.1.4.1 for more details).

In addition, Kreos has the option of requesting early repayment of the amounts due under the loan in the event of a change of control of the Company. With respect to the loan, Kreos benefits from first-ranking collateral comprised of the main tangible and intangible assets of the Company, in particular its business goodwill, the intellectual property rights relating to its main medical devices (with the exception of the Artus and Epygon intellectual rights in China), as well as a pledge of the Company's bank accounts and receivables.

21. DOCUMENTS AVAILABLE

Copies of the Registration Document are available free of charge at the Company's registered office, 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, as well as in an electronic version on the Company's website (www.affluentmedical.com) and on the website of the French Financial Markets Authority (*Autorité des marchés financiers* – AMF) (www.amf-france.org).

During the period of validity of the Registration Document, the following documents (or a copy of these documents) may be consulted:

- the Company's memorandum and bylaws;
- all reports, letters and other documents, historical financial information;
- valuations and statements prepared by an expert at the Company's request, some of which are included or referred to in the Registration Document; and
- the historical financial information included in the Registration Document.

All of these legal and financial documents relating to the Company and which must be made available to shareholders in accordance with the regulations in force may be consulted at the Company's registered office.

The Company intends to disclose its financial results in accordance with the requirements of applicable laws and regulations. Once the Company's shares are listed on the Euronext Paris regulated securities market, regulated information pursuant to the AMF General Regulations will also be available on the Company's website (www.affluentmedical.com).

22. GLOSSARY

AAA	Abdominal aortic aneurysm.
Aneurysm	An aneurysm is a localised dilation of the arterial wall resulting in the formation of a pouch of varying size, communicating with the artery by means of a narrowed area known as the neck. Aneurysms are usually saccular and can be several centimetres in diameter. A ruptured aneurysm is a serious complication regardless of its location and can be life-threatening.
Annuloplasty	We talk about annuloplasty during a conservative procedure to remedy a failure of the mitral heart valve, for example. In this context, annuloplasty reduces the calibre of the mitral ring through shortening by plication the attachment of the small valve, the support point being taken on both commissures.
Annulus	A ring-shaped structure. In anatomy, an annulus is a circular, cartilaginous, muscular structure or a circular opening in an organ or anatomical zone.
Apex	A term referring to the pointed end of a conical or pyramid-shaped organ, such as the lungs or heart.
CE marking	In force since 1993, CE marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European legislation. It must be affixed before a product may be placed on the European market.
Clean room	A room in which the concentration of airborne particles is controlled and which is constructed and used so as to minimise the introduction, production and retention of particles within the room. Other relevant parameters, such as temperature, humidity and pressure, are also controlled as appropriate.
CRO	Acronym for Contract Research Organisation – a company that provides services in the field of biomedical research and clinical trials.
Detrusor	A muscle found in the wall of the bladder which contracts during urination to release urine.
Endoleak	Blood flow that occurs between the stent graft and the aneurysm wall.
Endovascular	Refers to the inside of a blood vessel, such as the aorta.
Euroscore	Risk model that calculates the risk of death after cardiac surgery.
EVAR	Endovascular aneurysm repair – a medical procedure to repair an abdominal aortic aneurysm. This is less invasive than open surgical repair in which the abdomen is open.
Extracorporeal circulation	Extracorporeal circulation is when the blood flowing through the heart and lungs is diverted outside the body. This cardiopulmonary

	bypass technique diverts blood from the heart chambers so that the heart remains still and the surgeon can perform intracavity surgery without there being any extra bleeding.
FDA	The United States Food and Drug Administration.
Ischemia	Due to decreased arterial blood supply to an organ. This decrease essentially leads to a decrease in the oxygenation of the tissues of the organ below its needs and the disruption, or even the cessation, of its function.
KOL	Key opinion leaders. Renowned scientists (surgeons, cardiologists, specialists) who can act as prescribers of products marketed by the Company.
Laparotomy	Abdominal wall incision.
Minimally invasive surgeries or therapies	Surgeries or techniques that allow surgeons to reach their targets by making incisions in the one-centimetre range and then using long, thin instruments coupled with a video imaging system. Arthroscopies are procedures involving joints; laparoscopies or coelioscopies are procedures involving the abdominal cavity; and thoracoscopies are procedures involving the thorax.
Minimised atrial protrusion	This means minimising overflow into the atrium to reduce the risk of thrombosis when a mitral valve is implanted in place of a native valve.
NMPA	The National Medical Products Administration is the Chinese authority for food, cosmetics and medicines.
NYHA	Functional classification of the New York Heart Association which provides a simple way of classifying heart failure.
Pelvic floor	The pelvic floor is a set of muscles, tissues and ligaments that span the bottom of the pelvis. It comprises the perineum, the area of the pelvis that supports the genital organs in women, and the anus and bladder in men and women. Its role is to control the opening of the urethra, anus, and vagina, as well as prevent organ descent, known as prolapse.
Plicature	The act of folding or condition of being folded.
Prolapse	Descent (of an organ or part of an organ).
Prophylactic	Treatment to prevent disease.
Sphincter	A sphincter is a circular muscle located around a natural body passage or orifice (digestive tract, bladder, etc.). When it contracts, the orifice or passage of the body is closed totally or partially. Control over the sphincter can be voluntary or automatic (as a reflex to certain

