A French corporation (*société anonyme*) with share capital of €18,163,802
Registered office: 320, avenue Archimède
Les Pléiades III – Bâtiment B
13100 Aix-en-Provence
837 722 560 Aix-en-Provence Trade and Companies Register

2021 UNIVERSAL REGISTRATION DOCUMENT

Including the annual financial report

This Universal Registration Document (URD) was approved by the French Financial Markets Authority (Autorité des marchés financiers – AMF) on 29 April 2022, in its capacity as competent authority under Regulation (EU) No. 2017/1129.

The AMF approves this document after verifying that the information it contains meets the standards of completeness, comprehensibility and consistency. The Universal Registration Document bears the following approval number: R.22-017

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

The Universal 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). In this case, the securities note, the summary and all amendments made to the Universal Registration Document since its approval are approved separately in accordance with Article 10 (3), second subparagraph of Regulation (EU) 2017/1129.

This Universal Registration Document is valid until 29 April 2023 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 in the event of significant new factors or material mistakes or inaccuracies.

Pursuant to Article 19 of Regulation (EU) 2017/1129 of 14 June 2017, the Universal Registration Document approved by the AMF on 12 April 2021 under number I.21-007 is incorporated herein by reference (Affluent_Medical_Record_Document_21-007.pdf (affluentmedical.com)).

This document is a free translation into English of the original 2021 Universal Registration Document issued in French Language and is provided solely for information purposes. In case of any ambiguity or discrepancy between the French and the English version, the French language version of the 2021 Universal Registration Document shall prevail.

Copies of this Universal 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 Universal 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 Register under the number 837 722 560;

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

  - Kephalios, a simplified joint stock company 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 Register under number 531 557 650,

  - Kardiozis, a simplified joint stock company 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 Register under number 532 628 336,

  - Epygon, a simplified joint stock company whose registered office is located at 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France, registered in the Aix-en-Provence Trade and Companies Register 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 Register under number 11311520016,

  - MyoPowers Medical Technologies France, a simplified joint stock company with its registered office at 18, rue Alain Savary, 25000 Besançon, France, registered in the Besançon Trade and Companies Register under number 799 927 355,

  - Medev Europa, a 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 National Office of the Romanian Trade Register under number J40/524/2020 and unique identification code 42124756;

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

The Universal Registration Document describes the Company as it exists on the date of its registration.

The Universal Registration Document, prepared in accordance with Annex I of Commission Delegated Regulation (EU) 2019/980 of 14 March 2019 supplementing Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017, presents: the parent company financial statements for the year ended 31 December 2021, as well as the corresponding consolidated financial statements.

The Universal Registration Document incorporates by reference the consolidated financial statements prepared in accordance with IFRS for the financial years ended 31 December 2020 and 31 December 2019, presented in the registration document approved by the AMF on 12 April 2021 under approval

number I. 21-007. These financial statements were the subject of an audit report issued by the Company's Statutory Auditors.

Disclaimer

The Universal 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 Universal 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 Universal 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 Universal Registration Document is given only as at the date of approval of the Universal 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) 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 Universal 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 Universal Registration Document could also have a material adverse effect.

Rounding

Certain figures (including data expressed in thousands or millions) and percentages presented in the Universal Registration Document have been rounded. As applicable, the totals presented in this Universal 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 Universal Registration Document are not part of the Universal 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 Universal Registration Document.

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

1.1. Person responsible for the Universal Registration Document

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

1.2. Statement of the person responsible

"*I hereby certify that the information contained in this Universal Registration Document is, to the best of my knowledge, in accordance with the facts and does not contain any omission likely to alter its scope.*

I hereby certify that, to the best of my knowledge, the financial statements have been prepared in accordance with the applicable accounting standards and give a true and fair view of the assets, financial position and results of the Company and of all the companies included in the consolidation, and that this management report presents a true and fair view of the evolution of the business, results and financial position of the Company and of all the companies included in the consolidation and that it describes the main risks and uncertainties they face".

in Aix-en-Provence

on 29 April 2022

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 Universal Registration Document.

1.4. Third party information

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

1.5. Person responsible for the financial reporting

Affluent Medical

Mr Jérôme Geoffroy

Chief Financial Officer

Address: 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence
Telephone: 04.42.95.12.20 - Email address: investor@affluentmedical.com

1.6. Control of this Universal Registration Document

This Universal Registration Document was approved by the French Financial Markets Authority, as the competent authority under Regulation (EU) 2017/1129, on 29 April 2022.

The AMF only approves this Universal Registration Document as complying with the standards in terms of completeness, comprehensibility and consistency imposed by Regulation (EU) 2017/1129.

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

This Universal Registration Document may be used for the purposes of a public offering of securities or the admission of securities to trading on a regulated market if it is supplemented by amendments, where applicable, and a securities note and the summary approved in accordance with Regulation (EU) 2017/1129.

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. Alternate Statutory Auditors

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

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

Not applicable.

2.4. Statutory Auditors' fees

Please refer to Note 26 to the Group's consolidated financial statements prepared in accordance with IFRS as at 31 December 2021, in section 18.1.1. of this Universal Registration Document.

3. RISK FACTORS

Investors are invited to consider all of the information contained in the Universal 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 Universal 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 Universal 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) 2017/1129 (the "Prospectus 3" Regulation) and Delegated Regulation (EU) 2019/980, this chapter presents the Group's main specific risks which could, as at the date of approval of the Universal 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 order of decreasing importance corresponding to the criticality of the net risk calculated according to an approach combining the probability of occurrence, the magnitude of the negative impact of the risk according to the Group's assessment and the risk management systems existing at the date of approval of the Universal 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 limitation of certain human and industrial activities have been taken, particularly in countries where the Group is carrying out or plans to conduct clinical studies (Austria, Italy, Spain, Czech Republic, Germany, France, Serbia, Poland, Switzerland, Turkey, Romania, United Kingdom, Greece, Belgium, Luxembourg, Netherlands, United States of America, Morocco, Egypt). 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 related 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 (section 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 Universal 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 Universal Registration Document), the Group must conduct pre-clinical 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 (pre-clinical 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 pre-clinical 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 Universal 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 Universal Registration Document) causing a slowdown in patient recruitment as well as an extension in the planned duration of the study with a delay of approximately one year in the recruitment of approximately forty patients, given that as at the date of approval of the Universal Registration Document, 21 patients have benefitted from being implanted with the Kalios device. The follow-up of the implanted patients as well as the adjustments with the Kalios medical device could be carried out normally;
- on the identification of patients as part of the preparation of the clinical study on the Epygon and Artus medical devices (see section 5.2.3.3 for Epygon and 5.2.2 for Artus of the Universal 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 pre-clinical and clinical studies on the Artus, Kalios and Epygon medical devices:

- delays in obtaining authorisations from the administrative and regulatory authorities (local authorities, ethics committees, etc.) or in interactions with other bodies and third parties required to launch the pre-clinical and clinical trials planned by the Group;
- delays in receipt or global shortage of supplies and equipment needed to manufacture medical devices;
- delays in the manufacture of devices internally or at suppliers' sites following the infection of qualified personnel or contact of such personnel;
- delays or difficulties in launching clinical trials, including difficulties in recruiting and training investigators and clinical site staff, but also in opening new sites in current countries or in new countries;
- the 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;
- 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, thus leading 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 could 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 Universal Registration Document) – it has been delayed by for a significant amount of time compared with the Company's initial plan, firstly due to the additional time required 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 Universal Registration Document) and secondly due to the reduced number of patients because of the Covid-19 pandemic. In the Registration Document, the development plan envisaged an end of study allowing CE marking in the fourth quarter of 2022 and marketing in 2023. The Company now envisages an end of clinical study allowing CE marking and marketing in the first half of 2024. This delay of approximately 12 months is due to slowed or halted patient recruitment due to the COVID 19 pandemic. Indeed, for the period from January 2021 to the beginning of 2022, the countries and hospital infrastructures where the clinical study is taking place were heavily impacted by COVID-19. Resources were mobilised to meet the needs of patients with this virus, leading, for example, to the absence of an operating theatre available for non-emergency cardiac surgery;
- the European Dry Artus pilot study in humans was initiated in the 2nd half of 2022 and must be followed immediately by a pivotal study ending between the end of the 2nd half of 2023 and early 2024. At the same time, the pivotal clinical trial in the United States should start in 2023 and end at the end of 2025 (see section 5.2.2.2 of the Universal Registration Document); a pilot and pivotal study in Europe is also planned in patients with urinary incontinence, the start date of the study is planned for the 2nd half of 2023. This therapeutic extension was decided in 2022 and has no major consequences on the Company's long-term financial needs. In the Registration Document, the development plan envisaged an end of study allowing CE marking in the fourth

quarter of 2023 and marketing in 2024. The Company now envisages an end of clinical study allowing marketing in the second half of 2024. This delay of approximately six months is due in particular to a longer delay in the approval of the applications filed with the regulatory authorities. These teams have been impacted by COVID as well as the implementation of new European regulations on medical devices;

- Epygon's Minerva "First in Human" study for which the Company has obtained regulatory approvals in three countries, must be initiated during the 1st half of 2022 and end in the last quarter of 2022, the Company intends to initiate studies in Europe and the United States during the year 2023 based on the data obtained during the pilot phase (see section 5.2.3.3 of the Universal Registration Document). In the Registration Document, the development plan envisaged an end of study allowing CE marking at the end of the second half of 2025 and marketing in 2025. The Company now envisages an end of clinical development allowing CE marking and marketing at the end of the second half of 2025 or the start of 2026. This delay of approximately 6 months is due to slowed or halted patient recruitment due to the COVID 19 pandemic. Indeed, over the period from June 2021 to the beginning of 2022, the countries and hospital infrastructures where the clinical study is taking place were heavily impacted by COVID-19. Resources were mobilised to meet the needs of patients with this virus, leading, for example, to the absence of an operating theatre available for non-emergency cardiac surgery.

The development programmes for the Epygon and Artus devices also experienced delays compared to the initial programme providing for clinical studies in Europe in the course of 2019 and will be initiated in 2022 for Epygon and for Artus, it being specified that the "First in Human" study on Artus was carried out. 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. The delays in 2021 are explained in particular by the Covid pandemic slowing down the conduct of clinical studies, delays associated or not with the pandemic or additional requests in the processing of files by the health authorities for the authorisation of the pilot-pivotal study, difficulties in sourcing and recruiting qualified personnel. Additional tests were also carried out to validate medical devices before implantation in humans, in particular for Artus.

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 Universal 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 2024 and that, concerning the Group's two other products, Artus and Epygon, the first sales should begin in Europe in 2024 and 2026 and in the United States in 2025 and 2026/2027 respectively (see sections 5.1.1, 5.2.2.2, 5.2.3.2 and 5.2.3.3 of the Universal 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 Universal 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 Universal Registration Document), explaining the Group's strategy of seeking an industrial partner to which to license its Kardiozis technology for endoprosthesis with thrombogenic fibres. Concerning, the treatment of mitral insufficiency, two products implanted *via* the transcatheter* route are currently marketed for mitral valve repair (MitraClip)

[1] Financial data from the 2020 annual reports of the companies.

by Abbott Vascular (CE marking and FDA approval obtained respectively in 2008 and in 2013) and Pascal by Edwards Lifesciences (CE marking obtained in 2019) – see section 5.2.3.2 of the Universal Registration Document). A first device, the Tendyne developed by Abbott, obtained the CE marking* in 2020 and marketing was launched in 2021. Finally for the treatment of severe urinary incontinence, the AMS 800 device from Boston Scientific, mainly authorised for men, has dominated the artificial urinary sphincter* market since its marketing (see section 5.2 of the Universal 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 Universal 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 Universal 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 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 Universal Registration Document). Despite a single European regulation, the interpretation and documentary requirements between countries may be different. 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 Universal Registration Document), before a marketing authorisation can be obtained.

The Group hopes to market its Kalios, Artus and Epygon medical devices respectively in early 2024, second half of 2024 and in the second half of 2025 or early 2026 and obtain the marketing of the Artus and Epygon devices in the United States in 2025 and 2026/2027 respectively (see sections 5.1.1, 5.2.2.2, 5.2.3.2 and 5.2.3.3 of the Universal 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 expenses incurred, the market

value of the medical device and the related intellectual property, additional redevelopment expenses 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 Universal Registration Document). The Group has 33 patent families (of which 31 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 Universal Registration Document)). The protection of medical devices is ensured for Artus and Kalios until 2037, for Epygon until 2042 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
- the Group's domain names could 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 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 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 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 €50,000 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 and 30 April 2021; the Company and MyoPowers responded *via* submissions dated 10 March 2021 and 8 June 2021. The case on the merits was argued before the Paris Court of First Instance on 6 December 2021. Subject to an extension of deliberation, the decision on the merits will be rendered on 31 March 2022. 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 range from €8,000 to €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 Universal 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 Universal 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 materials necessary for its activities could be reduced or interrupted, in particular in the event of failure of one of its suppliers or increase in supply costs but also in the event of global shortage of raw materials in particular due to the impact of Covid. 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 Universal 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 Universal 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 pre-clinical and clinical trials, develop, test, manufacture and market its products, within expected time frames and at an acceptable cost. The use of a new supplier requires obtaining an authorisation from the notified body, which may take a long time and a modification of the clinical file must be re-approved in certain cases by the regulatory authorities of the country. The transition to the new European standard may extend depending on the instruction deadlines and requirements. 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 Universal 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. The electronic chips of the Artus device have become critical in terms of supply also due to the current global semiconductor crisis. The Artus device also requires a supply of titanium, which at the date of approval of the Universal Registration Document is not in short supply. Any delay in supply could have consequences on the manufacture of this device.
In addition, the Group is dependent on subcontractors for the performance of its pre-clinical 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 pre-clinical 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 Universal 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 5.3.7 of the Universal 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 Universal 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 cannot 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 Universal 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, on the date of approval of the Universal Registration Document, that it would be able to cover its financing needs for operations until September 2022.

On the basis of the consolidated financial statements, as at 31 December 2021, the Group's cash and cash equivalents amounted to €11,410 thousand. Cash flows used by operating activities in 2021 amounted to €12,364 thousand.

The total gross amount of financial debt and net financial debt of the Group as at 31 December 2021, taking into account repayable advances and innovation loans under Bpifrance aid contracts and State-guaranteed loans taken out by the Group amounted to €20,061 thousand and €8,651 thousand respectively (see Notes 11 and 8 to the Group consolidated financial statements under IFRS for the financial year ended on 31 December 2021 presented in section 18.1.1 of the Universal Registration Document):

(Amounts in thousands of euros)	Amounts in the consolidated statement of financial position at 31/12/2021
Lease liabilities	1,250
Repayable advances	13,113
State-guaranteed loans	2,970
Kreos bonds	1,370
OCA Head Leader bond loan	1,040
Derivative liability (mainly linked to the Kreos share subscription warrant)	310
Other loans and liabilities	2
Bank overdrafts	6
Total gross financial debt	**20,061**
Cash and cash equivalents	11,410
Total net financial debt	**8,651**

The Group should not be exposed to an immediate liquidity risk on the Bpifrance subsidy agreements and on the State-guaranteed loans 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 part of the Company's IPO in 2021, Kreos Capital V subscribed for Company shares in the amount of €2 million through debt conversion. Accordingly, following this transaction and the rescheduling of certain monthly maturities, a new debt repayment schedule was put in place.
As at 31 December 2021, the outstanding principal amounted to €1.4 million (see sections 8.1.3 and 20.4 of the Universal 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 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 repayment of around €4.1 million (including accrued interest) amounted to €3.0 million in 2021. The balance was repaid at the end of January 2022 (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. At the end of January 2022, the Company had finished repaying the convertible bonds of Head Leader.

The schedule of the Company's debt and interest repayments under its main financing contracts should be as follows for the 2022 and 2023 financial years:

	2022	2023
OCA Head Leader bond loan	€1.0 million	-
Kreos bonds	€1.5 million	-
Bpifrance innovation loan	€0.1 million	€0.2 million
Repayable advances (Piave Artus, Mivana Project)	-€	€0.4 million
State-guaranteed loan	€0.3 million	€0.7 million
TOTAL	**€2.9 million**	**€1.3 million**

The audit report by the Company's Statutory Auditors on the Group's consolidated financial statements prepared in accordance with IFRS for the financial year ended 31 December 2021 presented in section 18.3.1 of the Universal 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*".

The Company's financial statements at 31 December 2021 were prepared on a going concern basis (see Note 2.1 on the going concern and Note 25 on liquidity risk to the consolidated financial statements of the Group under IFRS for the financial year ended on 31 December 2021 presented in section 18.1.1 of the Universal 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 September 2022. 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.

The Board of Directors continues to actively study various solutions to continue financing its business and its development beyond its liquidity horizon.
These solutions could, without being restrictive, involve private placements to investors, capital increases, setting up bonds and obtaining public financing.

As of the date of the Universal Registration Document, the Company 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 believes that it should continue to recognise losses in the medium term in line with the stage of development of its products. Additional financing resources will therefore be necessary.

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 seek other sources of financing, in particular through capital increases or the establishment of bonds or obtaining public funding or seeking partnerships.

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 Universal 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 €5,000,000 per claim in the event of bodily injury following an accident with a maximum of €500,000 per insured person (employee, non-salaried executive or director);

- auto insurance for four vehicles taken out by Affluent Medical with Gan Assurances, including the following essential guarantees:

  . bodily injury: unlimited,
  . consequential property damage and intangible damage: €100,000,000 (of which consequential property damage: €1,530,000),
  . inexcusable misconduct: €1,500,000;

- 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
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: €362,851 - Theft: property damage (unlimited)/contents (€51,836) - Electrical breakdown and damage to IT and operating equipment: €34,523 - 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 (€1,000,000)/rental risk (€35,000)	27 February 2024

- 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 study of the Epygon medical device in: Austria, Spain and Italy	HBI Global	- Austria: o €3,500,000 for the clinical study 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
		CNA Hardy	- Poland: o €50,000 up to 10 patients	31 December 2025
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 the clinical study o €500,000 per patient	31 June 2027
		CNA Hardy	- Germany: o €5,000,000 per year o €500,000 per patient per year - Switzerland: o CHF 10,000,000 for the clinical study o CHF 1,000,000 per patient - Italy: o €5,000,000 for the clinical study o €1,000,000 per patient	30 June 2027 30 June 2027 30 June 2027
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

- Cargo insurance taken out by Kephalios SAS for an amount of transported values of €950,000 and including the following cover:

Guarantees	Amount insured
1/ Purchasing/Procurement	
. by road	€5,000 per claim and/or event
. by air	€5,000 per claim and/or event
. by place of storage and/or occasional transit during transport	€5,000 per claim and/or event
2/ Sales	
. by road	€30,000 per claim and/or event
. by air	€30,000 per claim and/or event
. by place of storage and/or occasional transit during transport	€30,000 per claim and/or event
3/ Traffic between plants, agencies, subcontractors, manufacturers	
	€30,000 per claim

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 Universal Registration Document). On the date of approval of the Universal Registration Document, the full exercise of all the instruments giving access to the share capital issued and allocated (including the Kreos BSA-2018 share subscription warrants) would allow the issue and subscription of 3, 575,549 new

ordinary shares, thus generating a dilution equal to 16.4% of the share capital on a fully diluted basis. 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 131,148 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 Universal 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 €1,000,000 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 repayable 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 repayable advances of €1,049,488 for Kephalios and €3,462,598 for Epygon depending on the achievement of key milestones.