	stimulations). In the urinary system, the sphincter is the muscle at the base of the urethra.
Stenosis	Anatomical modification that results in a narrowing of a structure (canal, vessel).
Sternotomy	A sternotomy is the surgical opening of the sternum. It is performed under general anaesthesia and consists of opening the sternum vertically so that the surgeon can operate on the heart, large vessels and/or coronary arteries.
TAA	Thoracic aortic aneurysm.
Thoracotomy	A thoracotomy is a surgical incision into the thoracic wall. Surgery may require opening the thorax or simply making an incision between the ribs.
Thrombogenic	Liable to produce or producing a thrombosis, which is the formation of clots in blood vessels.
Transapical route	Access through the tip of the heart requiring a small surgical thoracotomy performed by a surgeon.
Urinary retention	Inability to fully or partially empty the bladder.
Transcatheter implantation	A method that uses a catheter (thin tube) to introduce a new heart valve (transcatheter valve) into the defective valve.
Transfemoral route	Surgical access through the femoral artery for implant placement.
Transseptal route	Access to the left side of the heart by entering *via* the femoral route and then the right atrium and then puncturing the interatrial septum, a procedure performed by an interventional cardiologist.
Valvular heart disease	Valvular heart disease refers to various dysfunctions of the heart valves. These are common diseases whose causes have changed as health conditions have improved. All heart valves can be affected, but the aortic and mitral valves are the most commonly affected.

CONCORDANCE TABLE

Sections of Annex I of Commission Delegated Regulation (EU) No. 2019/980 of 14 March 2019 supplementing Regulation (EU) No. 2017/1129 of the European Parliament and of the Council of 14 June 2017		Affluent Medical Registration Document Section
SECTION 1	**PERSONS RESPONSIBLE, INFORMATION FROM THIRD PARTIES, EXPERT REPORTS AND APPROVAL OF THE COMPETENT AUTHORITY**	**1**
Point 1.1	Identify all persons responsible for the information contained in the registration document, or only part of this information, in which case it should be indicated which part it is. Where the persons responsible are natural persons, including members of the issuer's governance, management or supervisory bodies, indicate their name and function; in the case of legal entities, indicate their name and registered office.	**1.1**
Point 1.2	Provide a statement from the persons responsible for the registration document certifying that the information it contains is, to the best of their knowledge, true to the facts and that it does not contain any omissions that could alter its scope. Where applicable, provide a statement by the persons responsible for certain parts of the registration document certifying that the information contained in the parts for which they are responsible is, to the best of their knowledge, consistent with the facts and that the said parts do not contain any omissions likely to alter its scope.	**1.2**
Point 1.3	Where a statement or report attributed to a person acting as an expert is included in the registration document, provide the following information about that person: a) their name; b) their business address; c) their qualifications; d) if applicable, any significant interest they have in the issuer. If the statement or report was produced at the request of the issuer, indicate that this statement or report was included in the registration document with the consent of the person who endorsed the content of this part of the registration document for the purposes of the prospectus.	**1.3**
Point 1.4	When information comes from a third party, provide a certificate confirming that this information has been faithfully reproduced and that, as far as the issuer is aware and is able to verify it from the data published by this third party, no facts have been omitted which would render the information reproduced inaccurate or misleading. In addition, identify the source(s) of information.	**1.4**
Point 1.5	Provide a statement that: a) the [registration document/prospectus] has been approved by [name of competent authority], as the competent authority under Regulation (EU) No. 2017/1129; b) [name of competent authority] only approves this [registration document/prospectus] as complying with the standards of completeness, comprehensibility and consistency imposed by Regulation (EU) No. 2017/1129; c) this approval should not be considered as a favourable opinion on the issuer which is the subject of the [registration document/prospectus].	**1.5**
SECTION 2	**STATUTORY AUDITORS**	**2**
Point 2.1	Give the name and address of the issuer's statutory auditors for the period covered by the historical financial information (also indicate membership of a professional body).	**2.1 and 2.2**
Point 2.2	If the statutory auditors have resigned, were dismissed from their positions or were not reappointed during the period covered by the historical financial information, provide details of this information, if they are material.	**2.3**