As at 31 December 2021, the Company and its Subsidiaries benefited from the following grants:

At 31 December 2021 (in €)	Recipient entity at origin	Date obtained	Amount granted at 31 December 2021	Amount received at 31 December 2021	Amount still outstanding	Amount repaid at 31 December 2021	Amount to be repaid at 31 December 2021
R&D innovation loan	Affluent Medical	16 April 2020	€1,000,000	€1,000,000	€0	€0	€1,000,000[1]
PIAVE Artus (Share of grant)	MyoPowers	21 July 2016	€200,589	€117,000	€83,589[2]	-	-
PIAVE Artus (Share of repayable advances)			€7,795,560	€6,188,271	€1,607,289[2]	€0	€6,188,271[3]

PSPC Mivana (Share of grant)	Kephalios	28 September 2015	€965,382	€820,000	€145,382	-	-
	Epygon		€992,009	€833,537	€158,472	-	-
PSPC Mivana (Share of repayable advances)	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**	**€12,169,366**	**€3,296,260**	**€0**	**€10,398,829**

(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 2021.

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 repayable 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 repayable advances still to be obtained:

At 31 December 2021 (in €)	Recipient entity at origin	Future payments (+) and repayments (-) of aid programs					
		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 (Share of grant)	MyoPowers	83,589	-	-	-	-	-
PIAVE Artus (Share of repayable advances)		1,607,289	-2,055,000	-2,055,000	-2,056,000	-2,058,000	-
PSPC Mivana (Share of grant)	Kephalios	-	145,382	-	-	-	-
	Epygon	-	168,472	-	-	-	-
PSPC Mivana (Share of repayable advances)	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		**1,590,878**	**-639,618**	**-2,855,000**	**-3,306,000**	**-3,708,000**	**-1,900,000**

In addition, additional payments are planned for MyoPowers at the end of the repayment of the initial repayable advance (discounted maximum value of €8,224,000) during the next four years, on the basis of 1% of the annual revenues of MyoPowers generated above €20,000,000 in cumulative revenue. The total amount of the payments is capped at €4,000,000.

Additional repayments are planned:

- for Kephalios after repayment of the initial advance (discounted value of €1,150,000) during the next five (5) years above €10,000,000 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 €3,000,000;
- for Epygon after reimbursement of the initial advance (discounted value of €3,750,000) during the next five (5) years above €20,000,000 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 €6,000,000.

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

For Bpifrance repayable 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 (RTC):***

To finance their activities, the Group's subsidiaries have also opted for the research tax credit (*Crédit d'Impôt Recherche* – **RTC**), 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 RTC 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 RTC are respectively €1,180 thousand and €556 thousand for the 2020 and 2021 financial years. The repayment amount of the RTC requested by the Group for the 2021 financial year amounts to €1,044 thousand compared to €556 thousand for the 2020 financial year. The decrease in the amount of the RTC collected in 2021 compared to 2020 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 RTC 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 ruled out that the tax authorities may call into question the methods used to calculate research and development expenses used by the Group to determine the amounts of RTC. The risk of a dispute about these RTC 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 RTC is filed.

If the RTC 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.

As of the date of approval of the Universal Registration Document, the reported RTCs have not been subject to any refusal or correction by the tax authorities.

- ***State-guaranteed loans (PGE):***

In addition, to deal with the financial consequences of the Covid-19 pandemic, the Company and its Subsidiaries took out various State-guaranteed loans with credit institutions and financing companies (the "**PGE**"):

Group entity	Lending Bank	Loan amount	Interest rates
Kardiozis	Société Générale	€160,000 (as at 31 December 2020)	0.58%
Kephalios	Société Générale	€890,000 (as at 31 December 2020)	0.58%
Epygon	Société Générale	€90,000 (as at 31 December 2020)	0.58%
Affluent Medical	BNP Paribas	€1,000,000 (as at 31 December 2020)	1%
MyoPowers	CIC	€394,790 (obtained in 2021)	0.70%
Affluent Medical	BNP Paribas	€200,000 (obtained in 2021)	To be defined in 2022
Affluent Medical	Bpifrance	€200,000 (obtained in 2021)	2.35%
TOTAL		**€2,934,790**	

In accordance with the possibilities offered by the State-guaranteed loans, the Company and its subsidiaries have chosen to request an additional deferred repayment period of 12 months in addition to a first deferral period of 12 months for the State-guaranteed loans contracted in 2020.

For the State-guaranteed loans contracted in 2021, the Company and its subsidiaries intend to request an additional deferred repayment period of 12 months in addition to an initial deferral period of 12 months.

The amortisation of the State-guaranteed loans is planned over a period of four years, *i.e.* a start of repayments from fiscal year 2022 for the State-guaranteed loans obtained in 2020.

At 31 December 2021, the Company recognised accrued interest in the amount of €35 thousand.

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 2019, 2020 and 2021 amounted to -€16.589 thousand, -€14.319 thousand and -€15.488 thousand, respectively. These losses mainly result from investments in research and development as well as pre-clinical 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 repayable advances, grants, by the repayment 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 pre-clinical 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 2021, the amount of goodwill and other intangible assets amounted to €32,203 thousand and €20.695 thousand respectively in the Group's consolidated financial statements prepared in accordance with IFRS, respectively accounting for 45.98% and 29.55% 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 2021 (see section 18.1.1 of the Universal 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 and 31 December 2021, the Group did not identify any indication of impairment for depreciable intangible assets.

With regard to goodwill, the Group has carried out annual impairment tests (see Notes 3 and 4 to the Group consolidated financial statements as at 31 December 2021 appearing in section 18.1.1 of the Universal 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 book values, 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 COMPANY

4.1. Company name

The Company name is: **Affluent Medical**.

The Company has not changed its corporate name since 31 December 2021.

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 Register 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 6 February 2018 for a period of 99 years from its registration on 23 February 2018, and expiring on 22 February 2117, unless it is dissolved early or extended.

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

The Company's registered office is located at:

320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence
France
Telephone: 04 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 appearing on the Company's website is not part of the Universal Registration Document.

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

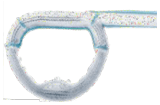
Affluent Medical is a company developing next-generation minimally invasive medical devices, at a clinical stage, with the aim of saving the lives and improving the quality of life of millions of patients around the world affected by severe pathologies in the fields of urology and structural heart.

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:

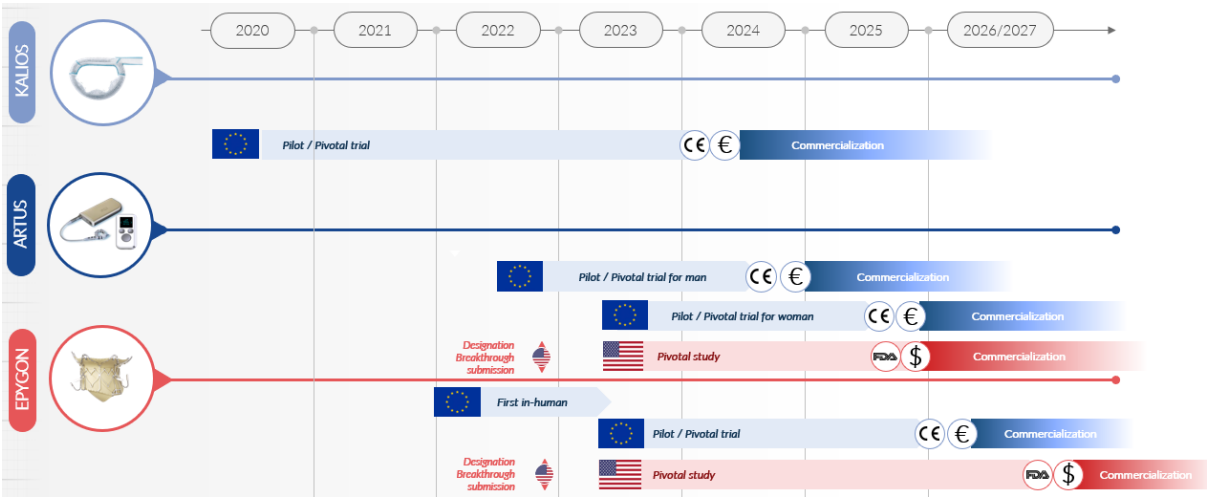
- three innovative implantable best-in-class prostheses:
    - Artus: artificial sphincter for the treatment of moderate to severe urinary incontinence restoring complete control of the bladder, by closing or opening the urinary flow at the will of the patient using a simple remote control and designed 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 endoprostheses 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 2023: 21 patients have been recruited out of the planned 62	1st half 2024	-
Artus (section 5.2.2)		Moderate to severe urinary incontinence	- In Europe: Clinical stage – Dry study - Successful feasibility study in 2018 - Pilot/pivotal study launched in the second half of 2022 in Spain, Italy, the Czech Republic and other countries in Europe covering approximately 10 centres: expected recruitment of 70 patients - Pilot/pivotal study in women launched in the second half of 2023 in Spain, Italy, the Czech Republic, France and other countries in Europe - In the United States: submission for "breakthrough designation" at the end of 2022 with the launch of the clinical programme in 2023	2nd half 2024	2nd half 2025
Epygon (section 5.2.3.3)		Mitral valve replacement	<u>In Europe:</u> Clinical stage – Minerva study - Pilot study launched in the 1st half of 2022 in Austria, Spain and Italy with the expected recruitment of 15 patients - Pivotal study in the 2nd half of 2023 <u>In the United States:</u> submission for "breakthrough designation" at the end of 2022 with the launch of the clinical programme in 2023.	2nd half 2025/ beginning of 2026	End of 2026/beginning of 2027
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 marketing



[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 (see also section 3.4.1 of the Registration Document).

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, 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 urethra. 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 2022 with a view to obtaining CE marking in the second half of 2024 for marketing in 2024, a specific clinical development will also be carried out for women with a study planned for 2023 with CE marking in the second half of 2025 as well as its marketing. 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 second half of 2023 to register the device with the FDA and marketing in 2025.

- **Kalios and Epygon implants for the treatment of mitral insufficiency:**

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

[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 University, Montreal, Québec, Canada) – Artificial Urinary Sphincter: Report of the 2015 Consensus Conference – Neurology and Urodynamics 35:S8-S24 (2016).

marketing. However, a few so-called transcatheter devices have appeared or are under development for mitral valve repair and replacement. The valve is compressed and introduced into the heart by a catheter that enters the body through a small incision in the thorax or *via* a peripheral artery. It is then deployed under imaging guidance in the heart in less than 30 minutes. This technique appeared first for the treatment of the aortic valve (TAVI – transcatheter aortic valve implantation) and is now 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 first half of 2024 for marketing in 2024. 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 *via* transapical* or transseptal* routes, both being minimally invasive. Epygon will be the subject of a pilot study in the first half of 2022, which should be followed by a pivotal study starting in the 2nd half of 2023 with a view to obtaining CE marking in the 2nd half of 2023 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 half of 2023 for registration with the FDA at the end of 2026 and marketing in 2027. 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 endoprostheses 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 endoprosthesis makes it possible to generate a natural coagulation, controlled inside the aneurysm sac, which binds the prosthesis to the aorta and

[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.

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 to the marketing of endoprostheses incorporating Kardiozis thrombogenic fibre technology (see section 5.2.4.2 "*Strategy and objective for the marketing 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 strengths 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 20277);

- 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 Universal 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;

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

- 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,

    - 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 marketing 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, Annals of Thoracic Surgery 2021*);

- initial marketing of products expected in the short term, starting in 2024, for Kalios and Artus;

- 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 33 patent families (31 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 2042 (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 Universal 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 the Artus, Kalios and Epygon products are all at a clinical stage, the introduction on the market of Euronext has provided the Company with the funds necessary to finance its clinical studies and to obtain regulatory authorisations for the marketing of the Group's remaining medical devices subject to the success of 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 September 2022.

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;
- using the implants 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* pre-clinical 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 Mitralflex 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 "Optimise" 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 State-guaranteed 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 Operations Director and Jérôme Geoffroy as Chief Financial and Administrative Officer.

2021

- Authorisation from the competent Spanish and Italian authorities for the launch of the Minerva pilot clinical study in the Murcia, Madrid and Florence centres.

- Authorisation of the competent Italian authority for the launch of the pivotal clinical trial Optimise in the Humanitas and Sacco centres in Italy.
- Reinforcement of the management team with the arrival of Wenzel Hurtak as Vice-President (Operations) for the Epygon medical device, Jean-Dominique Behety as Programme Director – Kalios and Éric Jague as Regulatory Affairs Director.

- Publication in the famous journal "THE ANNALS OF THORACIC SURGERY", of pre-clinical data that confirm the potential of the Epygon mitral valve to restore blood flow and reduce the risk of heart failure.

- Listing on the Euronext regulated market of Affluent Medical on 14 June 2021.

- €2.5 million in subsidies and repayable advances obtained from Bpifrance by Artus as part of the PIAVE project with the achievement of new key milestones.

- Authorisation to conduct the pilot/pivotal Dry clinical trial for Artus in the Czech Republic.

- R&D expansion at the Aix-en-Provence, Besançon and Colleretto Giacosa sites in Italy.

- Start of the pre-clinical study for new sizes of the Epygon mitral valve.

- Success of the first postoperative adjustment of the Kalios mitral ring 11 months after implantation.

2022

- Reinforcement of the management team with the arrival of Marion Mélot as Programme Director – Artus.

- Request to open new centres for Kalios and Epygon in Europe.

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:

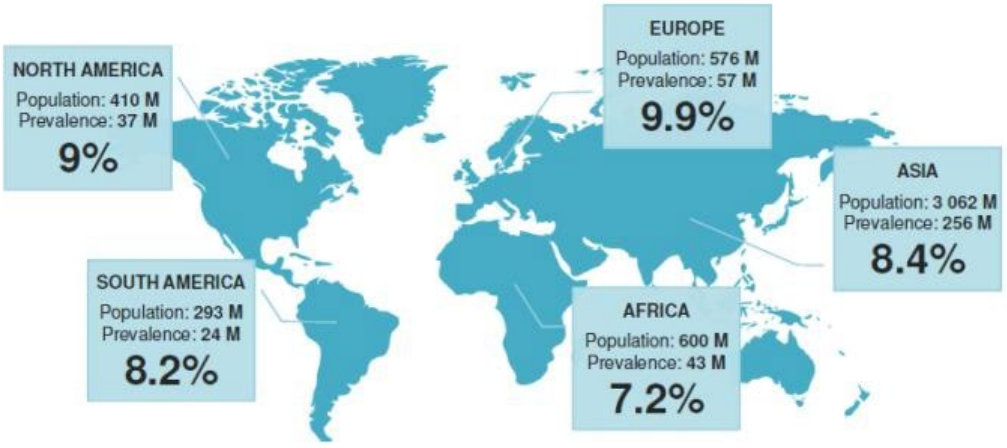
- stress incontinence characterised by involuntary urine leak by the urethra (urethral meatus) occurring during physical effort, coughing and sneezing. This is a sparse jet leak that occurs abruptly during exercise, most often in a standing position, without prior feeling of need (51% of cases of urinary incontinence in women and 10% in men8);
- 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 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 context9. 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 men10.

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 treated12 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%[13]. 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].

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

Prevalence of urinary incontinence by continent



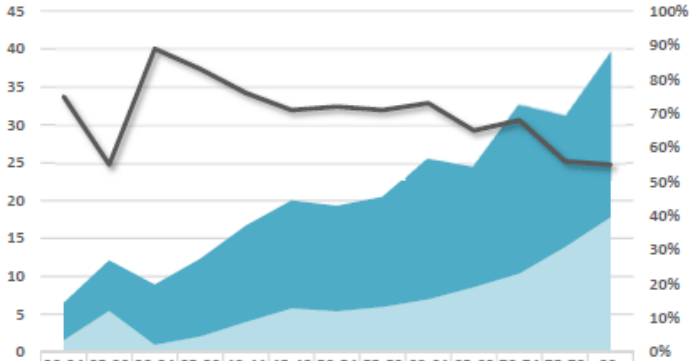
Source: Milsom I. "How big is the problem? Incontinence in numbers", Gothenburg Continence Research Centre.

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 million15 people with an estimated total cost of €4.5 billion.16

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% to 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%

[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 urinary incontinence]. François Haab, April 2007.

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

[17] Saxer S, Halfens, RJ, De Bie, RA, 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 Sep; 17(18):2490-6

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

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% 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

[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.

    - 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:

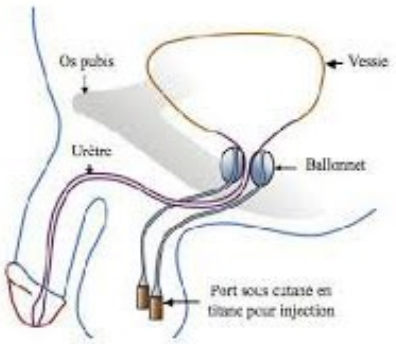
- With regard to stress urinary incontinence:
  - positioning of slings: this surgery is often recommended in cases of urethral hypermobility, a synthetic suburethral sling is placed by transobturator (TOT: trans-obturator tape) or externalised by retropubic approach (TVT: tension-free vaginal tape)

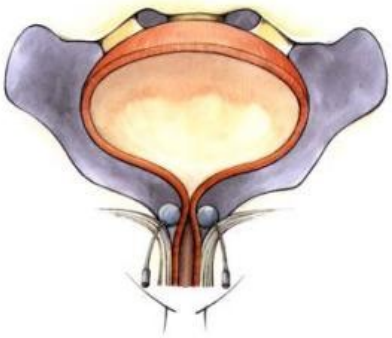

Support bands

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,



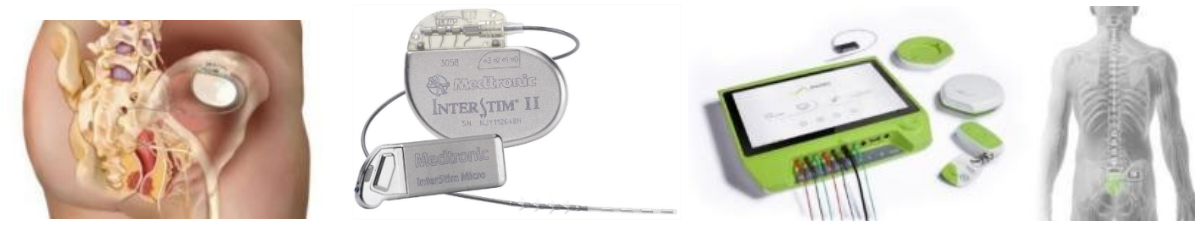


Source: Urofrance

  - the fitting of an artificial sphincter which is the standard treatment for the most difficult cases and cases of sphincter insufficiency. As at the date of approval of the Universal 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),



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

[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.
[23] ISS AG 2020.
[24] IMS Consulting Group: US Market Opportunity Assessment for Artus.