SECTION 3	**RISK FACTORS**	**3**
Point 3.1	Provide a description of the significant risks that are specific to the issuer, broken down into a limited number of categories, in a section entitled "Risk factors". In each category, the most significant risks according to the assessment carried out by the issuer, the offeror or the person requesting the admission to trading on a regulated market should be indicated first, taking into account their negative impact on the issuer and the likelihood of their occurrence. These risks must be corroborated by the content of the registration document.	**3.1 to 3.4**
SECTION 4	**INFORMATION CONCERNING THE ISSUER**	**4**
Point 4.1	Indicate the company name and the commercial name of the issuer.	**4.1**
Point 4.2	Indicate the issuer's place of registration, registration number and Legal Entity Identifier (LEI).	**4.2**
Point 4.3	Indicate the date of incorporation and the term of the issuer, if this is not indefinite.	**4.3**
Point 4.4	Indicate the issuer's registered office and legal form, the legislation governing its activities, the country in which it is incorporated, and the address and telephone number of its registered office (or principal place of business, if this is different from its registered office) as well as its website, if it has one, with a disclaimer stating that the information on the website is not part of the prospectus, unless this information is incorporated by reference in the prospectus.	**4.4**
SECTION 5	**OVERVIEW OF BUSINESS ACTIVITIES**	**5**
Point 5.1	Main activities	**5.1**
Point 5.1.1	Describe the nature of the transactions carried out by the issuer and its main businesses – including the related key factors – mentioning the main categories of products sold and/or services provided during each financial year of the period covered by the historical financial information.	**5.1.1** **5.1.2**
Point 5.1.2	Mention any significant new product and/or service launched on the market and, to the extent that the development of a new product or service has been publicly announced, state its progress.	**5.2.2.2 - Artus** **5.2.3.2 - Kalios** **5.2.3.3 - Epygon** **5.2.4 - Kardiozis**
Point 5.2	Main markets Describe the principal markets in which the issuer operates, by breaking down its total revenue by type of activity and by geographic market, for each financial year of the period covered by the historical financial information.	**5.2.2.1 – Urinary incontinence** **5.2.3.1 – Mitral regurgitation** **5.2.4.1 – Abdominal aortic aneurysm**
Point 5.3	Indicate significant events in the development of the issuer's business.	**5.2.1**

Point 5.4	Strategy and objectives Describe the issuer's strategy and objectives, both financial and non-financial (if applicable). This description takes into account the issuer's future outlook and challenges.	**5.1.2** **5.2.2.2 - Artus** **5.2.3.2 - Kalios** **5.2.3.3 - Epygon** **5.2.4.2 - Kardiozis** **5.3.1 – Management** **5.3.2 – Scientific Committee** **5.3.4 – Quality** **5.3.5 – Industralisation** **5.3.6 - Marketing**
Point 5.5	If it has an influence on the issuer's business or profitability, provide information, in summarised form, on the degree of dependence of the issuer on patents or licenses, industrial or commercial contracts or financial or new manufacturing processes.	**5.3.3**
Point 5.6	Indicate the elements on which any statement by the issuer concerning its competitive position is based.	**5.2.2.2 - Artus** **5.2.3.2 – Kalios** **5.2.3.3 – Epygon** **5.2.4.1 - Kardiozis**
Point 5.7	Investments	**5.4**
Point 5.7.1	Describe the significant investments (including their amount) made by the issuer during each financial year of the period covered by the historical financial information, up to the date of the registration document.	**5.4.1**
Point 5.7.2	Describe all significant investments by the issuer that are in progress or for which firm commitments have already been made, including their geographical distribution (in France and abroad) and their financing method (internal or external).	**5.4.2**
Point 5.7.3	Provide information on joint ventures and companies in which the issuer holds a share of capital likely to have a significant impact on the valuation of its assets and liabilities, its financial position or its results.	**5.4.3**
Point 5.7.4	Describe any environmental issue that may influence the issuer's use of its property, plant and equipment.	**5.4.4**
SECTION 6	**ORGANISATIONAL STRUCTURE**	**6**
Point 6.1	If the issuer is part of a group, briefly describe this group and the issuer's position within it. This description may consist of an organisation chart or be accompanied by it, if this helps to clarify the organisational structure of the Group.	**6.1**
Point 6.2	List the issuer's significant subsidiaries, including their name, country of origin or establishment as well as the percentage of capital and, if different, the percentage of voting rights held therein.	**6.2**
SECTION 7	**REVIEW OF THE FINANCIAL POSITION AND RESULTS**	**7**
Point 7.1	Financial position	**7.1**
Point 7.1.1	Insofar as this information does not appear elsewhere in the registration document and where it is necessary to understand the issuer's business as a whole, to provide a true and fair view of the evolution and results of its business as well as its position for each	**7.1.1 to 7.1.3**

	financial year and interim period for which historical financial information is required, indicating the reasons for any significant changes that have occurred. This presentation consists of a balanced and exhaustive analysis of the evolution and results of the issuer's business, as well as its position, in relation to the volume and complexity of these activities. To the extent necessary to understand the issuer's evolution, results or position, the analysis includes key performance indicators, of a financial and, where applicable, non-financial nature, relating to the specific activity of the company. This analysis contains, where appropriate, references to the amounts published in the annual financial statements and additional explanations of these amounts.	
Point 7.1.2	To the extent that this information does not appear elsewhere in the registration document and is necessary to understand the issuer's business as a whole, the disclosure also includes information on: a) the probable future development of the issuer's business; b) its research and development activities. The requirements set out in point 7.1 may be satisfied by the inclusion of the management report referred to in Articles 19 and 29 of Directive No. 2013/34/EU of the European Parliament and of the Council ([1]).	**7.1.1 to 7.1.3**
Point 7.2	Operating income (loss)	**7.2**
Point 7.2.1	Disclose significant factors, including unusual or infrequent events or new developments, that materially affect the issuer's operating revenue, and indicate the extent to which it is affected.	**7.2.1**
Point 7.2.2	When historical financial information shows significant changes in net revenue or net income, explain the reasons for these changes.	**7.2.1.1 to 7.2.1.5**
SECTION 8	**CASH AND CAPITAL**	**8**
Point 8.1	Provide information on the issuer's capital (short-term and long-term).	**8.1**
Point 8.2	Indicate the source and amount of the issuer's cash flows and describe these cash flows.	**8.2**
Point 8.3	Provide information on the issuer's financing needs and structure.	**8.3**
Point 8.4	Disclose any restrictions on the use of capital that have materially affected or may materially affect, directly or indirectly, the issuer's business.	**8.4**
Point 8.5	Provide information on the expected sources of funding that will be required to honour the commitments referred to in section 5.7.2.	**8.5**
SECTION 9	**REGULATORY ENVIRONMENT**	**9**
Point 9.1	Provide a description of the regulatory environment in which the issuer operates and which may have a significant impact on its activities and mention any measure or any factor of an administrative, economic, budgetary, monetary or political nature that has materially influenced or could materially affect, directly or indirectly, the issuer's business.	**9.1 to 9.3**
SECTION 10	**TREND INFORMATION**	**10**
Point 10.1	Provide a description of:	**10.1**