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 684,000 in 2019, and that this number could reach as many as 1,152,000 procedures in 2024 and 1,420,000 by 2026, *i.e.* an average annual growth rate of 11% over ten years.26

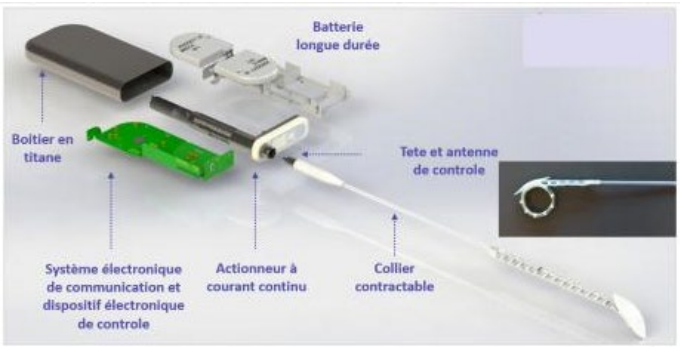
The urology sector is a sector of interest for a large number of major players in the medical devices sector, with nearly twenty transactions completed since 2015, five of which are more specifically related to the treatment of urinary incontinence for a cumulative amount of approximately €3.5 billion:27

- 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 C.R. Bard in 2017 for €8.5 million (urine collection system to 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.



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:

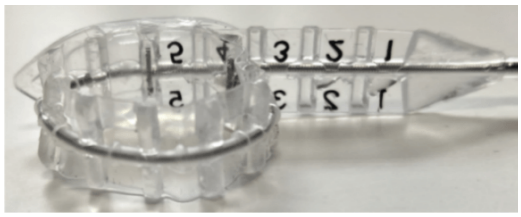
[25] Optima Insights – Urinary Incontinence (UI) Devices – September 2020.

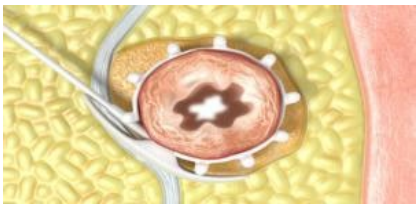
[26] ISS AG 2020 Allied Market Research. Global Urinary Incontinence Devices Market. Opportunity Analysis and Industry Forecast 2017-2023.

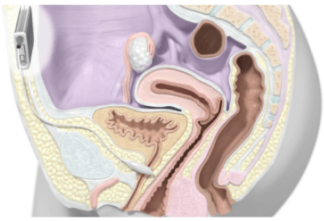
[27] Merger Market – "Opérations réalisées dans le secteur de l'urologie et notamment liées au traitement de l'incontinence urinaire depuis 2015" [Surgical procedures completed in the urology sector and linked in particular to the treatment of urinary incontinence since 2015].

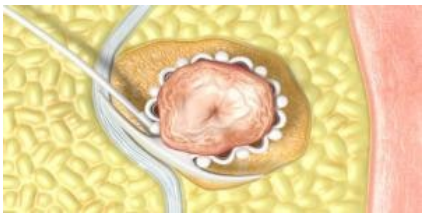
- to be invisible (compact implantable device);
- to be reliable (battery life of ten years – acceleration tests on the test bench currently indicate a battery life of more than ten years);
- to be secure (security system integrated into the device with data analysis, dual remote control for the patient);
- 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

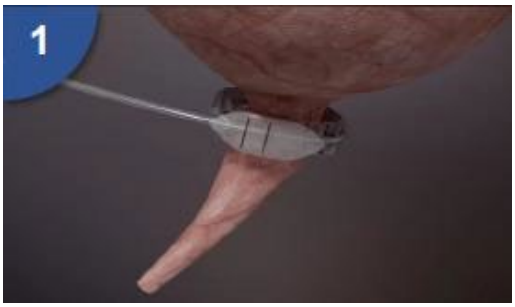








Artus can be implanted thanks to minimally invasive surgery and is faster than conventional surgery (around 30 minutes). This surgery can be a celioscopy or laparoscopy, which is less invasive than the open surgery currently used. This operation will reduce the length of hospitalisation. The cuff on 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	✓

► Pre-clinical 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

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

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.

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 pre-clinical 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 half of 2022 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 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 and in the 1st half of 2022 to meet all the requirements associated with the new regulations for medical devices, with approval expected in the 2nd half of 2022 in Spain. In the Czech Republic, authorisation to conduct the clinical study was obtained at the end of 2021. The clinical trial may begin once the additional validation trials have been finalised. 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 2024 for anticipated awarding in the 2nd half of 2024.

At the same time, Affluent Medical intends to carry out additional animal studies in the 2nd half of 2022 in accordance with the FDA recommendations for a pivotal clinical study in the United States starting in 2023 (FDA filing to conduct the pivotal study potentially as part of a 510(k) (see section 9.1.2 of the Universal Registration Document) in the 2nd half of 2022 for patient recruitment in the 2nd half of 2022) for potentially obtaining approval during the 2nd half of 2025.

► **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 product29

Product offering	UroMems *Electronic artificial urinary sphincter*	ZSI  *ZSI 375*	Boston Scientific  *AMS 800™*	affluent MEDICAL  *ARTUS™*
CE Approval	×	✓	✓	×
FDA Approval	×	×	✓	×
Launch date	-	-	1987	2024
User friendly	✓	×	×	✓✓✓
Efficiency	-	-	✓	✓✓✓
Targets men and women	✓	×	×	✓
Surgery type	-	✓	✓	✓✓
Remote control	✓	×	×	✓
				Price: €8,000 - €10,000(*)

(*) Average selling price depending on the market

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.

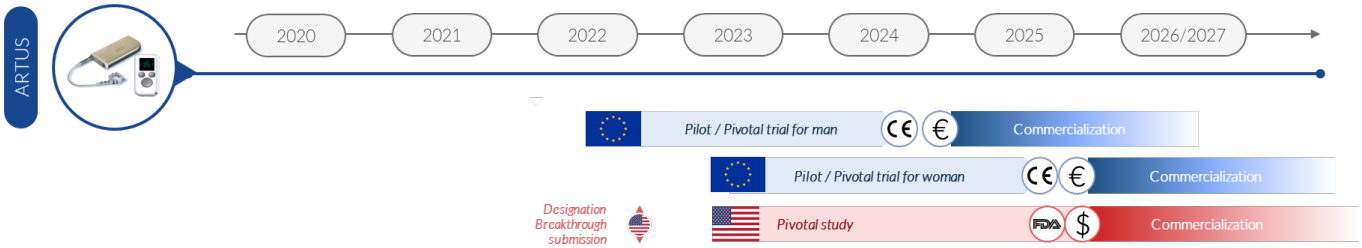
► Strategy and objectives for the development of Artus

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 Universal 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 been designed to adapt to men as well as women. A study on women with moderate to severe incontinence is also planned and should start in 2023 for approval at the end of 2025.

Affluent Medical intends to take advantage of the 2023 and 2024 financial year to initiate discussions regarding the reimbursement of the Artus device in Europe (see section 5.3.6 of the Universal 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. A "breakthrough therapy" is a priority status granted by the US Food and Drug Administration to a medical device undergoing validation and likely to provide a decisive therapeutic advance. This status will be requested for the Artus product with the FDA at the end of 2022. Once obtained, the FDA works with the application company to expedite the approval process.

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



In the Registration Document, the development plan envisaged an end of study allowing CE marking in the fourth quarter of 2023 and marketing in 2024. The Company now envisages an end of clinical study allowing marketing in the second half of 2024. This delay of approximately six months is due in particular to a longer delay in the approval of the applications filed with the regulatory authorities. These teams have been impacted by COVID as well as the implementation of new European regulations on medical devices.

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 insufficiency 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

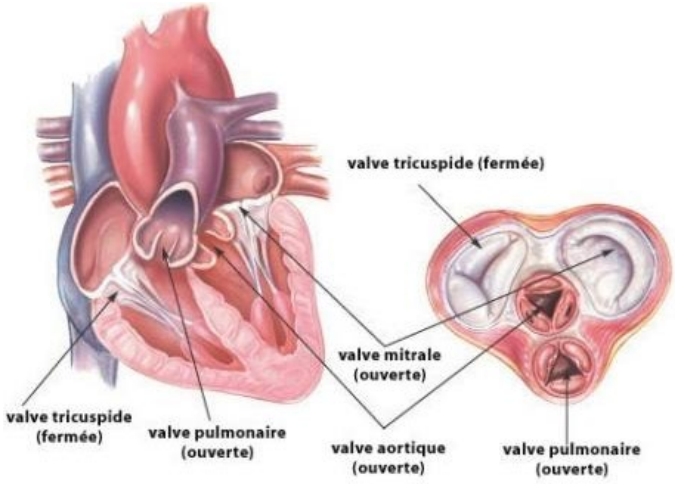
Among the most important cardiac pathologies are valvular heart disease* corresponding to malfunctioning of the cardiac valves. In the absence of treatment, the heart gradually becomes exhausted and no longer provides sufficient flow resulting in generalised heart failure.

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

[30] World Heath Organization – Health topics – Cardiovascular diseases – Overview.

valvules which open to allow blood to pass and then close to prevent backflow. There are four 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

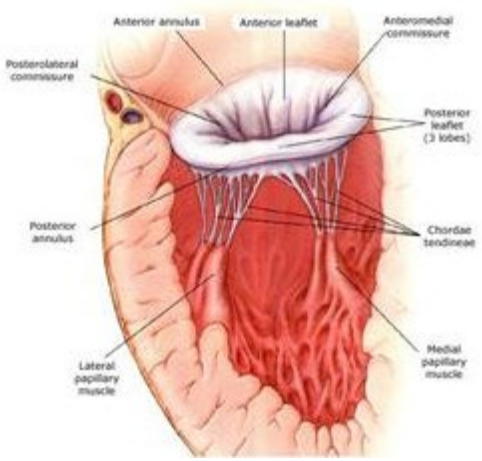
These valves can be impaired in several ways: either they do not open enough and prevent blood circulation known as valve stenosis (in 46% of cases);31 or they do not close and the lack of continence causes a leak called insufficiency (in 12% of cases); or, finally, they can have both types of malfunction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

[31] Institut Mutualiste Montsouris – Prof. François Laborde.

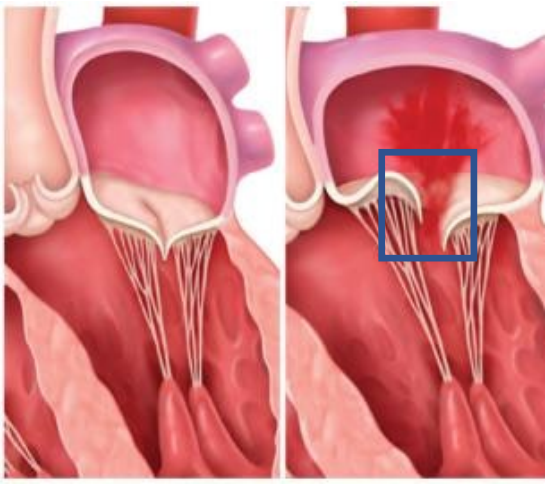
two valvules. The primary chordae insert on the free margin of the valvules and the secondary chordae insert on the lower (or ventricular) face of the valvules. The pillars are also called “papillary muscles”. Their insertion and the number of chordae attached to them varies.



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 valvulopathy 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 valvulopathy with aortic stenosis33 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:

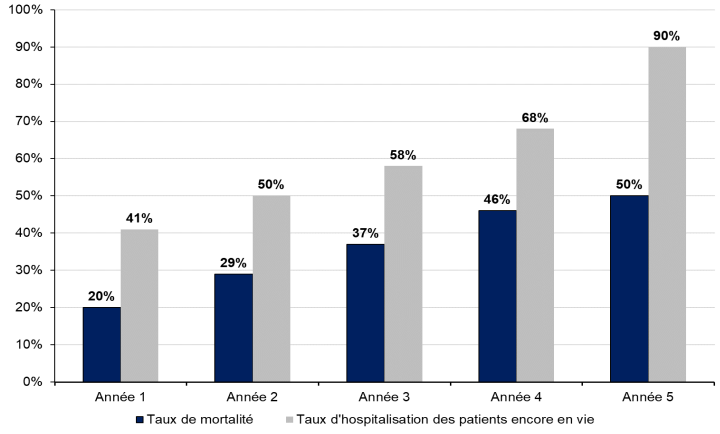
- functional by dilatation of the left ventricle that is found in many heart diseases;
- organic by defect of the chordae tendineae and papillary muscle system or the anterior or posterior leaflets of the mitral valve; or
- infectious by destruction of the valve by bacteria (infectious endocarditis).

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.

Patients with severe mitral regurgitation not operated on:
Mortality and hospitalisation rates



32 S. Douedi – H. Douedi – August 2020 "Mitral Regurgitation".

33Panagiotis A. & *al.* "Insuffisance Mitrale : Mise au Point en 2016" [Mitral Insufficiency: Update in 2016] – Rev Med Suisse 2016; 12:1042-8/Grave C. & *al.* "Hospitalisations pour Valvulopathie en France : Caractéristiques des patients et évolution 2006-2016" [Hospitalisations for heart disease in France: Patient characteristics and evolution 2006-2016] Santé Publique France – July 2019/Dziadzko V. & *al.* "Outcome and undertreatment of mitral regurgitation: a community cohort study" Lancet. 2018 March 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".

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 criteria 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 5.2.3.3 of the Universal 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.

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

[35] "Chirurgiens cardiaques associés: L'insuffisance mitrale et ses traitements" – https://www.chirurgien-cardiaque.com/chirurgie-des-valves-cardiaque/remplacement-valvulaire/.

[36] Transcatheter mitral valve implantation market size (Emergen research – September 2020).

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.

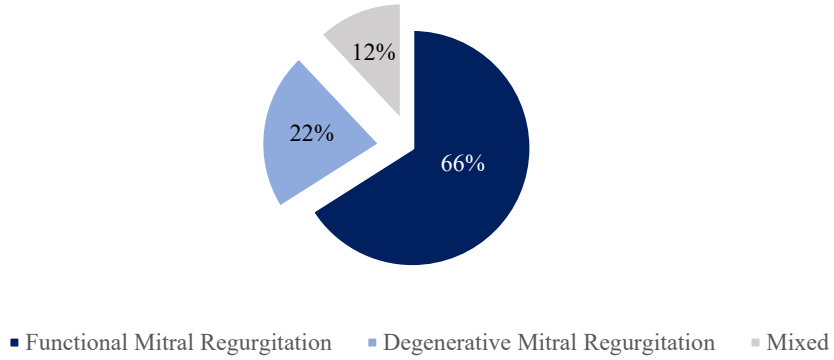
The expansion of TMVI (transcatheter mitral valve implantation) therapy technologies to lower risk patients or patients with functional mitral regurgitation is made possible by new technologies developed by established players in another segment of heart valves (TAVI for aortic valves) such as Edwards 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).

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

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

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) 600,000 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.

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

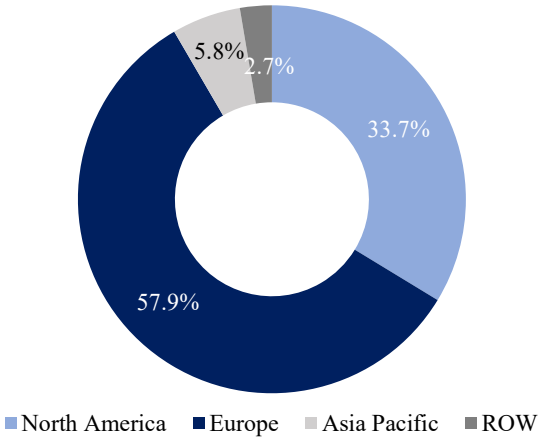
Finally, the increasing expenditures of healthcare systems in developed countries that better reimburse this type of procedure and the development of more systematic diagnosis of at-risk patients will help support this emerging market.

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

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

[42] Azoth Analytics – Estimates, May 2017.

Global market share of transcatheter mitral value replacement by size and region, 2022 (%)



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:

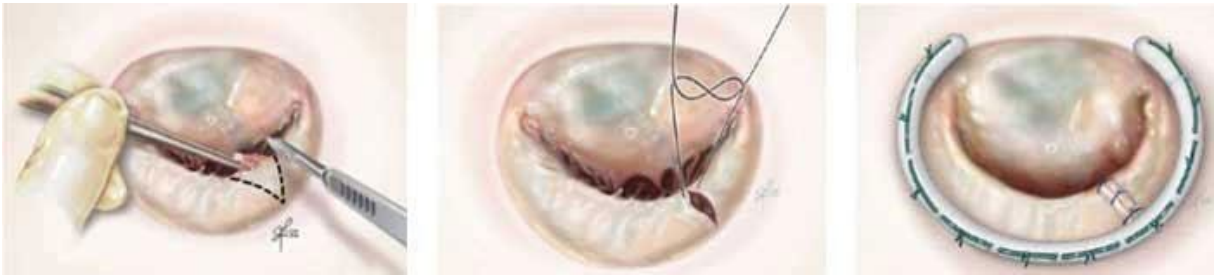
Target	Purchaser	Year	Transaction value	Stage of development
Cephea	Abbott	2019	Not available	First human trials
Millipede	Boston Scientific	2018	$90M + option to acquire the remaining capital for $450M	Several patients implanted in clinical studies
Harpoon Medical	Edwards Lifescience	2017	$20M including 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 Lifescience	2016	$690M	CE marking
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 ring 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.

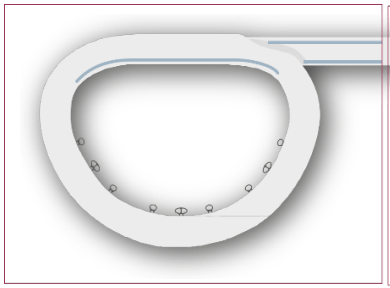
The D-shaped mitral ring re-establishes the anteroposterior and transverse diameters of a normal mitral valve for optimal hemodynamic performance.