	a) the main recent trends affecting production, sales and inventories as well as costs and selling prices between the end of the last financial year and the date of the registration document; b) any significant change in the Group's financial performance that occurred between the end of the last financial year for which financial information was published and the date of the registration document, or provide an appropriate negative statement.	
Point 10.2	Report any trends, uncertainties, constraints, commitments or events of which the issuer is aware and which is reasonably likely to have a material impact on the issuer's outlook, at least for the current financial year.	**10.2**
SECTION 11	**EARNINGS FORECASTS OR ESTIMATES**	**11**
Point 11.1	When an issuer has published a profit forecast or estimate (which is still open and valid), this must be included in the registration document. If a profit forecast or estimate has been published and is still in progress, but is no longer valid, provide a statement to that effect, together with an explanation of why the forecast or estimate is no longer valid. Any such prediction or estimate is not subject to the requirements set out in points 11.2 and 11.3.	**N/A**
Point 11.2	When an issuer elects to include a new profit forecast or estimate, or a previously published profit forecast or estimate in accordance with point 11.1, that profit forecast or estimate must be clear and unambiguous and contain a statement setting out the main assumptions on which the issuer bases it. The forecast or estimate complies with the following principles: a) assumptions relating to factors that may be influenced by members of the governance, management or supervisory bodies must be clearly distinguished from assumptions relating to factors that are totally beyond their control; b) the assumptions must be reasonable, easily understandable by investors, specific and precise and unrelated to the general accuracy of the estimates underlying the forecast; c) in the case of a forecast, the assumptions highlight for the investor the factors of uncertainty that could significantly change the outcome of the forecast.	**N/A**
Point 11.3	The prospectus contains a statement certifying that the profit forecast or estimate has been developed and prepared on the basis of: a) comparable to historical financial information; b) in line with the issuer's accounting policies.	**N/A**
SECTION 12	**CORPORATE GOVERNANCE, MANAGEMENT AND SUPERVISORY BODIES AND EXECUTIVE MANAGEMENT**	**12**
Point 12.1	Give the name, business address and position, within the issuer, of the following persons, mentioning the main activities they carry out outside the issuer when these activities are significant in relation to the issuer: a) members of governance, management or supervisory bodies; b) general partners, in the case of a partnership limited by shares; c) founders, if the company was founded less than five years ago; d) any Chief Executive Officer whose name can be mentioned to prove that the issuer has the appropriate expertise and experience to conduct its own affairs. Indicate the nature of any family ties between any of the persons referred to in points a) to d). For each person who is a member of an administrative, management or supervisory body and for each person referred to in points b) and d) of the first paragraph, provide detailed information on their relevant management expertise and experience, as well as the following information: a) the name of all companies and partnerships limited by shares in which this person has been a member of a governance, management or supervisory body or general partner, at any time during the last five years (also indicate whether he or she has always held	**12.1**

	this position or not). It is not necessary to list all the subsidiaries of the issuer in which the person is also a member of a governance, management or supervisory body; b) details of any convictions for fraud pronounced during at least the last five years; c) details of any bankruptcy, receivership, liquidation or receivership of undertakings concerning the persons referred to in points a) and d) of the first paragraph who have held one or more of these positions during the last five years at least. ; d) details of any questioning and/or official public sanction pronounced against these persons by statutory or regulatory authorities (including designated professional bodies). Indicate also whether these persons have already, at least during the last five years, been deprived by a court of the right to exercise the function of member of a governance, management or supervisory body of an issuer or of intervening in the management or conduct of the business of an issuer. If there is no such information to disclose, it must be stated expressly.	
Point 12.2	Conflicts of interest between corporate governance bodies and executive management Potential conflicts of interest between the duties of any of the persons referred to in point 12.1 towards the issuer and its private interests and/or other duties must be clearly indicated. In the absence of such conflicts of interest, a declaration to this effect must be made. Indicate any arrangement or agreement concluded with the main shareholders or with customers, suppliers or others, pursuant to which any of the persons referred to in point 12.1 has been selected as a member of a governance, management or Supervisory Board or as a member of the Executive Management. Provide details of any restrictions accepted by the persons referred to in point 12.1 concerning the sale, within a certain period of time, of the securities of the issuer that they hold.	**12.2**
SECTION 13	**COMPENSATION AND BENEFITS**	**13**
	For the last financial year just ended, indicate, for any person referred to in point 12.1, first paragraph, points a) and d):	
Point 13.1	Indicate the amount of compensation paid (including any conditional or deferred compensation) and benefits in kind granted by the issuer and its subsidiaries for services of any type provided to them by the employee. This information must be provided on an individual basis, unless individualised information is not required in the issuer's country of origin and the issuer does not disclose it otherwise.	**13.1**
Point 13.2	The total amount provisioned or otherwise recognised by the issuer or its subsidiaries for the purpose of paying pensions, retirement or other similar benefits.	**13.2**
SECTION 14	**OPERATING PROCEDURES OF CORPORATE GOVERNANCE AND MANAGEMENT BODIES**	**14**
	For the financial year just ended for the issuer, and unless otherwise specified, provide the following information concerning any person referred to in point 12.1, first paragraph, point a):	
Point 14.1	The date of expiry of the current mandate of this person, if applicable, and the period during which he or she remained in office.	**14.1** **12.1.1**
Point 14.2	Information on service contracts binding the members of the corporate governance, management or supervisory bodies to the issuer or any of its subsidiaries and providing for the granting of benefits at the end of such a contract, or an appropriate statement attesting to the absence of such benefits.	**14.2**

Point 14.3	Information on the issuer's Audit Committee and Compensation Committee, including the names of the members of these committees and a summary of the mandate under which they serve.	**14.3**
Point 14.4	A statement as to whether or not the issuer complies with the corporate governance regime(s) applicable to it. If the issuer does not comply, a statement to that effect should be included, together with an explanation of the reasons for the lack of compliance.	**14.5**
Point 14.5	Potential material impacts on corporate governance, including future changes in the composition of the governance and management bodies and committees (insofar as this has already been decided by the corporate governance and management bodies and/or the shareholders' meeting).	**N/A**
SECTION 15	**EMPLOYEES**	**15**
Point 15.1	Indicate either the number of employees at the end of the period covered by the historical financial information, or their average number during each financial year of this period, up to the date of the registration document (as well as changes in this number, if they are material) and, if possible, if this information is important, the breakdown of employees by major business category and by site. If the issuer employs a large number of temporary workers, also indicate the average number of temporary workers during the most recent financial year.	**15.1**
Point 15.2	**Shareholdings and stock options** For each of the persons referred to in point 12.1, first paragraph, points a) and d), provide the most recent information possible concerning the shareholding held in the share capital of the issuer and any existing options on such shares.	**15.2** **15.3**
Point 15.3	Describe any agreement providing for employee shareholding in the issuer's share capital.	**15.4**
SECTION 16	**MAJOR SHAREHOLDERS**	**16**
Point 16.1	Insofar as such information is known to the issuer, provide the name of any person who is not a member of a governance, management or supervisory body who directly or indirectly holds a percentage of the share capital or voting rights of the issuer to be notified under the applicable national legislation, as well as the amount of the interest thus held on the date of the registration document. In the absence of such persons, provide an appropriate statement indicating the absence of such persons.	**16.1**
Point 16.2	Indicate whether the issuer's main shareholders hold different voting rights, or provide an appropriate statement indicating the absence of such voting rights.	**16.2**
Point 16.3	To the extent that such information is known to the issuer, indicate whether it is owned or controlled, directly or indirectly, and by whom; describe the nature of this control and the measures taken to prevent it from being abused.	**16.3**
Point 16.4	Describe any agreement known to the issuer, the implementation of which could, at a later date, result in a change of control over it.	**16.4**
SECTION 17	**TRANSACTIONS WITH RELATED PARTIES**	**17**
Point 17.1	Details of transactions with related parties [which, for this purpose, are those provided for in the standards adopted pursuant to Regulation (EC) No. 1606/2002 of the European Parliament and of the Council ([2])] entered into by the issuer during the period covered	**17.1**