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.

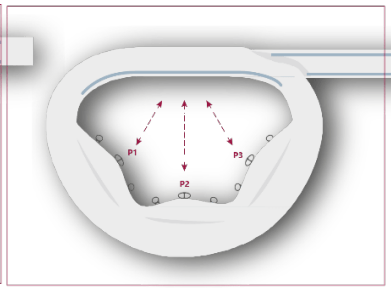
Kalios is the only mitral annuloplasty device that can be adjusted percutaneously to treat both residual and recurrent mitral regurgitation at any time after implantation, repeatedly and with a beating heart, thus avoiding a new procedure. Affluent Medical estimates that Kalios would avoid a new procedure 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.

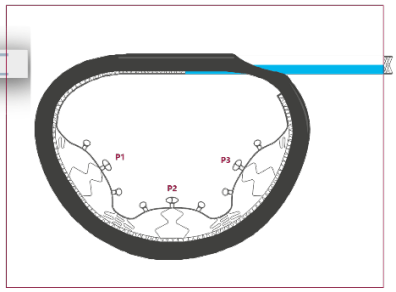
This percutaneous adjustment of the ring is carried out by a balloon catheter with connectors, similar to balloons for angioplasty: the balloon is inserted into the connection line of the ring through a subcutaneous entry that can be retrieved by a small incision of the skin, most often in the subclavian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



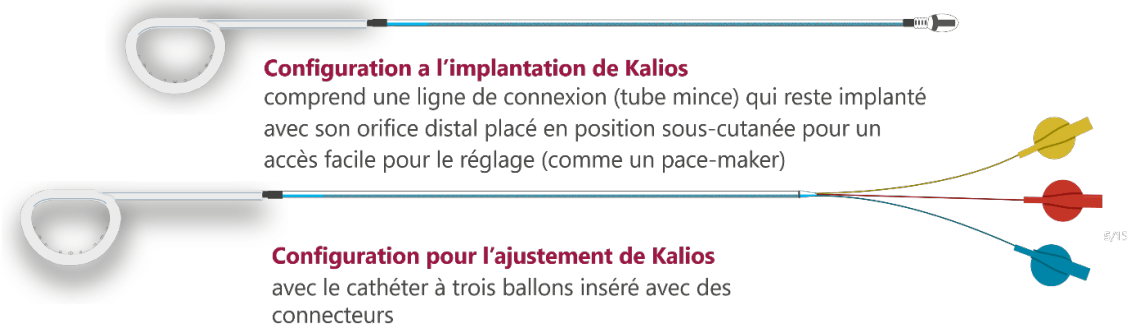
The Kalios implant is in the shape of a traditional Carpentier ring



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



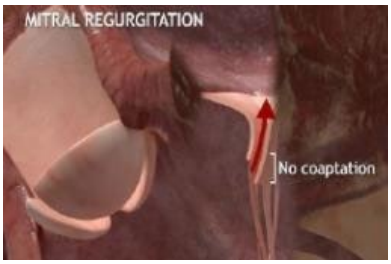
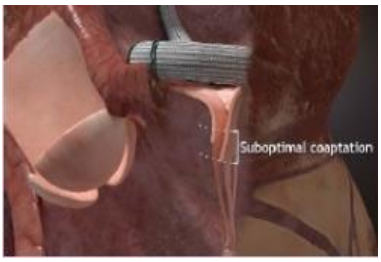
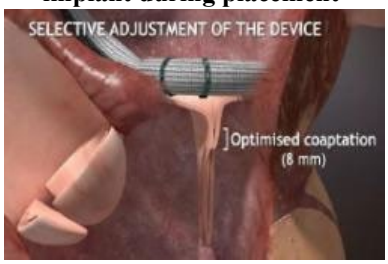
The innovative adjustment option offered by Kalios has many advantages for the monitoring of this disease, which remains progressive and may subsequently recur in mitral regurgitation.

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.

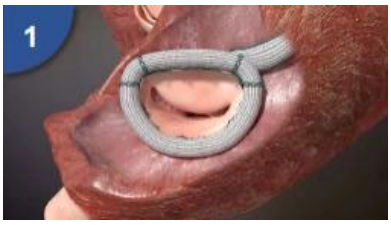
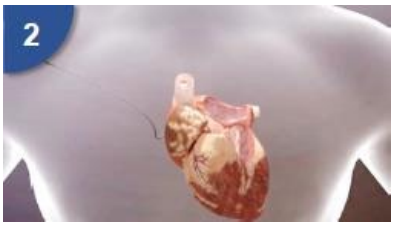
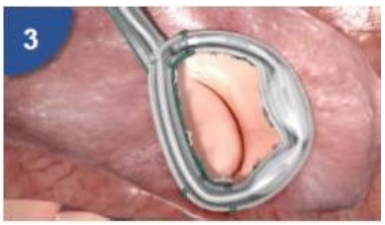
The Kalios ring is implanted in the heart in a similar way to other rings. It takes about 20 to 30 minutes to fix and the intervention lasts between 1.5 and 2 hours. The incision is more or less long thanks to the

use of minimally invasive techniques. Adjustment is infinitely simpler: a one-centimetre 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

► **Pre-clinical and clinical completed studies – Kalios clinical development plan**

The Kalios ring has undergone numerous pre-clinical 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 pre-clinical study on six Île-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* pre-clinical 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 Universal Registration Document, 21 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 half of 2022 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 section 3.1.1 of the Universal 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).

On 16 September 2021, the Company announced the successful first adjustment of the Kalios mitral ring on a patient suffering from postoperative recurrence of severe mitral insufficiency. Professor Alberto Albertini (GMV Maria Cecilia Hospital de Cotignola, Italy) successfully performed the percutaneous adjustment of the first Kalios mitral annuloplasty device, 11 months after its implantation in a patient, following a severe case of recurrent mitral insufficiency. Following the successful implantation of a Kalios adjustable mitral ring, a simple trace of residual leakage was observed on a patient operated on in August 2020 for major mitral insufficiency, following myocardial infarction (4+). At the end of a period of stability, a major mitral incompetence (or regurgitation) of grade 4+ and NYHA IV appeared related to a deterioration and dilation of the left ventricle which required re-intervention in order to resolve this leak and thus improve the patient's prognosis. The adjustment, carried out without any surgical procedure in July 2021, with the introduction of balloons into the subcutaneous line making it possible, under ultrasound monitoring, to reduce the size of the ring, led to a significant reduction in

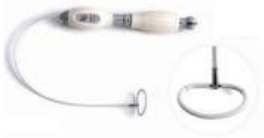
the leakage at its initial level (1+) and verified the immediate result. The patient, who is under scheduled medical monitoring, is currently classified as NYHA I and therefore has no limitations on their day-to-day activities.

This study should make it possible to submit the CE marking file in early 2024 and it is expected that the marking will be awarded in the same year.

► **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.

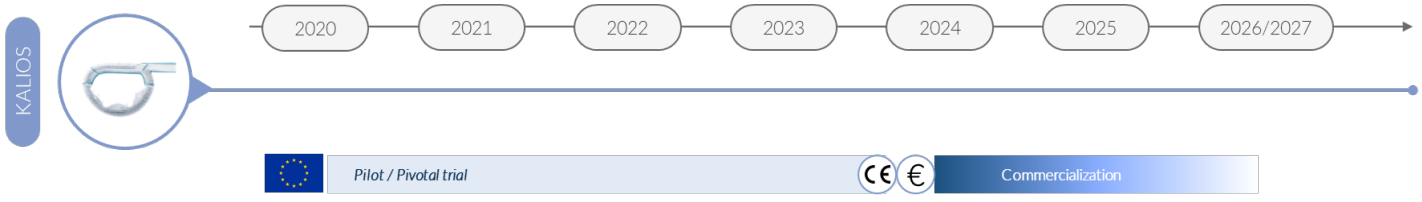
Summary diagram of the competitive positioning of the Kalios product compared to the most comparable rings43

Product offering	Abbott ATTUNE™	Edwards Lifesciences Valtech CARDINAL	Edwards Lifesciences Valtech CARDIOBAND	affluent MEDICAL KALIOS™ 1
CE Approval	✓	✓	✓	×
Adjustable multiple times	×	×	×	✓
Adjustable shape	✓	✓	✓	✓✓✓
Adjustable on beating / stopped heart	Implanted under extracorporeal circulation, adjustable once	Beating heart / adjustable once	Beating heart / adjustable once; transcatheter	Beating heart (multiple adjustments during and after the operation) Price: ~€4,000(*)

(*) Average selling price depending on the market

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

Affluent Medical's objective is to be able to market Kalios in Europe from 2024 after obtaining CE marking in the same year.



In the Registration Document, the development plan envisaged an end of study allowing CE marking in the fourth quarter of 2022 and marketing in 2023. The Company now envisages an end of clinical study allowing CE marking and marketing in the first half of 2024. This delay of approximately 12 months is due to slowed or halted patient recruitment due to the COVID 19 pandemic. Indeed, over the period from January 2021 to the beginning of 2022, the countries and hospital infrastructures where the clinical study is taking place were heavily impacted by COVID-19. Resources were mobilised to meet the needs of patients with this virus, leading, for example, to the absence of an operating theatre available for non-emergency cardiac surgery.

Affluent Medical benefits from intellectual protection for its Kalios device until 2037 with various

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

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 the event 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.

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 and 2023 for the coverage of the cost of the Kalios ring in Europe (see section 5.3.6 of the Universal Registration Document) through a pharmaco-economic study conducted in 2023. 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 2023 for the commercial launch of Kalios in 2024.

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

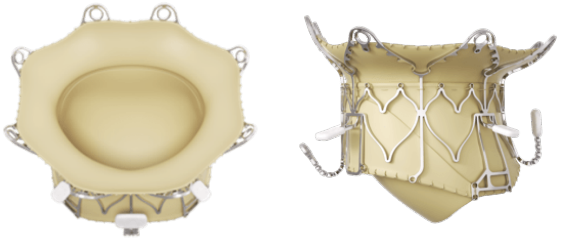
- **The Epygon implant**

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 pre-clinical 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 workload.

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:

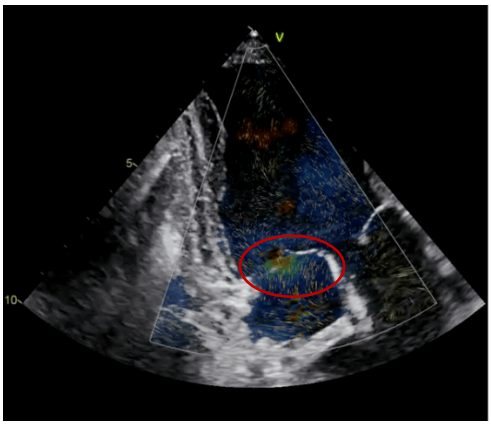
- the D-shaped nitinol stent mimics the native annulus while minimising perivalvular leakage;
- the asymmetric ventricular stent ensures minimal interference with myocardial contraction and prevents obstruction of blood flow from the left ventricle;
- the ventricular stent has one leaflet only;
- a minimum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

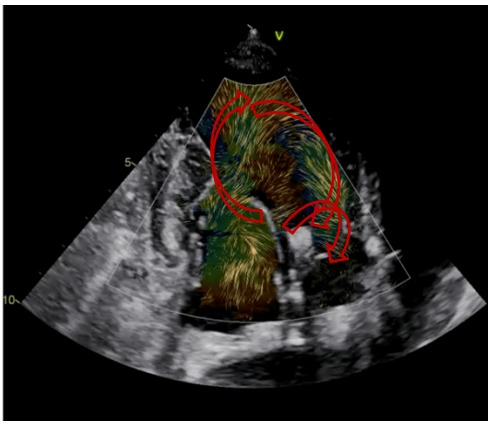
In addition, the valve has a strong anatomical anchorage with engagement arms to maintain the papillary muscles and prevent left ventricular sphericity. There is no risk of bioprosthesis migration. As a monobloc device, Epygon is easier to implement than other devices.

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.

<u>Imaging of the pre-and post-implantation blood circulation</u>



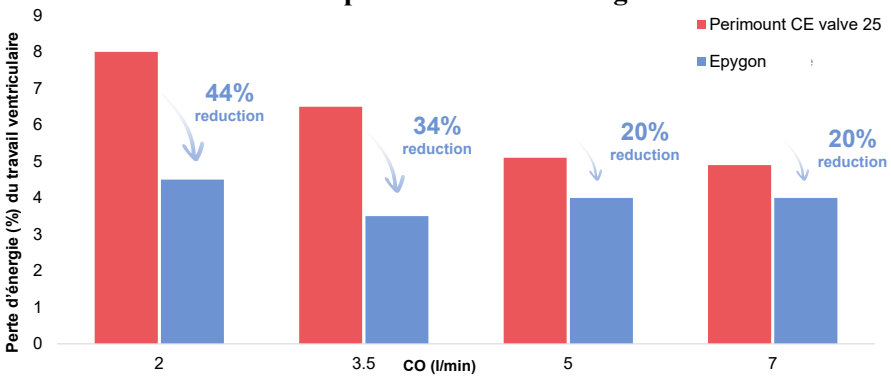
Mitral regurgitation



Restoration of natural blood flow

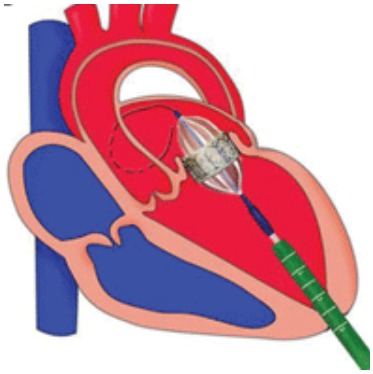
A comparison study relative to a tricuspid valve adapted for aortic indications (Perimount CE valve 25 from Edwards Lifesciences) has demonstrated that the Epygon valve reduces the effort furnished by the heart by 20% to 44% depending on the volume of blood pumped.

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

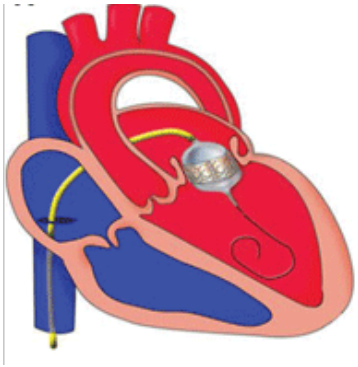


In many cases, this will permit recovering better cardiac function, especially in frail and weakened patients, with a very low ejection fraction (effective blood flow pumping). Restoring natural blood flow is key to recovering the functioning of the left ventricle and thus the patient's quality of life, 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

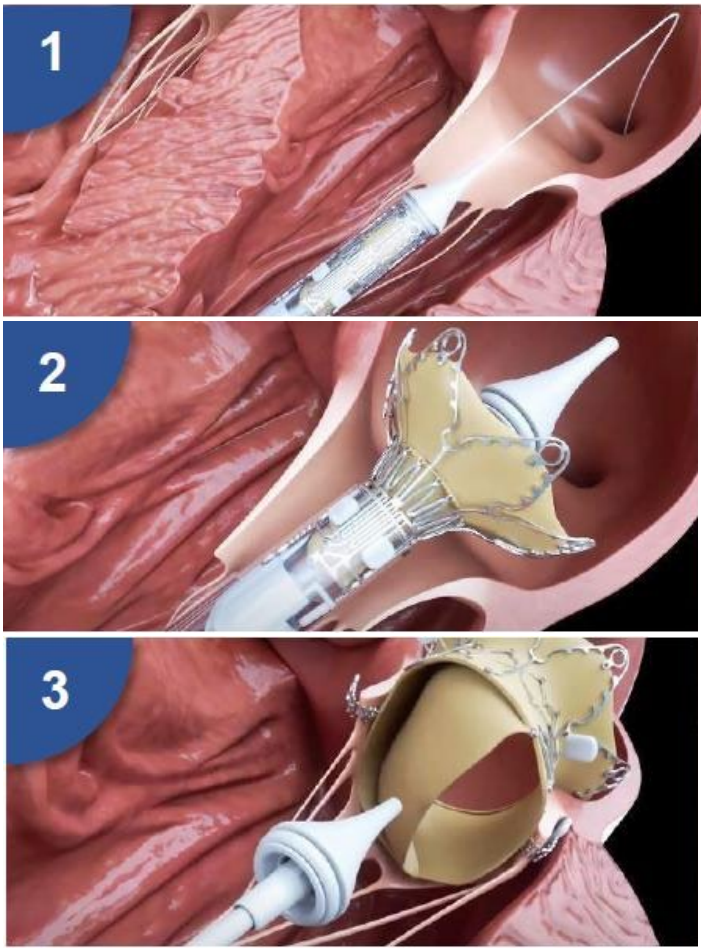
In this type of minimally invasive operation, the mitral valve is brought to the desired location *via* the large vessels of the body or through a slight incision in the chest without open-heart surgery or extracorporeal blood circulation. The positioning system or delivery catheter is adjusted to the 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 ring 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 maintain 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.

► **Pre-clinical studies conducted – Epygon clinical development plan**

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

Ex vivo and *in vivo* pre-clinical 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 pre-clinical 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 2023.

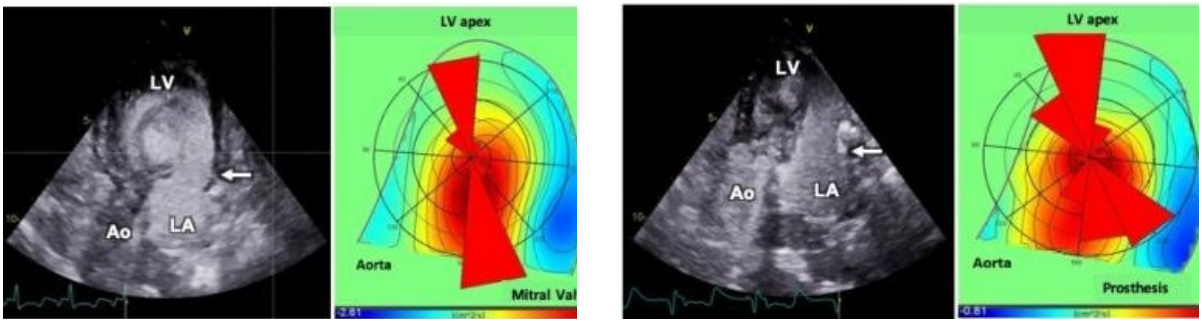
The results of the pre-clinical study were presented at the AATS Congress in New York in April 2020. The presentation entitled "Pre-clinial results of innovative transcatheter mitral prothesis specially designed to maintain physiological left ventricular vortex flow" showed that pre-clinical *in vivo* 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 intraventricular 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 transcatheter system.