	by the historical financial information up to the date of the registration document must be disclosed in accordance with the relevant standard adopted under Regulation (EC) No. 1606/2002, if applicable to the issuer. If this is not the case, the following information must be published: a) the nature and amount of all transactions that, considered individually or as a whole, are material to the issuer. When transactions with related parties have not been concluded at market conditions, explain why. In the case of outstanding loans including guarantees of any type, indicate the amount outstanding; b) the amount or percentage for which transactions with related parties are included in the issuer's revenue.	
SECTION 18	**FINANCIAL INFORMATION CONCERNING THE ASSETS AND LIABILITIES, FINANCIAL POSITION AND RESULTS OF THE ISSUER**	**18**
Point 18.1	Historical financial information	**18.1**
Point 18.1.1	Provide audited historical financial information for the last three financial years (or any shorter period during which the issuer has been operating) and the audit report prepared for each of these financial years.	**18.1.1**
Point 18.1.2	**Change of accounting reference date** If the issuer has changed its accounting reference date during the period for which historical financial information is required, the audited historical financial information covers a period of at least 36 months, or the entire period of the issuer's activity if that is shorter.	**18.1.2**
Point 18.1.3	**Accounting standards** Financial information must be prepared in accordance with International Financial Reporting Standards, as adopted in the Union in accordance with Regulation (EC) No. 1606/2002. If Regulation (EC) No. 1606/2002 is not applicable, the financial information must be prepared in accordance with: a) the national accounting standards of a Member State for EEA issuers, as provided for in Directive No. 2013/34/EU; b) the national accounting standards of a third country equivalent to Regulation (EC) No. 1606/2002 for third country issuers. If the national accounting standards of the third country are not equivalent to Regulation (EC) No. 1606/2002, the financial statements must be restated in accordance with said regulation.	**18.1.3**
Point 18.1.4	**Change in accounting standards** The latest audited historical financial information, containing comparative information for the previous financial year, must be prepared and presented in a form corresponding to the accounting framework that will be adopted in the next annual financial statements to be published by the issuer, taking into account standards, accounting methods and legislation applicable to these annual financial statements. Changes in the accounting framework applicable to an issuer do not require that the audited financial statements be restated solely for the purposes of the prospectus. However, if the issuer intends to adopt a new accounting framework in its future financial statements, it must present at least one complete set of financial statements (within the meaning of IAS 1 "Presentation of financial statements", as established by Regulation (EC) No. 1606/2002), including comparative information, in a form corresponding to the framework to be adopted in the next annual financial statements that the issuer will publish, taking into account the accounting standards, methods and legislation applicable to these annual financial statements.	**18.1.4**
Point 18.1.5	When prepared in accordance with national accounting standards, audited financial information must include at least: a) the balance sheet; b) the income statement;	**18.1.5**

	c) a statement showing all changes in equity or changes in equity other than those resulting from equity transactions with owners and distribution to owners; d) cash flow statements; (e) accounting methods and explanatory notes.	
Point 18.1.6	**Consolidated financial statements** If the issuer prepares its annual financial statements on both an individual and consolidated basis, include at least the annual consolidated financial statements in the registration document.	**18.1.6**
Point 18.1.7	**Date of latest financial information** The date of the balance sheet for the last financial year for which the financial information was audited must not date back: a) more than eighteen months before the date of the registration document, if the issuer includes audited interim financial statements; b) more than 16 months before the date of the registration document, if the issuer includes, in the registration document, unaudited interim financial statements.	**18.1.7**
Point 18.2	Interim and other financial information	**18.2**
Point 18.2.1	If the issuer has published quarterly or half-yearly financial information since the date of its last audited financial statements, these must be included in the registration document. If this quarterly or half-yearly financial information has been audited or reviewed, the audit or review report must also be included. If not, please specify. If it was prepared more than nine months after the date of the last audited financial statements, the registration document must contain interim financial information, possibly unaudited (in which case this fact must be specified), covering at least the first six months of the financial year. Interim financial information is prepared in accordance with the requirements of Regulation (EC) No. 1606/2002. For issuers not covered by Regulation (EC) No. 1606/2002, the interim financial information must include comparative financial statements covering the same period of the previous financial year, although the requirement for comparative balance sheet information may be satisfied by the presentation of the closing balance sheet in accordance with the financial reporting framework applicable.	**N/A**
Point 18.3	Audit of historical annual financial information	**18.3**
Point 18.3.1	Historical annual financial information must be independently audited. The audit report must be prepared in accordance with Directive No. 2014/56/EU of the European Parliament and of the Council ([3]) and Regulation (EU) nº 537/2014 of the European Parliament and of the Council ([4]). When Directive No. 2014/56/EU and Regulation (EU) No. 537/2014 do not apply: a) historical annual financial information must be audited or include a statement indicating whether, for the purposes of the registration document, it presents a true and fair view, in accordance with the auditing standards applicable in a Member State or an equivalent standard; b) if the audit reports on the historical financial information have been rejected by the statutory auditors or if they contain reservations, modifications of opinion, limitations of liability, or observations, these reservations, modifications, limitations or observations must be reproduced in full and accompanied by an explanation.	**18.3.1** **18.3.2**
Point 18.3.2	Indicate which other information contained in the registration document has been audited by the statutory auditors.	**18.3.3**
Point 18.3.3	Where financial information in the registration document is not taken from the issuer's audited financial statements, indicate the source and specify that it has not been audited.	**18.3.4**

Point 18.4	Financial information pro forma	**18.4**
Point 18.4.1	In the event of a material change in gross values, describe how the transaction could have affected the issuer's assets, liabilities and results, had it occurred at the beginning of the period covered or on the date indicated. This obligation will normally be fulfilled by the inclusion of pro forma financial information. The pro forma financial information must be presented in accordance with note 20 and include all the data referred to therein. They must be accompanied by a report prepared by accountants or independent statutory auditors.	**N/A**
Point 18.5	Dividend policy	**18.5**
Point 18.5.1	Describe the issuer's dividend distribution policy and any applicable restrictions. If the issuer has not established a policy on this matter, include an appropriate statement indicating the absence of such policy.	**18.5.1**
Point 18.5.2	For each financial year of the period covered by the historical financial information, provide the amount of the dividend per share, possibly adjusted to allow comparisons, when the number of the issuer's shares has changed.	**18.5.2**
Point 18.6	Legal and arbitration proceedings	**18.6**
Point 18.6.1	Indicate, for a period covering at least the last twelve months, any administrative, legal or arbitration proceedings (including pending proceedings or threatened proceedings of which the issuer is aware) that could have or has recently had significant effects on the financial position or profitability of the issuer and/or the group, or provide an appropriate negative statement.	**18.6**
Point 18.7	Significant change in the issuer's financial position	**18.7**
Point 18.7.1	Describe any significant change in the Group's financial position since the end of the last financial year for which audited financial statements or interim financial information have been published, or provide an appropriate negative statement.	**18.7**
SECTION 19	**ADDITIONAL INFORMATION**	**19**
Point 19.1	Share capital Provide the information in points 19.1.1 to 19.1.7 in the historical financial information at the date of the most recent balance sheet:	**19.1**
Point 19.1.1	Indicate the amount of share capital issued and, for each category of shares: a) the total authorised share capital of the issuer; b) the number of shares issued and fully paid up and the number of shares issued but not fully paid up; c) the par value per share, or the fact that the shares have no par value; as well as d) a reconciliation of the number of shares outstanding on the opening date and the closing date of the financial year. If more than 10% of the share capital was paid up by means of non-cash assets during the period covered by the historical financial information this must be specified.	**19.1.1**
Point 19.1.2	Indicate whether there are any shares that do not represent the capital, their number and their main characteristics.	**19.1.2**
Point 19.1.3	Disclose the number, book value and nominal value of shares held by the issuer itself or on its behalf, or by its subsidiaries.	**19.1.3**

Point 19.1.4	Indicate the amount of convertible, exchangeable securities or securities accompanied by warrants, indicating the terms and conditions of conversion, exchange or subscription.	**19.1.4**
Point 19.1.5	Provide information on the conditions governing any right of acquisition and/or any obligation attached to the authorised but not issued capital, or any undertaking aiming to increase the capital.	**19.1.5**
Point 19.1.6	Provide information on the share capital of any member of the Group subject to an option or a conditional or unconditional agreement to place it under option and the details of these options, including the identity of the persons to whom they report.	**19.1.6**
Point 19.1.7	Provide a history of the share capital for the period covered by the historical financial information, highlighting any changes that have occurred.	**19.1.7**
Point 19.2	Memorandum of association and bylaws	**19.2**
Point 19.2.1	Where applicable, indicate the register and the entry number in the register; briefly describe the corporate purpose of the issuer and indicate where it can be found in the latest updated version of the memorandum of association and the bylaws.	**19.2.1**
Point 19.2.2	Where there are several existing classes of shares, describe the rights, privileges and restrictions attached to each class.	**19.2.2**
Point 19.2.3	Briefly describe any provision of the issuer's memorandum of association, bylaws, charter or regulation that would delay, defer or prevent a change in its control.	**19.3**
SECTION 20	**MATERIAL AGREEMENTS**	**20**
Point 20.1	Summarise, for the two years immediately preceding the publication of the registration document, each material contract (other than contracts entered into in the normal course of business) to which the issuer or any other member of the group is a party. Summarise any other contract (other than contracts entered into in the normal course of business) entered into by any member of the group and containing provisions conferring on any member of the group a significant obligation or right for the whole group, on the date of the registration document.	**20.1 to 20.3**
SECTION 21	**DOCUMENTS AVAILABLE**	**21**
Point 21.1	Provide a statement that, during the period of validity of the registration document, the following documents may be consulted: a) the latest up-to-date version of the issuer's memorandum of association and bylaws; b) all reports, letters and other documents, assessments and statements prepared by an expert at the issuer's request, some of which are included or referred to in the registration document. Indicate on which website the documents can be consulted.	**21**