The Minerva study provides for the inclusion of around 15 patients with a planned recruitment in several centres: one in Austria (Vienna), one in Italy (Florence), four in Spain (Murcia, Madrid, Barcelona and Badalone) and one in Serbia. 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 (Badalone to be confirmed). As the training of investigators has been completed, the clinical study should be launched in the 1st half of 2022 and end in the 4th quarter of 2022. Patients will be monitored over a period of 12 months. The Company intends to publish interim results of the Minerva study in 2023.

Immediately after the Minerva feasibility study, Affluent Medical intends to launch, in the 2nd half of 2023, a pilot study in several 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 in the 2nd half of 2023. Concerning the United States, the Company intends to launch in the 2nd half of 2022 the work required to conduct a pre-clinical study to be able to submit a dossier to the FDA for the conduct of a feasibility study.

The results of the pre-clinical study of the Epygon mitral valve in animal tests were published in April 2021 in the reference journal “The Annals of Thoracic Surgery” after acceptance by a reading

committee. The article entitled "Novel transcatheter mitral prosthesis designed to preserve physiological ventricular flow dynamics" shows that the Epygon mitral valve:

- is easy to implant;
- deploys quickly;
- reproduces the natural physiological filling of the left ventricle, allowing the restoration of native blood flow; and
- is safe (no major complications have occurred following its implantation).

These pre-clinical results *in vivo* confirm the expected haemodynamic performance of the Epygon transcatheter mitral valve. Additional clinical trials should now confirm the ability of the Epygon valve to fuel the recovery of the left ventricle in order to provide a response to the pathology of functional mitral regurgitation, which is under-diagnosed, and to unmet medical needs.

► **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, marketing in 2021
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 clinical trials conducted on humans (on hold)
HighLife Medical		Double components – 3 leaflets 5.2.3.2.1.1 Transseptal route	Ongoing feasibility study on five patients
Epygon Affluent Medical		D-shaped valve, asymmetrical, one single leaflet Self-expanding stent with bovine pericardium Physiological restoration	Ongoing feasibility study on 15 patients

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.

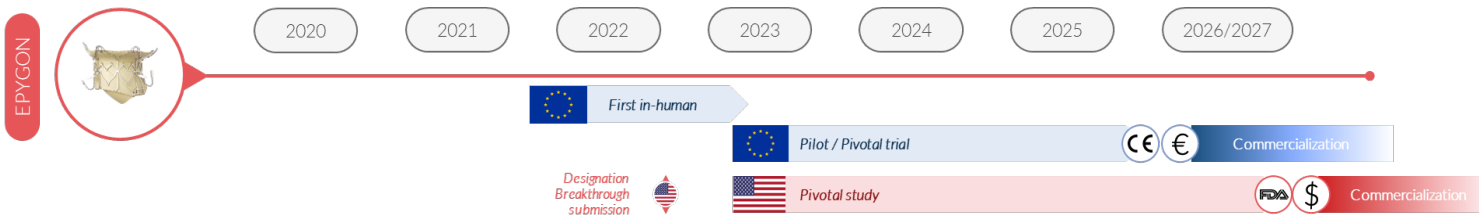
Summary diagram of the competitive positioning of the Epygon product compared to the most comparable transcatheter mitral valves[44]

	HighLife	innoheart	Medtronic	Edwards Lifesciences	neovasc	Abbott	affluent MED CAL
Product offering	Highlife	Saturn	INTREPID	CARDIAQ	TIARA	TENDYNE™	EPYGON™
CE Approval	×	×	×	×	×	✓	×
FDA Approval	×	×	×	×	Early feasibility	Clinical study	×
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
							Price: ~€35,000 - €50,000(*)

(1) Pre-clinical study
(*) Average selling price depending on the market region

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

Affluent Medical's objective is to be able to market Epygon in Europe in 2026. FDA approval in the United States is expected in late 2026 or early 2027. 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.



In the Registration Document, the development plan envisaged an end of study allowing CE marking at the end of the second half of 2025 and marketing in 2025. The Company now envisages an end of clinical development allowing CE marking and marketing at the end of the second half of 2025 or the start of 2026. This delay of approximately 6 months is due to slowed or halted patient recruitment due to the COVID 19 pandemic. Indeed, over the period from June 2021 to the beginning of 2022, the countries and hospital infrastructures where the clinical study is taking place were heavily impacted by COVID-19. Resources were mobilised to meet the needs of patients with this virus, leading, for example,

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

to the absence of an operating theatre available for non-emergency cardiac surgery.

Affluent Medical benefits from intellectual property protection for its Epygon device until 2042 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 for 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 2023/2024 to launch discussions at the end of 2024 for the reimbursement of the Epygon transcatheter mitral valve in Europe and the United States (see section 5.3.6 of the Universal 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

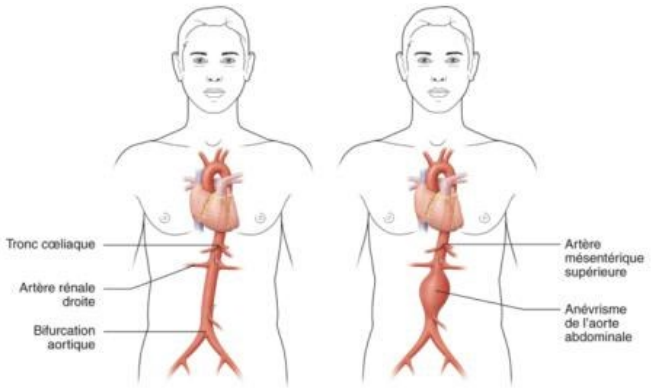
The vascular system is an interconnected network of blood vessels (veins and arteries) connected to the heart and lungs in order to bring oxygen and nutrients to all the organs and tissues of the body. Diseases affecting the vascular system are the result of damage to the blood vessels and can have consequences 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

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

abdominal aorta so that the diameter is greater than three centimetres whereas the normal size is about two centimetres.



Source: Elsevier – 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	5.2.4.1.1.1 0
5.2.4.1.1.2 4 – 5	5.2.4.1.1.3 0.5 – 5
5 – 6	5.2.4.1.1.4 3 – 15
5.2.4.1.1.5 6 – 7	5.2.4.1.1.6 10 – 20
5.2.4.1.1.7 7 – 8	5.2.4.1.1.8 20 – 40
5.2.4.1.1.9 > 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 diameter 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.

► Abdominal aortic aneurysm treatment

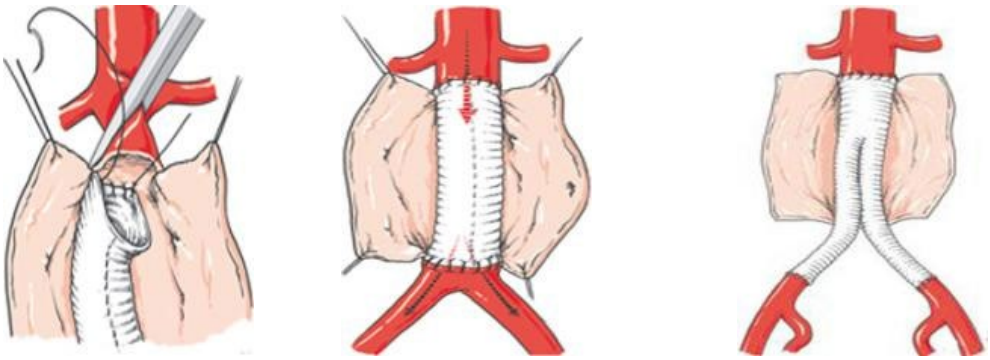
The curative treatment of AAA is either surgical or endovascular*.

[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.

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



5.2.4.1.1.10

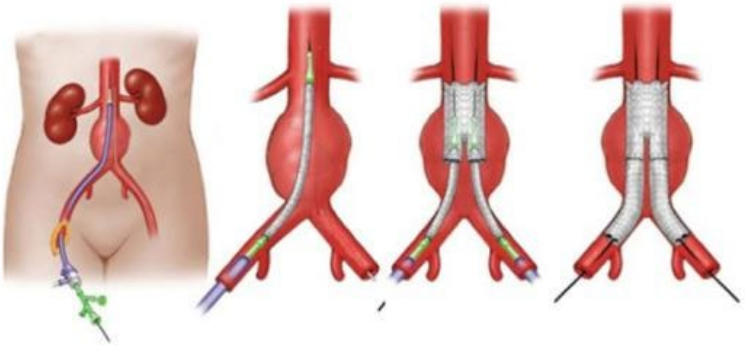
Source: CHIRVTT

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 endoprosthesis 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 endoprostheses 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
Need for reoperation after 8 years	10%	28%

	Open surgery	5.2.4.1.1.11 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). Improving 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 EVARs.[51] The most frequent type II endoleaks (representing 52.7 to 67% of endoleaks according to these same meta-analyses) are the consequence 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 an onerous procedure and can cause an infection risk.

The purpose of monitoring endoprostheses 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 diameter), 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 endoprostheses 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, W.L. 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 endoprosthesis 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 endoprostheses 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 endoprostheses 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 endoprostheses 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.

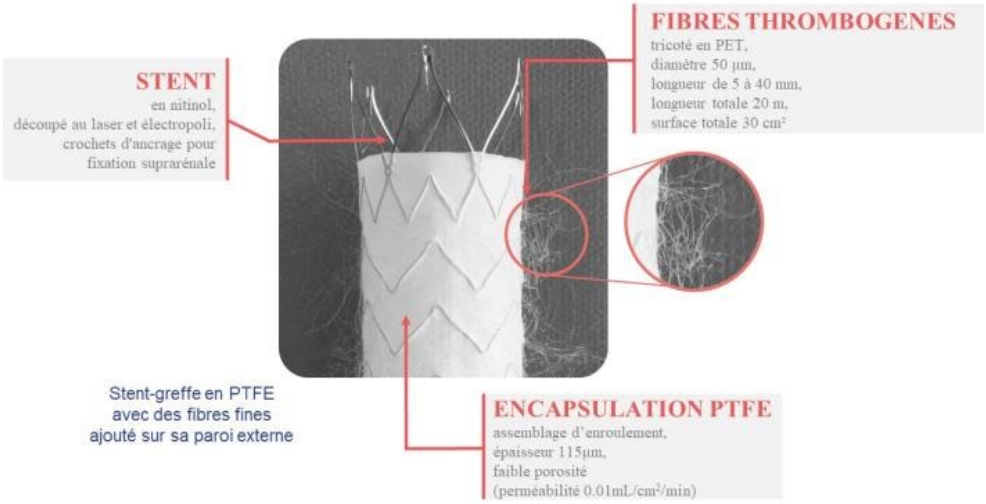
This technology could thus significantly increase the market for endoprostheses, which is limited by the risk of endoleaks, through more systematic treatment, simple monitoring of the evolution of AAA and thus interventions carried out earlier.

[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

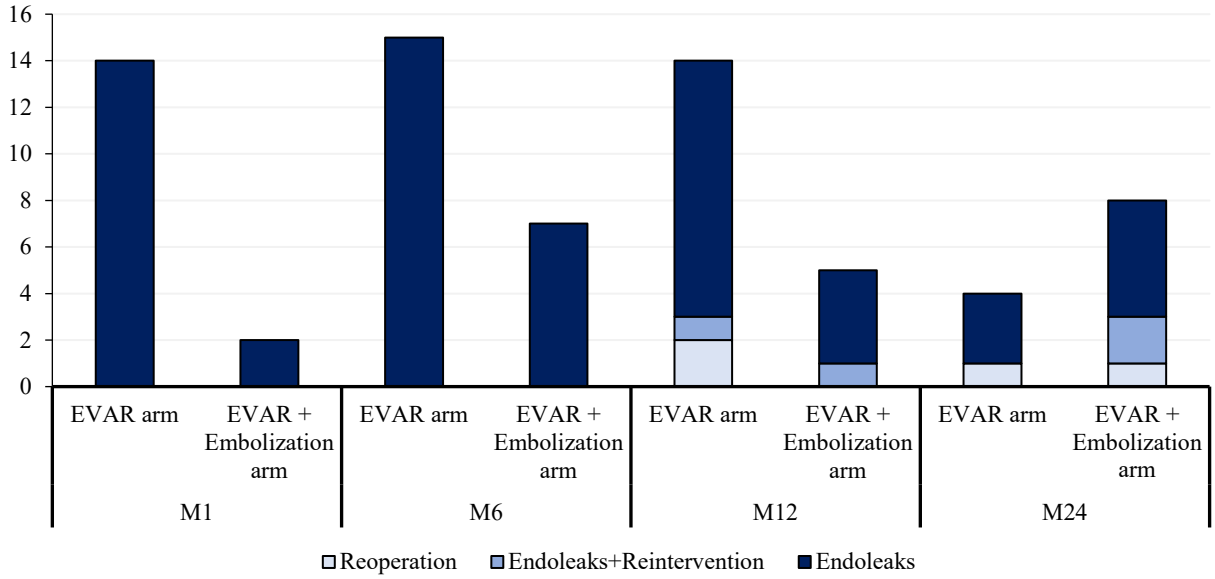
The SCOPE 1 clinical trial began in 2015 under the supervision of Professor Dominique Fabre, thoracic and vascular surgeon at the Marie Lannelongue – Le Plessis-Robinson hospital, in collaboration with *Université Paris-Sud Saclay* and with the participation of Professor Frédéric Cochennec, vascular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

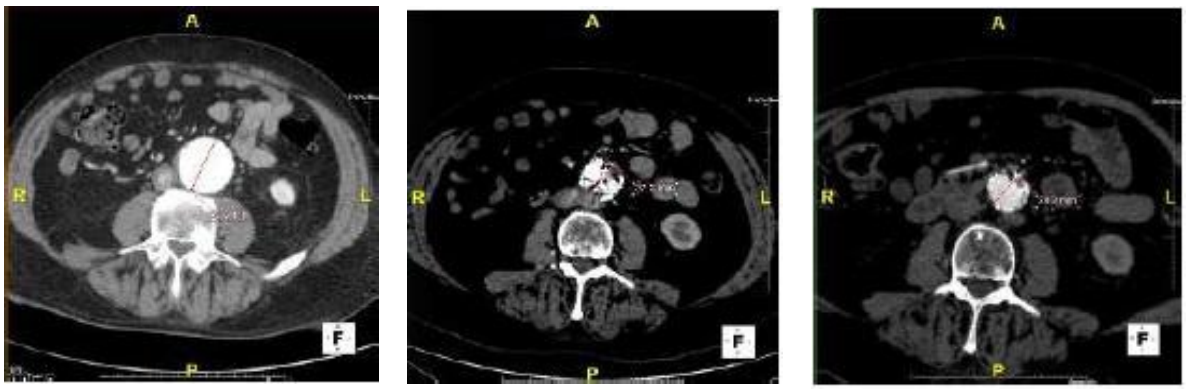
- 45 patients in the control arm: patients implanted using the EVAR procedure alone;
- 46 patients in the experimental arm: patients implanted according to the EVAR procedure accompanied by aneurysm sac embolisation.

Endoleaks & Secondary operations



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.

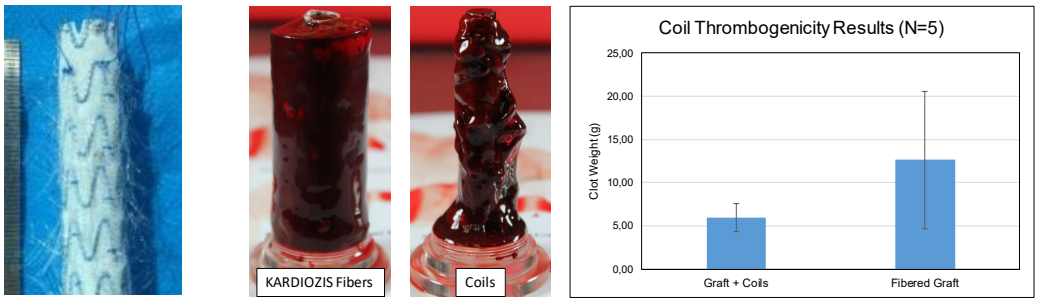
The results were presented on Saturday, 9 February 2019 at the CACVS congress (Controversies And Updates in Vascular Surgery) in Paris.

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 endoprostheses 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 pre-clinical 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

Mr 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, Mr 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. Mr Michel Finance is a graduate of EM Lyon, a chartered accountant, and was also a director of France Biotech (the French association of life science entrepreneurs) until December 2021.

Olivier Pierron – Deputy CEO

Mr 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, Mr 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

Mr 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, Mr 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. Mr 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

Prof. 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 Montsouris* (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 pre-clinical studies in various surgical fields including cardiothoracic and vascular surgery.

Wenzel Hurtak – VP Operations Epygon

Mr 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. Mr 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. Mr Wenzel Hurtak is a graduate engineer in physics and materials sciences from the University of Groningen.

Jean-Dominique Behety – Director of the Kalios Programme

Mr Jean-Dominique Behety has devoted his entire career to the medical device industry. He started as a qualification technician at Ela Medical in the early 1990s. After that he joined SAIME, which became ResMed Paris, a leading player in the field of in-home and hospital respiratory support, where he successively held the positions of Methods Manager, Head of Production, Head of R&D and Head of Operations, and ultimately managed the Group's last industrial site in Europe. His tasks included spearheading strategic changes, such as overhauling processes, developing a service-based business and several reorganisations. From 2018, he broadened his field of expertise by engaging in various entrepreneurial projects before joining Affluent Medical in May 2021.

Marion Mélot – Artus Programme Director

With a general engineering background from the Technological University of Compiègne, Ms Marion Mélot has 20 years of experience in active implantable medical devices. She participated in the development of the Carmat artificial heart from its development to CE marking and the approval for the first clinical trials in the US. She followed the growth of the company, taking on the roles of production manager, R&D project manager, product manager and then programme manager.

Pascale Lagrange – Quality Assurance Director

Ms 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.

Éric Jague – Regulatory Affairs Director

Mr Éric 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. Mr Éric 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 Latrémouille
- 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 Fribourg (HFR)

Nicolas Barry Delongchamps
- Professor of Urology at Cochin hospital

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

Véronique Phé
Professor of Urology at Hôpital Tenon-Paris – Urology department

Prof. Niall Galloway
Associate Professor of Urology, Emory Clinic, Atlanta

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[55]") system to ensure appropriate territorial 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 Universal Registration Document, the Group's portfolio of patents comprises 33 patent families and patent applications in force (scheduled for filing, filed, under examination or granted) (31 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.

[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 Research 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 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
Ring with changeable element (2)	Kephalios	October 2013	October 2034	**Delivered in Europe, the US, and China/incl. divisional**	1
Cage	Kephalios	February 2014	January 2035	**Issued in the US, Europe, Japan and China** Under examination in Canada	2
Flow sensor	Kephalios	April 2015	April 2036	**Issued in Europe and in the US**	3
Transcatheter Annuloplasty ring	Kephalios	July 2017	July 2037	Examination in progress in Europe, the US, and in the following countries: BR, CA, CN.	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, Europe and in Canada**	6
Medical device with artificial contractile structure	MyoPowers Medical Technologies	July 2010	July 2031	**Issued in the US, Europe and in Canada**	7
Medical device with artificial contractile structure	MyoPowers Medical Technologies	December 2011	December 2032	**Issued in the US, Europe, Canada and China** Examination in progress in the US (div) and Canada	8
Medical device with artificial contractile structure	MyoPowers Medical Technologies	February 2014	February 2034	**Issued in the US, Europe, Japan,** Examination in progress in the US (div)	9
Artificial contractile structure and medical device	MyoPowers Medical Technologies	November 2017	November 2037	**Issued in TW,** Under examination in Europe, the US and the following countries: BR, CA, CN, HK, IL	10
Artificial contractile structure	MyoPowers Medical Technologies	November 2017	November 2037	Examination in progress in Europe, the US, 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 US, and in the following countries: TW, BR, CA, CN, IL	12
Endoprosthesis and delivery device	Kardiozis	June 2012	June 2033	**Delivered in Europe, the US, China and Australia and in the following countries: BR, CA, JP, KR, MX, SG, ZA**	13
Delivery device, delivery system and stent-graft	Kardiozis	December 2018	December 2038	Examination in progress in Europe, the US and in the following countries: AU, CA, CN, MX, MY, ZA	14
Endoprosthesis with Fibres	Kardiozis	September 2019	September 2039	Examination in progress in Europe, the US, and in the following countries: BR, CA, CN, IN	15
Sandwiched Fibres	Kardiozis	September 2020	September 2040	Examination in progress in Europe, the US, and in the following countries: BR, CA, CN, IN	16

Object	Registered holder	Date of priority filing	Regular term (1)	Status	Reference
Graft modification for fibre attachment	Kardiozis	January 2021	January 2041	PCT filing complete	17
Stent modification for fibre attachment	Kardiozis	January 2021	January 2041	PCT filing complete	18
Fibre in Suture	Kardiozis	January 2021	January 2041	PCT filing complete	19
Heart valve prosthesis	Epygon	April 2012	April 2033	**Issued in China, Australia, Russia, Singapore, Canada, the US and South Korea and in the following countries: BR, ID, IL, MX, MX and ZA** Examination in progress in Europe, and in the following countries: 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	**Delivered in Brazil, China, Japan, Macau, the US and Europe** Examination in progress in the following countries: CA, IN	22
Inclined Leaflet	Epygon	March 2014	March 2035	**Issued in Japan, the US and Europe** Examination in progress in the following countries: BR, CA, CN, IN, HK	23
Percutaneous triangular resection	Epygon	January 2015	January 2036	**Delivered in the US, China (incl. Macau) and Japan** Examination in progress in Europe and in the following countries: BR, CA, IN	24
AMLL Paddle	Epygon	June 2015	June 2036	**Issued in the US, Europe(3) and in the following countries: AU, CN, HK, ID, JP, Macau, MX, RU, SG, ZA** Examination in progress in the following countries: BR, CA, IL, IN	25
Delivery system	Epygon	March 2017	March 2037	Examination in progress in Europe and the US and in the following countries: AU, BR, CA, CN, HK, IL, IN, JP, KR	26
Valve leaflet with variable thickness	Epygon	February 2017	February 2038	Examination in progress in Europe and the US	27
Pericardial tissue treatment	Epygon	February 2017	February 2038	Under investigation in Europe and the US and in the following countries: AU, CA, CN, HK, IN, KR	28
Crimping device for heart valve	Epygon	December 2018	December 2038	**Issued in Europe** Examination in progress in Europe and the US and in the following countries: CA, CN, HK, IN, JP	29
Reinforcement patches	Epygon	August 2021	August 2042	Under investigation in Europe, within 12 months of priority	30
Single operator crimper	Epygon		March 2042	Filing expected before the end of March 2022	31

(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 (patent maintained with amendment at first instance, with possibility of appeal). 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, and China.

In particular, no. 1 corresponding to patent application WO 2015/058808 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 WO 2015/121075 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 patent no. 1 will expire in October 2034 and patent 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, Singapore, Canada 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 2042.

► **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 endoprosthesis 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, 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 Universal 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 at 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:**

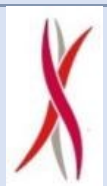
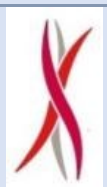
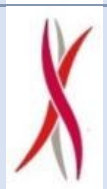
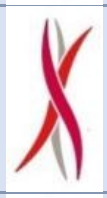
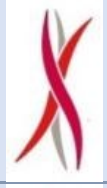
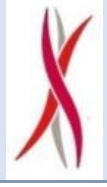
The Group uses the verbal or figurative trademarks "AFFLUENT MEDICAL", "ARTUS", "MYOPOWERS", "EPYGON", "KALIOS", "4EVAR", "KARDIOZIS", "KEPHALIOS" and "MITRALFLEX" described in the table below, which lists the trademarks in force (both those that have already been registered and those that are still 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, Australia	24 January 2013	24 January 2023
ARTUS	MYOPOWERS	Switzerland	22 January 2013	22 January 2023

Name	Holder	Territory	Filing date	Renewal date
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
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	Macau	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

Name	Holder	Territory	Filing date	Renewal date
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	KARDIOZIS	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
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	Macau	25 May 2018	21 December 2025

Name	Holder	Territory	Filing date	Renewal date
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)
	MYOPOWERS	Hong Kong	25 May 2018	24 May 2028
	MYOPOWERS	Macau	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 at 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 Universal 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 Materiovigilance. It is a system that enables 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 Materiovigilance 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

This is to certify that: Kephalios, Les Pléiades III-B, 320 Avenue Archimède, Aix-en-Provence, 13100, France

Holds Certificate Number: MD 667500

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, verification, validation, control of manufacture and distribution of sterile implantable systems for mitral valve repair.

For and on behalf of BSI: Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-01-15 Effective Date: 2019-01-15

Latest Revision Date: 2019-01-15 Expiry Date: 2022-01-14

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...making excellence a habit.

Epygon ISO 13485:2016 certificate

bsi.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Epygon Italie Srl, Via Ribes, 5, Colleretto Giacosa (TO), 10010, Italy

Holds Certificate Number: MD 642657

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and manufacturing of sterile mitral valve system for clinical use.

Previous Certificate expired on January 30, 2020

Recertification Audit ended on September 6, 2019

For and on behalf of BSI: Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-01-31 Effective Date: 2020-06-16

Latest Revision Date: 2020-06-16 Expiry Date: 2023-01-30

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...making excellence a habit.

MyoPowers ISO 13485:2016 certificate

DEKRA

CERTIFICATE

Number: 2196264

The management system of:

MyoPowers Medical Technologies France SAS

18 Rue Alain Savary

25000 Besançon

France

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design, development and manufacturing of active implantable medical devices for the treatment of incontinence

Certificate expiry date: 1 January 2023

Certificate effective date: 22 January 2020

Certified since: 22 January 2020

DEKRA Certification B.V.

B.T.M. Holtus, Managing Director

J.A. van Vugt, Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

Each subsidiary is audited annually by the certification body according to the requirements of the ISO 13485 standard (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:

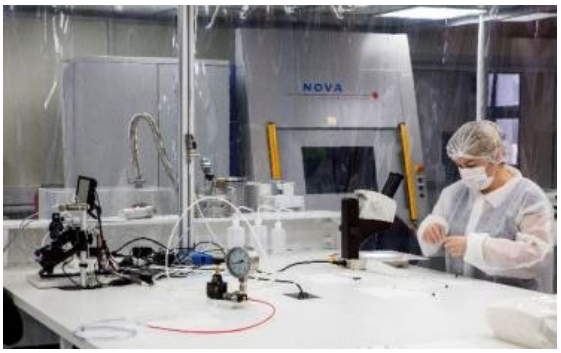
- Besançon, in the premises of MyoPowers, for the production of the Artus artificial sphincter;

- 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 for the marketing of Artus and Epygon, 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 415 m^2. Additional space was rented in 2021 allowing employees to

have a more spaced working environment necessary in times of Covid. 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 Bio Industry 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. In 2021, a new 200 m^2 R&D laboratory was rented in the Biopark to carry out product validation tests (durability, pulsatile flow, fatigue), the development of new pericardium treatment technology, and to have a space for training operators in the manufacturing of R&D prototypes (non-sterile).

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 Universal 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 Universal 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 Universal 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 endoprosthesis;

- 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 5.2.2.2 of the Universal Registration Document), around €4,000 for Kalios (see section 5.2.3.2 of the Universal Registration Document) and between €35,000 and €50,000 thousand for Epygon (see section 5.2.3.3 of the Universal 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 Main investments made

The amounts of investments made over the last three financial years (excluding right-of-use assets) are as follows:

(In thousands of euros)	Financial year 2019 (1)	Financial year 2020 (1)	Financial year 2021 (1)
Intangible assets	3	0	0
5.4.1.1.1.1 Tangible assets (excluding right-of-use assets)	196	304	333
Shareholdings in equity affiliates	0	0	0
Total acquisitions	**199**	**304**	**333**

(1) Data extracted or calculated from the consolidated financial statements prepared under IFRS as at 31 December 2021 presented in section 18.1 of the Universal Registration Document and the consolidated financial statements prepared under IFRS as at 31 December 2020 and 31 December 2019 incorporated by reference.

The main investments made by the Group correspond to investments in laboratory and IT equipment.

On 27 March 2018, the Company benefited from the contribution of shares in EPYGON SAS, KARDIOZIS SAS, KEPHALIOS SAS and MYOPOWERS MEDICAL TECHNOLOGIES France. 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 on 1 January 2019 (see Note 4.1 to the consolidated financial statements prepared in accordance with IFRS as at 31 December 2021 presented in section 18.1 of the Universal Registration Document).

The Company devotes a significant portion of its resources to the research and development of its products. Research expenses are systematically recognised as expenses. In addition, due to the uncertainties inherent in the development of the Company's products, the criteria required for development expenses to be recognised as an asset, as defined by IAS 38 – *Intangible assets*, were considered as not met.

Investments in affiliates correspond to the interests held indirectly by Affluent Medical in the two joint ventures in China accounted for under the equity method (see section 5.4.3 of the Universal Registration Document).

5.4.2 Main investments in progress and future investments

For the time being, the Company does not plan to make any significant investments for which the Company's management bodies have made firm commitments.
In the future, it will continue to devote a significant portion of its resources to the research and development of its products. New investments could be made to replace defective equipment.

5.4.3 Information concerning joint ventures and companies in which Affluent Medical holds a significant interest

Affluent Medical directly holds 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 Medev Europa SRL, a wholly-owned subsidiary of MyoPowers (see section 6.2 of the Universal Registration Document).

These companies are fully consolidated in the Company's consolidated financial statements at 31 December 2021 (please refer to Note 2.3 to the Group's consolidated financial statements under IFRS for the year ended 31 December 2021).

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 Universal Registration Document).

Investments in these joint ventures are accounted for using the equity method (see Notes 2.3 and 5 to the Group's consolidated financial statements under IFRS for the year ended 31 December 2021).

Shanghaï 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.

On the basis of the balance sheet items of the two joint ventures available at 31 December 2020, and in view of the expenses incurred by the two joint ventures during the 2021 financial year, the Company decided to use an equivalence value of zero at 31 December 2021.

The Group has no debt, related receivables or commitments to these two joint ventures.

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 particles 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.

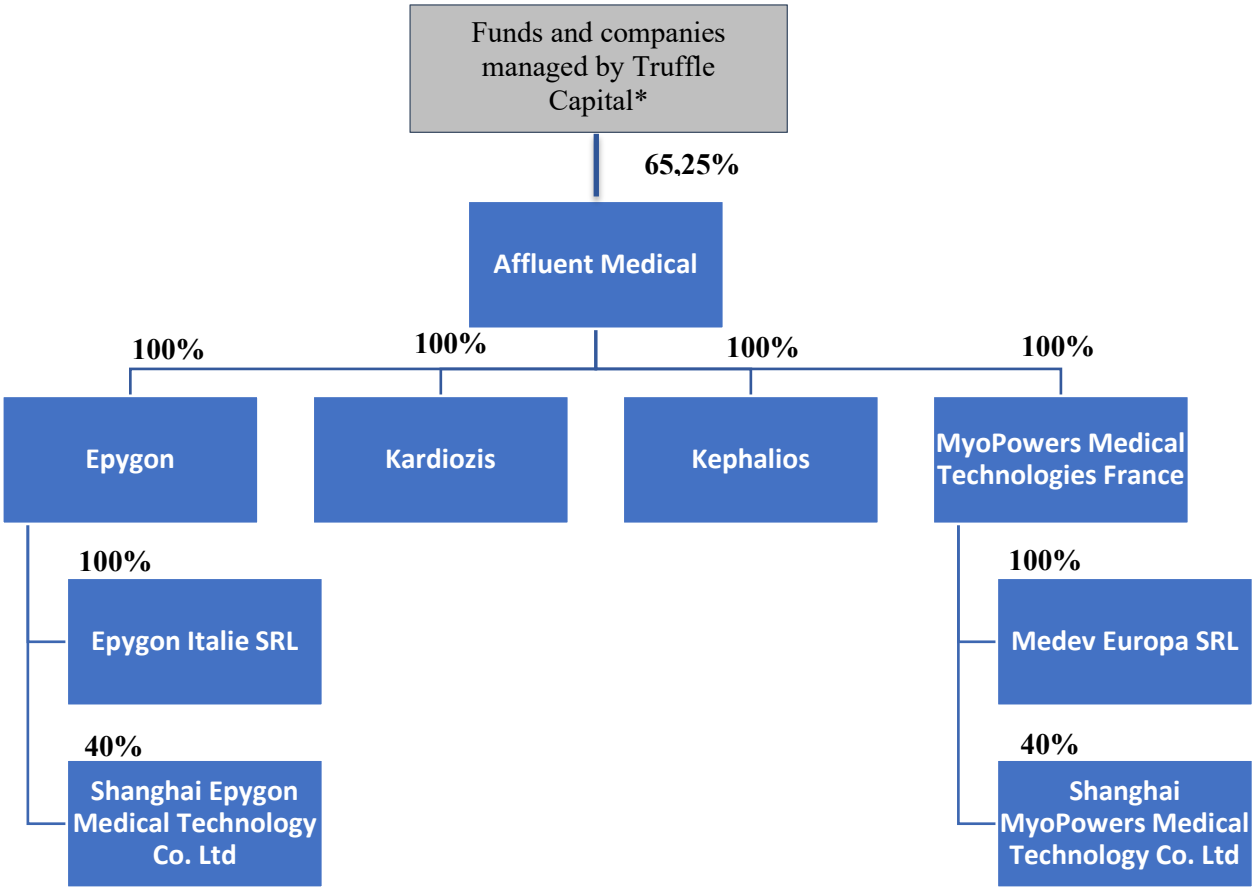
6 ORGANISATIONAL STRUCTURE

6.1 Legal organisational structure

As at the date of approval of the Universal 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 Universal Registration Document).

Affluent Medical is the Group's parent company, which sets the strategy and oversees all support functions for the various operational entities.



**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.*

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 Register, 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 Register 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 Register, 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 Register 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 Register 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 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 National Office of the Romanian Trade Register under number J40/524/2020 and unique identification code 42124756 ("**Medev Europa**") was created in 2020 and has no operational activity at the date of approval of the Universal 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

AFFLUENT MEDICAL's main intra-group flows consist of:

- Annual invoicing for administrative services and consulting services provided by AFFLUENT MEDICAL to its subsidiaries Kephalios, Kardiozis, MyoPowers Medical Technologies France and Epygon, amounting to €5,580,906.15 for the financial year ended 31 December 2021;
- A cash management agreement between AFFLUENT MEDICAL and its subsidiaries Kephalios, Kardiozis, MyoPowers Medical Technologies France and Epygon (Participating Companies). This agreement provides for the pooling of the subsidiaries' cash resources under the management of AFFLUENT MEDICAL (Centralising Company), which coordinates all of the Group's cash needs and surpluses, and thus optimises cash management for the entire Group, and as a result, reduces financial and banking fees, increases the financial resources of each party and ensures fair compensation of cash surpluses.
  The sums made available by the Centralising Company are made available through the application of interest rates in accordance with market practices.

7 REVIEW OF THE FINANCIAL POSITION AND RESULTS

Readers are invited to read this analysis of the Group's financial position and results together 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, 2020 and 2021 and any other financial reporting included in the Universal Registration Document.

The consolidated financial statements prepared in accordance with IFRS as at 31 December 2021 are presented in Chapter 18 *Financial reporting on the Group's portfolio, financial position and results* of the Universal Registration Document.

The consolidated financial statements prepared in accordance with IFRS for the financial years ended 31 December 2020 and 31 December 2019 are incorporated by reference in the Universal Registration Document and are presented in the registration document approved by the AMF on 12 April 2021 under approval number I. 21-007.

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 joint ventures entered into with Shanghai Zuquan Investment Management Company Limited (see section 6.1 of the Universal Registration Document).

The Group's research and development (R&D), pre-clinical 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 Universal 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 Group 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 €58 million, mainly related to R&D expenses and pre-clinical and clinical studies as well as overheads and operating expenses. Operating expenses dedicated to R&D, pre-clinical and clinical activities, regulatory affairs and quality, and excluding general administrative expenses, represent approximately 81% of the Company's total expenses in 2021 (83% in 2020).

As R&D, pre-clinical 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 marketing or license agreement stage, which could generate revenues in the form of lump sums or royalties (refer to section 5.1.1 of the Universal 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, CIC and Bpifrance; and
- the research tax credit as well as its pre-financing from the specialised organisation Neftys (see section 8.1.5 of the Universal 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 pre-clinical 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 Universal 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 (RTC);
- 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, State-guaranteed loans 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 2021, 31 December 2020 and 31 December 2019

SIMPLIFIED STATEMENT OF FINANCIAL POSITION (Amounts in thousands of euros)	31/12/2021 IFRS	31/12/2020 IFRS	31/12/2019 IFRS
Non-current assets	55,360	56,915	59,136
Current assets	14,675	7,911	6,116
Total assets	**70,035**	**64,826**	**65,252**
Equity	43,535	35,289	30,964
Non-current liabilities	19,197	19,772	24,780
Current liabilities	7,303	9,765	9,508
Total liabilities	**70,035**	**64,826**	**65,252**

7.1.3.1 Non-current assets

NON-CURRENT ASSETS (Amounts in thousands of euros)	31/12/2021 IFRS	31/12/2020 IFRS	31/12/2019 IFRS
Goodwill	32,203	32,203	32,203
Intangible assets	20,695	22,566	24,442
Tangible assets	2,005	1,781	1,746
Shareholdings in equity affiliates	-	14	414
Non-current financial assets	457	351	331
Total non-current assets	**55,360**	**56,915**	**59,136**

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 thousand.

Internally developed technologies recorded as intangible assets are amortised over a period of 15 years, mainly explaining the decrease in intangible assets between the various financial years presented (see Note 4.1 to the Group's consolidated financial statements under IFRS for the financial year ended 31 December 2021).

Tangible assets mainly comprise:

- rights-of-use recognised in accordance with IFRS 16 – *Leases*;
- laboratory equipment and tools; and
- IT equipment.

The decrease in the book value of equity affiliates reflects the development expenses incurred by the joint ventures (refer to section 7.1.3 of the Universal 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 at the time of the issue of tranches A and B of the non-convertible bond with Kreos Capital. They amounted to €256 thousand at 31 December 2019, 2020 and 2021;
- the cash account of the liquidity contract set up in 2021 with Kepler Cheuvreux following the Company's IPO on the Euronext Paris market (€67 thousand at 31 December 2021).

7.1.3.2 Current assets

CURRENT ASSETS (Amounts in thousands of euros)	31/12/2021 IFRS	31/12/2020 IFRS	31/12/2019 IFRS
Other receivables	3,265	2,261	3,989
Cash and cash equivalents	11,410	5,650	2,126
Total current assets	**14,675**	**7,911**	**6,116**

Other receivables include:

- receivables in respect of the research tax credit (abbreviated RTC, or "CIR" in French) amounting to €1,044 thousand as at 31 December 2021, €509 thousand as at 31 December 2020 and €2,109 thousand as at 31 December 2019;
- VAT credit amounting to €1,642 thousand as at 31 December 2021, €1,038 thousand as at 31 December 2020 and €1,324 thousand as at 31 December 2019. 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 and 2021 compared to 2019 is explained by the fact that in 2020 and 2021 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 thousands of euros)	31/12/2021 IFRS	31/12/2020 IFRS	31/12/2019 IFRS
Share capital	18,164	15,257	11,900
Premiums	80,546	62,683	47,701
Translation reserve	22	21	24
Other items in comprehensive income	10	(22)	(20)
Reserves and net income attributable to shareholders of the parent company	(55,207)	(42,649)	(28,641)
Equity attributable to owners of the Group	**43,534**	**35,289**	**30,964**
Non-controlling interests	-	-	-
Total equity	**43,534**	**35,289**	**30,964**

The share capital as at 31 December 2021 is set at €18,163,802.00 and is divided into 18,163,802 ordinary shares with a nominal value of €1.00.

The change in equity during the financial year 2021 mainly corresponds to:

- the capital increase in cash for a total amount of €23,000 thousand and by offsetting receivables for an amount of €2,000 thousand with Kreos Capital V at the time of the Company's IPO;
- the allocation of capital increase costs incurred in 2021 for -€1,575 thousand;
- the impact of share-based payment (IFRS 2) in the amount of €42 thousand;
- the cancellation of the change in treasury shares and the gains and losses realised under the liquidity contract for a total of -€435 thousand; and
- the loss of -€14,820 thousand for financial year 2021.

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 Universal 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.

See the consolidated statement of changes in equity presented in the financial statements prepared under IFRS at 31 December 2021 in section 18.1.1. of the Universal 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 thousands of euros)	31/12/2021 IFRS	31/12/2020 IFRS	31/12/2019 IFRS
Repayable advances	13,113	9,489	6,052
State-guaranteed loans	2,970	2,155	-
Bond loan	-	4,593	13,782
Other loans and liabilities	2	9	48
Non-current financial liabilities	**16,085**	**16,248**	**19,882**
Non-current lease liabilities	913	731	811
Non-current derivative liabilities	-	-	995
Total non-current financial liabilities	**16,998**	**16,978**	**21,687**
Pre-financing of research tax credit receivables		-	669
Bond loan	2,410	3,573	2,621
Other loans and liabilities		-	-
Bank overdrafts	6	2	1
Current financial liabilities	**2,416**	**3,575**	**3,290**
Current lease liabilities	337	226	202
Current derivative liabilities	310	1,351	270
Total current financial liabilities	**3,063**	**5,152**	**3,762**
Total financial liabilities	**20,061**	**22,131**	**25,449**

Repayable advances (presented in non-current financial liabilities) increased by €7,061 thousand between 31 December 2019 and 31 December 2021 following:

- the collection of repayable advances in 2020 in the amount of €2,755 thousand (innovation loan with Bpifrance for €1 million and Mivana project for €1.8 million);
- the receipt of a repayable advance of €2,529 thousand as part of the PIAVE Artus project in 2021; and
- the recognition of accrued interest in 2020 and 2021 in respect of the additional payments provided for in the repayable advances contracts of the PIAVE Artus and Mivana projects (detailed in section 20.2.1 of the Universal Registration Document) in the amount of €1,834 thousand (€758 thousand in 2020 and €1,076 thousand in 2021).

The Company set up four State-guaranteed loans in 2020 for a total amount of €2.1 million and three State-guaranteed loans in 2021 for a total amount of €0.8 million (see section 18.1.1. Note 11 to the consolidated financial statements under IFRS as at 31 December 2021 of the Universal Registration Document and section 8.1.4 of the Universal 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 ("2018 CB" 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.

During the 2019 financial year, bond increased overall by €7,726 thousand.

Bonds amounted to €16,403 thousand as at 31 December 2019 of which €13,782 thousand in non-current financial liabilities and €2,621 thousand in current financial liabilities. They are made up of:
- tranches A and B of the non-convertible bond issued in October 2018 in favour of Kreos Capital in the amount of €7,261 thousand (of which €2,621 thousand in current financial liabilities);
- the convertible bond issued in March 2018 ("2018 CB" with a nominal value of €2.85 million) for €2,797 thousand;
- the convertible bond issued in April 2018 ("Financing CB", with a nominal value of €3 million) for €2,730 thousand; and
- the bond in favour of Truffle Innov FRR France and Truffle Biomedtech Crossover Fund for €4 million (first tranche of "**2019 CB**"), whose value 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 bond 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).

In financial year 2021, bond issues decreased overall by €5,756 thousand to reach €2,410 thousand (of which €2,410 thousand in current financial liabilities).

Bonds issued to Kreos Capital (tranches A and B) were repaid in the amount of €2,164 thousand and a decrease related to the offsetting of receivables in the amount of €2,000 thousand as part of the capital increase at the time of the Company's IPO. As at 31 December 2021, non-convertible bonds issued to Kreos Capital totalled €1,370 thousand.

On 25 February 2021, Head Leader Limited notified the Company of its request for the repayment of convertible bonds in the event of the admission of the Company's shares to trading on the Euronext Paris regulated market. The bond for the benefit of Head Leader (second tranche of the 2019 CB) were repaid in the amount of €3,000 in the course of 2021 and amounted to €1,040 thousand as at 31 December 2021 in accordance with IFRS 9. The balance was repaid at the end of January 2022.

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 €1,013 thousand (of which €202 thousand due in less than one year) at 31 December 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 2021, the Company renewed the lease for its premises in Aix-en-Provence, extended the lease in Besançon, set up a new lease for additional premises in Colleretto Giacosa (Italy) and set up new vehicle leasing contracts generating an additional debt of €576 thousand. The Company repaid €283 thousand in 2021.

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 2020 CB in June 2019, the derivative liabilities relating to the conversion options were recorded in equity on the conversion date.

Following the request for the repayment of the second tranche of the 2019 CBs by Head Leader Limited on 25 February 2021, the derivative liability relating to the conversion option was cancelled and the change in fair value was recorded in the income statement in accordance with IFRS 9 for the 2021 financial year.

Derivative liabilities at 31 December 2021 relate exclusively to the share subscription warrants attached to tranche A and B of the non-convertible bond issued to Kreos Capital.

Please refer to section 8.1 of the Universal Registration Document for more information on the Group's financing sources.

7.1.3.5 Non-current liabilities

NON-CURRENT LIABILITIES (Amounts in thousands of euros)	31/12/2021 IFRS	31/12/2020 IFRS	31/12/2019 IFRS
Non-current financial liabilities	16,085	16,248	19,882
Non-current lease liabilities	913	731	811
Employee benefits commitments	96	117	86
Non-current provisions	130	228	103
Deferred tax liabilities	1,973	2,440	2,669
Derivative liabilities	-	-	995
Other non-current liabilities	-	9	234
Total non-current liabilities	**19,196**	**19,772**	**24,780**

Non-current financial liabilities and their evolution are presented in sections 7.1.3.4 and 8.1 of the Universal 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 Universal Registration Document).

7.1.3.6 Current liabilities

CURRENT LIABILITIES (Amounts in thousands of euros)	31/12/2021 IFRS	31/12/2020 IFRS	31/12/2019 IFRS
Current financial liabilities	2,416	3,575	3,290
Current lease liabilities	337	226	202
Trade payables and related accounts	1,793	2,352	3,704
Other current liabilities	2,448	2,261	2,043
Derivative liabilities	310	1,351	270
Total current liabilities	**7,304**	**9,765**	**9,508**

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 €200 thousand at 31 December 2021 (€300 thousand in 2019 and 2020).

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 share subscription warrants in the absence of a fixed exchange rate (see section 18.1.1. of the Universal Registration Document Note 11 to the consolidated financial statements under IFRS as at 31 December 2021).

Current financial debts (including current derivative liabilities and debts related to current lease obligations) increased by €1,390 thousand between 31 December 2019 and 31 December 2020 to reach €5,152 thousand, mainly due to the following:

- recognition of the derivative liability on the second tranche of the 2019 CB bond issue, the value of which at 31 December 2020 was €1.0 million;
- an increase in the current portion of the Kreos non-convertible bond to approximately €0.5 million.

Current financial liabilities (including current derivative liabilities and debts related to current lease obligations) decreased by €2,090 thousand between 31 December 2020 and 31 December 2021 to reach €5,152 thousand due in particular to the decrease during financial year 2021 due to the following:

- the current portion of the Kreos non-convertible bond issue decreased by approximately €0.8 million;
- the cancellation of the derivative liability on the second tranche of the 2019 CB bond issue for €1.0 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 and 2021 is mainly due to the shortening of the supplier payment period.

7.2 Operating results

7.2.1 Presentation and analysis of the consolidated income statement of Affluent Medical prepared in accordance with IFRS for the financial years ended 31 December 2021, 2020 and 2019

INCOME STATEMENT (Amounts in thousands of euros)	31/12/2021 IFRS 12 months	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months
Revenue	-	-	-
Other operating income	1,451	824	1,429
OPERATING EXPENSES			
Purchases consumed	(2,518)	(3,108)	(5,483)
External expenses	(5,496)	(3,563)	(3,899)
Personnel expenses	(4,405)	(4,694)	(3,607)
Taxes and duties	(88)	(67)	(34)
Other current operating income and expenses	145	46	14
Provisions	98	(125)	-
Depreciation and amortisation	(2,420)	(1,907)	(2,260)
OPERATING INCOME	**(13,233)**	**(12,594)**	**(13,841)**
Share of net income of equity affiliates	(14)	(398)	(1,190)
OPERATING INCOME after share of net income of equity affiliates	**(13,247)**	**(12,992)**	**(15,031)**
Net finance income (expense)	(2,010)	(1,536)	(1,769)
Income taxes	437	209	210
NET INCOME (LOSS)	**(14,820)**	**(14,319)**	**(16,589)**

7.2.1.1 Revenue and other operating income

OPERATING INCOME (Amounts in thousands of euros)	31/12/2021 IFRS 12 months	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months
Revenue	-	-	-
Other operating income	1,451	824	1,429

Other operating income consists mainly of:

- research tax credits amounting to €1,101 thousand in 2021, €380 thousand in 2020 and €1,087 thousand in 2019; and
- subsidies spread over the duration of the expenses incurred as part of the Mivana and PIAVE Artus development projects in the amount of €305 thousand in 2021 (of which €272 thousand for the Mivana project, €33 thousand for the PIAVE Artus project), €408 thousand in 2020 (of which €375 thousand for the Mivana project, €33 thousand for the PIAVE Artus project) and €330 thousand in 2019.

7.2.1.2 Operating income

The table below allows their comparison through the use of specific sub-totals:

PURCHASES CONSUMED, OTHER EXTERNAL EXPENSES AND EXTERNAL SERVICES (Amounts in thousands of euros)	31/12/2021 IFRS 12 months	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months
Purchases consumed	(2,518)	(3,108)	(5,483)
Sub-total purchases consumed	***(2,518)***	***(3,108)***	***(5,483)***
Fees	(4,595)	(2,969)	(3,117)
Missions and receptions	(215)	(128)	(414)
Sub-total other external expenses	***(4,809)***	***(3,098)***	***(3,531)***
Maintenance and repairs	(223)	(152)	(86)
Advertising, publications, public relations	(44)	(21)	(38)
Rentals and rental expenses	(64)	(58)	(39)
Insurance premiums	(64)	(48)	(42)
Studies, research, documentation and seminars	(23)	(9)	(22)
Miscellaneous	(269)	(178)	(142)
Sub-total other external services	***(687)***	***(465)***	***(368)***
Total purchases consumed, other external expenses and external services	**(8,015)**	**(6,671)**	**(9,382)**

Purchases consumed 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 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).

Between 2020 and 2021, purchases consumed decreased by nearly €0.6 million in line with the level of activity of the Optimise II study launched in 2019 for the Kalios product.

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;
- Fees for missions and travel primarily performed in the context of the various pre-clinical studies initiated.

In 2020 and 2021, the Company incurred costs related to the IPO and the concomitant capital increase for a total amount of €2,910 thousand (€155 thousand in 2020 and €2,755 thousand in 2021). Of this amount, the Company recognised as expenses €1,181 thousand in fees not directly related to the capital increase in 2021 and recognised, in addition to the share premium, the fees directly related to the capital increase for €155 thousand in 2020 and €1,575 thousand in 2021.

In line with the travel restrictions linked to the Covid-19 pandemic, travel and missions expenses were significantly reduced in 2020 and increased in part in 2021.

Other external services consist of:

- maintenance costs, rental expenses and maintenance expenses for the various premises occupied by the Group in Paris, Aix-en-Provence, Besançon and Colleretto Giacosa (France) 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 thousands of euros)**	**31/12/2021 IFRS 12 months**	**31/12/2020 IFRS 12 months**	**31/12/2019 IFRS 12 months**
Personnel expenses	(4,405)	(4,694)	(3,607)
Of which share-based payments (IFRS 2)	*(42)*	*(959)*	*(437)*

The Group had an average workforce of 48 employees for the year ended 31 December 2021 compared to 42 employees for the year ended 31 December 2020 and 40 employees for the year ended 31 December 2019. 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 €42 thousand as at 31 December 2021, €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.

AMORTISATION, DEPRECIATION AND PROVISIONS **(Amounts in thousands of euros)**	**31/12/2021 IFRS 12 months**	**31/12/2020 IFRS 12 months**	**31/12/2019 IFRS 12 months**
Depreciation and amortisation	(2,420)	(1,907)	(2,260)
Provisions net of reversals	98	(125)	-
Amortisation, depreciation and provisions	**(2,322)**	**(2,032)**	**(2,260)**

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 €1,844 thousand in 2021, 2020 and 2019;
- tangible assets (excluding right-of-use assets) for €247 thousand in 2021, €204 thousand in 2020 and €185 thousand in 2019; and
- right-of-use accounts recognised in accordance with IFRS 16 – *Leases* for €299 thousand in 2021, €231 thousand in 2020 and €197 thousand in 2019.

SHARE OF INCOME OF EQUITY AFFILIATES (Amounts in thousands of euros)	31/12/2021 IFRS 12 months	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months
Share of income of equity affiliates	(14)	(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 equity affiliates reflects the development expenses incurred by the Joint Ventures.

7.2.1.3 Net finance income (expense)

NET FINANCE INCOME (EXPENSE) (Amounts in thousands of euros)	31/12/2021 IFRS 12 months	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months
Interest expenses	(3,036)	(2,129)	(1,884)
Foreign exchange income	-	1	(3)
Change in fair value of financial instruments	1,041	597	132
Effect of accretion	(19)	(36)	(17)
Other	4	30	3
Net finance income (expense)	**(2,010)**	**(1,536)**	**(1,769)**

Net finance income (expense) for the financial years presented is strongly negative given the financing put in place since the creation of the Company and the increase in interest paid as a result. It is partially offset by the change in fair value under IFRS of derivative liabilities.

Net finance income (expense) includes:

- amortised cost and accrued interest on bonds;
- accrued interest of €1,076 thousand (€758 thousand in 2020; €372 thousand in 2019) on repayable advances (Mivana and PIAVE Artus);
- 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 net finance income (expense).

7.2.1.4 Income taxes

INCOME TAXES (Amounts in thousands of euros)	31/12/2021 IFRS 12 months	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months
Income taxes	437	209	210
Of which income tax	*30*	*20*	*19*
Of which deferred tax	*407*	*188*	*192*

The Group recognised income tax at the level of its Italian subsidiary between 2019 and 2021. The other entities have been making losses since the creation of the Group.

Affluent Medical had tax losses that can be carried forward indefinitely in France amounting to €85,279 thousand as at 31 December 2021.

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 current rate in France, *i.e.* 26.5%. 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 2021.

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 (see section 18.1.1. of the Universal Registration Document Note 4.1 to the consolidated financial statements under IFRS as at 31 December 2021).

The change in deferred tax 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 euros)	31/12/2021 IFRS 12 months	31/12/2020 IFRS 12 months	31/12/2019 IFRS 12 months
Number of shares at the end of the periods presented	**18,163,802**	**15,256,824**	**11,899,967**
Weighted average number of shares outstanding	**16,873,582**	**13,360,416**	**11,899,967**
Net income for the period – attributable to shareholders of the parent company (in thousands of euros)	(14,820)	(14,319)	(16,589)
Basic earnings per share (€/share)	**(0.88)**	**(1.07)**	**(1.39)**
Diluted earnings per share (€/share)	**(0.88)**	**(1.07)**	**(1.39)**

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.

7.3 Activity of Group companies over the last two financial years

7.3.1 Income for AFFLUENT MEDICAL SA

AFFLUENT MEDICAL SA (Amounts in thousands of euros)	31/12/2021	31/12/2020
Operating income	5,822	4,003
Of which revenue		
Operating expenses	(5,029)	(3,185)
Net finance income (expense)	(650)	(924)
Exceptional income (expense)	25	
Corporate tax	-	-
Net income (loss)	**168**	**(105)**

Operating income mainly consists of the re-invoicing of the Company's services to its subsidiaries. The increase for 2021 *versus* 2020 is €1.8 million. This change is mainly due to the increase in external expenses, and in particular the costs related to the IPO in June 2021 for €1.2 million, the additional costs associated with a company listed on the regulated market, the expenses of clinical and regulatory consultants totalling €0.5 million.

Operating expenses for 2021 break down as follows:

- External expenses represent expenses of €3.2 million in 2021 compared to €1.5 million in 2020. This increase is mainly due to expenses related to the Company's IPO, as well as additional costs of providing services for clinical or regulatory activities;

- Salaries and expenses amounted to €1.7 million in 2021 compared to €1.6 million in 2020. This increase is mainly due to the reinforcement of the teams to cope with the increase in activity and strengthen the skills, in particular, of the regulatory activities.

7.3.2 Subsidiaries' income

(Amounts in thousands of euros)	31/12/2021	31/12/2020
EPYGON		
Operating income	29	308
Net income (loss)	(6,070)	(5,427)
KARDIOZIS		
Operating income	101	12
Net income (loss)	(401)	(1,111)

KEPHALIOS		
Operating income	16	279
Net income (loss)	(3,519)	(3,561)
MYOPOWERS MEDICAL TECHNOLOGIES FRANCE		
Operating income	48	113
Net income (loss)	(4,292)	(2,866)
EPYGON ITALIE SRL		
Operating income	2,298	1,815
Net income (loss)	83	65

The change in losses in 2021 compared to 2020 is partly due to the increase in the re-invoicing of Affluent Medical's services due to IPO fees, as well as the amounts received associated with the research tax credit.

The company Epygon continues to develop its eponymous mitral valve, the increase in research and development activities, the costs associated with the IPO as well as an increase in the research tax credit in 2021 led to a decrease in net income of -€0.6 million in 2021 compared to 2020 to stand at -€6.1 million.

Epygon Italy is also involved in the development of the Epygon mitral valve. Its net income in 2021 is in line with that of 2020.

The company Kardiozis is looking for a partnership for its Kardiozis product, employees have been made available to the Group's other programmes, thus generating operating income for the year 2021. Net income amounted to a -€0.4 million or an increase of €0.7 million compared to 2020.

The company Kephalios continues to develop its Kalios mitral repair ring. Net income for 2021 was -€3.5 million compared to -€3.6 million in 2020. The additional expenses associated with the IPO are partly offset by the reduction in production requirements and by the increase in the research tax credit.

The company MyoPowers continues to develop its Artus artificial sphincter for urinary incontinence. Net income for 2021 was -€4.2 million compared to -€2.8 million in 2020. The reduction in the research tax credit related to the payment of €2.5 million in repayable advances from BPI, the increase in research and development expenses, the costs associated with the IPO as well as the strengthening of local teams lead to net income down €1.4 million in 2021 compared to 2020.

8 CASH AND CAPITAL

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 Universal Registration Document are made on the basis of the Group's consolidated financial reporting prepared in accordance with IFRS and should be read jointly with IFRS, together with the consolidated financial reporting presented in Chapter 18 *Financial reporting on the Group's portfolio, financial position and results* of the Universal 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 2018/2021 and previously, the Group was able to raise more than €93 million in dilutive and non-dilutive financing of which:

- Capital increase of €23.0 million in cash in 2021;
- Capital increases of €7.5 million in 2020;
- Repayable advances of €10.4 million received BPI Innovation loan for €1 million; Piave project €6.2 million; Mivana project €3.2 million (including €1.4 million prior to 31 December 2017);
- €2.9 million in State-guaranteed loans;
- €13.85 million in convertible bond issuances (€2.85 million in 2018 CBs; €3 million in Financing CB; €8 million in the 2019 CB);
- €8.0 million in non-convertible bonds issued to Kreos Capital;
- €4.5 million in research tax credit between 2018 and 2021;
- €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 thousands of euros)**	**31/12/2021** **IFRS**	**31/12/2020** **IFRS**	**31/12/2019** **IFRS**
Non-current financial liabilities	16,085	16,248	19,882
Non-current lease liabilities	913	731	811
Non-current derivative liabilities	-	-	995
Current financial liabilities	2,416	3,575	3,290
Current lease liabilities	337	226	202
Current derivative liabilities	310	1,351	270
Total financial liabilities	**20,060**	**22,131**	**25,449**
Cash and cash equivalents	**11,410**	**5,650**	**2,126**
Net debt	**8,650**	**16,481**	**23,323**

The change in financial liabilities is presented in detail in section 7.1.3.4 of the Universal Registration Document.

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 liabilities related to:
    - the repayments made in 2020 on the 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 collection of repayable advances of €1,759 thousand for the Mivana project;
- the issuance of a Bpifrance Innovation loan for €1,000 thousand;
- the issuance of State-guaranteed loans in the amount of €2,140 thousand;
- the recognition of accrued interest for additional payments under the repayable advance contracts for the PIAVE Artus and Mivana projects in the amount of €758 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 €3,524 thousand.

The €7,831 thousand decrease in net debt in 2021 compared to 2020 is mainly due to:

- the net decrease in non-current and current liabilities related to:
    - the repayments made in 2021 on the non-convertible bonds issued to Kreos Capital for an amount of €2,164 thousand,
    - the €2,000 thousand reduction in this bond as part of the offsetting of receivables made during the Company's capital increase in 2021,
    - the repayment of the second tranche of the 2019 CBs to Head Leader in the amount of €3 million in 2021;
- the receipt of a repayable advance of €2,529 thousand as part of the PIAVE Artus project;
- the recognition of accrued interest for additional payments under the contracts for repayable advances for the PIAVE Artus and Mivana projects in the amount of €1,076 thousand;
- the issuance of State-guaranteed loans in the amount of €795 thousand;
- the recognition of new liabilities related to lease obligations amounting to €576 thousand, offset by repayments of €278 thousand;
- the cancellation of the derivative liability in respect of the conversion option of the second tranche of the 2019 CBs (valued at €1 million at 31 December 2020) due to the absence of a conversion option in 2021 given the ongoing redemption of these obligations;
- the increase in cash and cash equivalents between 31 December 2020 and 31 December 2021 for €5,760 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 Universal Registration Document:

Periods	Contribution value In thousands of euros	Gross amounts raised and conversions In thousands of euros	Total In thousands of euros	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).
2021	**-**	**23,000**	**23,000**	IPO on the Euronext Paris Growth market
2021	**-**	**2,000**	**2,000**	Capital increase through the conversion of debt
Total	**59,500**	**43,328**	**102,828**	

Affluent Medical subsidiaries benefited from capital increases of €23.4 million before 31 December 2017.

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 2021, 31 December 2020 and 31 December 2019:

CHANGE IN BOND LOANS (Amounts in thousands of euros)	Kreos bonds	Financing CBs*	2018 CBs**	2019 CBs**	Total
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
(-) Repayment	(1,952)	-	-	-	(1,952)
(+/-) Accrued interest	-	88	84	113	285
(+/-) Conversion	-	(2,882)	(2,943)	(3,718)	(9,543)
At 31 December 2020	**5,483**	-	-	**2,684**	**8,167**
(+) Impact of amortised cost	52	-	-	1,203	1,254
(-) Repayment	(2,164)	-	-	(3,000)	(5,164)
(+/-) Accrued interest	-	-	-	153	153
(+/-) Conversion	(2,000)	-	-	-	(2,000)
At 31 December 2021	**1,370**	-	-	**1,040**	**2,410**

*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 BONDS, IN REDEMPTION VALUE (Amounts in thousands of euros)	Kreos Capital bonds loan	Financing CBs*	2018 CBs**	2019 CBs*	Total
At 31 December 2021	**1,367**	-	-	**1,000**	**2,367**
Share at less than one year	1,367	-	-	1,000	**2,367**
Share between one and five years	-	-	-	-	-
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 3,000,000 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 Universal 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 Universal 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 principal remaining due, 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 of the Universal Registration Document Note 11 to the consolidated financial statements under IFRS as at 31 December 2021).

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 2021, the amount of the Kreos Capital bonds to be repaid stood at €1,370 thousand and the number of Affluent Medical shares that may be issued upon exercise of the 131,148 BSA 2018-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 8,000,000 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 2,300,000 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 4,000,000 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 Universal 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 repayment of convertible bonds in the event of the admission of the Company's shares to trading on the Euronext Paris regulated market. The bond for the benefit of Head Leader (second tranche of the 2019 CB) were repaid in the amount of €3,000 thousand in the course of 2021 and amounted to €1,040 thousand as at 31 December 2021 in accordance with IFRS 9. The balance was repaid at the end of January 2022.

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 State-guaranteed loans

The tables below show the change in repayable advances and State-guaranteed loans as shown in the consolidated financial statements prepared in accordance with IFRS as at 31 December 2021, 2020 and 2019:

CHANGE IN REPAYABLE ADVANCES – IFRS STANDARDS (Amounts in thousands of euros)	BPI innovation	Project MIVANA – Epygon	Project MIVANA – Kephalios	Project PIAVE Artus	Total
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
Grant	(90)	-	-	-	(90)
Financial expenses	13	-	-	-	13
At 31 December 2020	**919**	**3,317**	**1,259**	**3,944**	**9,489**

(+) Collection	-	-	-	2,529	2,529
(-) Repayment	-	-	-	-	-
(+) Accrued interest	-	448	104	524	1,076
Grant	-	-	-	-	-
Financial expenses	19	-	-	-	19
At 31 December 2021	**938**	**3,765**	**1,362**	**7,048**	**13,113**

MATURITIES OF STATE-GUARANTEED LOANS, IN REPAYMENT VALUE (Amounts in thousands of euros)	**BPI Innovation**	**Project Mivana – Epygon**	**Project Mivana – Kephalios**	**Project PIAVE Artus**	**Total**
At 31 December 2021	**1,000**	**3,766**	**1,362**	**7,048**	**13,175**
Share at less than one year	100	-	-	-	100
Share between one and five years	800	2,319	892	6,188	10,199
Share at more than five years	100	1,447	470	859	2,876

CHANGE IN STATE-GUARANTEED LOANS (Amounts in thousands of euros)	**BNP Paribas State-guaranteed loan**		**Bpifrance State-guaranteed loan**	**Société Générale State-guaranteed loan**	**Société Générale State-guaranteed loan**	**Société Générale State-guaranteed loan**	**CIC State-guaranteed loan**	**Total**
At 31 December 2020	**1,008**	-	-	**91**	**161**	**896**	-	**2,155**
(+) Collection		200	200	-	-	-	395	795
(+/-) Accrued interest	6	**3**	-	-	1	5	4	20
At 31 December 2021	**1,015**	**203**	**200**	**91**	**162**	**900**	**399**	**2,970**

MATURITIES OF STATE-GUARANTEED LOANS, IN REPAYMENT VALUE (Amounts in thousands of euros)	**BNP Paribas State-guaranteed loan**		**Bpifrance State-guaranteed loan**	**Société Générale State-guaranteed loan**	**Société Générale State-guaranteed loan**	**Société Générale State-guaranteed loan**	**CIC State-guaranteed loan**	**Total**
At 31 December 2021	**1,014**	**203**	**200**	**91**	**162**	**900**	**398**	**2,970**
Share at less than one year	170	-	-	11	20	113	-	**314**
Share between one and five years	844	186	179	80	142	789	381	**2,600**
Share at more than five years	-	17	21	-	-	-	17	**55**

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 €1,000 thousand 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).

State-guaranteed loans

During 2020, the Group contracted four PGE to strengthen its cash position in the current context of the Covid-19 pandemic:

- State-guaranteed loan 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 État Coronavirus" guarantee fund of up to 90.00%. The company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 1%;
- State-guaranteed loan 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 État Coronavirus" guarantee fund of up to 90.00%. The company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 0.58%;
- State-guaranteed loan 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 État Coronavirus" guarantee fund of up to 90.00%. The company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 0.58%; and
- State-guaranteed loan 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 État Coronavirus" guarantee fund of up to 90.00%. The company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 0.58%.

The Company requested the amortisation of these loans over four years after an addition one-year delay, in accordance with the legislation.

During 2021, the Group contracted three PGE to strengthen its cash position in the current context of the Covid-19 pandemic:

- State-guaranteed loan taken out by Affluent Medical 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 État Coronavirus" guarantee fund of up to 90.00%;
- State-guaranteed loan taken out by Affluent Medical in the amount of €200 thousand with BNP Paribas, bearing no interest and repayable in arrears, after a deferral period of 12 months. This loan benefits from a State guarantee under the "FDG État Coronavirus" guarantee fund of up to 90.00%;
- State-guaranteed loan taken out by Affluent Medical in the amount of €200 thousand with Bpifrance, bearing interest at 2.35% and repayable in arrears, after a deferral period of 12 months. This loan benefits from a State guarantee under the "FDG État Coronavirus" guarantee fund of up to 90.00%.

The Company requested the amortisation of these loans over four years after an additional one-year delay, in accordance with the legislation.

Mivana project repayable 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 contract 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, CE/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 in 2024 (one payment);
- €800 thousand in 2025 (one payment);
- €1,100 thousand in 2026 (one payment);
- €1,350 thousand in 2027 (one payment).

Kephalios received a total of €1,712 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 in 2024 (one payment);
- €250 thousand in 2025 (one payment);
- €350 thousand in 2026 (one payment);
- €450 thousand in 2027 (one payment).

These contracts provide for additional payments detailed in section 20.2.1 of the Universal Registration Document.

As at 31 December 2021, based on revenue forecasts, the Company has made an estimate of the additional payments. The debt recognised in this respect amounted to €470 thousand for Kephalios and €1,447 thousand for Epygon as at 31 December 2021.

PIAVE Artus project repayable advance

On 21 July 2016, as part of the PIAVE Artus project, MyoPowers entered into a contract 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 €6,188 thousand in repayable advances and €117 thousand in subsidies in connection with this contract 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 (four instalments).

This contract provides for additional payments detailed in section 20.2.2 of the Universal Registration Document.

As at 31 December 2021, based on revenue forecasts, the Company has made an estimate of the additional payments. The debt recognised in this respect amounted to €886 thousand as at 31 December 2021.

8.1.5 Financing by the research tax credit

The Group benefits from the research tax credit in France. The research tax credit ("**RTC**") amounts to €1101 thousand in 2021, €380 thousand in 2020 and €1,087 thousand in 2019.

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 RTC receivables

As at 31 December 2019, a portion of the receivables related to the RTC 2018 and RTC 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 RTC;
- 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:

- RTC: €164 thousand;
- RTC: €505 thousand.

As at 31 December 2020 and 31 December 2021, the Company no longer had any pre-financed RTC receivables in its accounts.

8.2 Cash flows

The information below is taken from the consolidated financial statements at 31 December 2021 prepared in accordance with IFRS presented in Chapter 18 *Financial reporting on the Group's portfolio, financial position and results* of the Universal Registration Document. Cash flows at 31 December 2019 are derived from the consolidated financial statements prepared in accordance with IFRS for the financial years ended 31 December 2020 and 31 December 2019, presented in the Universal Registration Document approved by the AMF on 12 April 2021 under approval number I. 21-007.

Affluent Medical SA Summarised consolidated cash flow statement	Financial year 2021 IFRS	Financial year 2020 IFRS	Financial year 2019 IFRS

	€ thousands	€ thousands	€ thousands
Cash flows consumed by operating activities	**(12,364)**	**(8,936)**	**(11,412)**
Cash flows from investing activities	**(160)**	**(304)**	**(185)**
Cash flows from financing activities	**18,281**	**12,762**	**10,386**
Increase (Decrease) in cash	**5,757**	**3,522**	**(1,211)**
Opening cash and cash equivalents	5,648	2,126	3,336
Closing cash and cash equivalents	11,405	5,648	2,126

8.2.1 Cash flows consumed by operating activities

Cash consumption related to operating activities amounted to €12,364 thousand for the year ended 31 December 2021, €8,936 thousand for the year ended 31 December 2020 and €11,412 thousand for the year ended on 31 December 2019. This cash consumption is mainly related to the Group's medical device development activities in line with the stage of completion of clinical and pre-clinical studies.

8.2.2 Net cash flows from investing activities

Cash consumption from investing activities amounted to €160 thousand in 2021, €304 thousand in 2020 and €185 thousand in 2019. These relate mainly to acquisitions of tangible or intangible assets.

8.2.3 Net cash flows from financing activities

Cash flows from financing activities	Financial year 2021 IFRS € thousands	Financial year 2020 IFRS € thousands	Financial year 2019 IFRS € thousands
Capital increase net of capital increase costs	21,425	7,456	-
Collection of repayable advances	2,529	2,755	3,659
Bank borrowings	795	2,140	-
Issue of convertible and non-convertible bonds, net of fees	-	4,000	7,872
Redemption of non-convertible and convertible bonds	(5,164)	(1,952)	(516)
Gross financial interest paid	(521)	(715)	(775)
Other movements related to the pre-financing of the research tax credit	-	(711)	276
Repayment of lease liabilities	(283)	222	(184)
Other cash flows from financing activities (liquidity contract)	500	-	-
Share subscription warrants (BSA)	-	11	55
Cash flows from financing activities	**18,281**	**12,762**	**10,386**

In particular, in 2021 the Group completed:

- a capital increase concomitant with the Company's IPO for €21,425 thousand net of fees;
- the collection of repayable advances of €2,529 thousand (refer to section 8.1.4 of the Universal Registration Document);

- the collection of State-guaranteed loans for an amount of €795 thousand;
- the repayment of €3,000 thousand of the convertible bonds (2019 CB) issued to Head Leader Limited;
- the repayment of maturities for the Kreos Capital loan in the amount of €2,164 thousand;
- the payment of €500 thousand on a liquidity contract entrusted to Kepler Cheuvreux.

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 Universal 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 €4,000 thousand for the benefit of Head Leader Limited; and
- 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 Universal Registration Document);
- the issue of non-convertible bonds in the amount of €4,000 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 €4,000 thousand for the benefit of funds managed by Truffle Capital; and
- the repayment of maturities for the Kreos Capital loan in the amount of €516 thousand.

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 Universal 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 Universal Registration Document, that it would be able to finance its activities until the end of September 2022, in view of the cash balance at its disposal to date.

In order to finance its development and future investments, the Board of Directors continues to actively study various solutions to continue the financing of its activity and its development beyond its liquidity horizon. These solutions could, without being restrictive, involve private placements to investors, capital increases, setting up bonds and obtaining public financing.

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. (See chapter 18 Notes to the annual consolidated financial statements - Note 2)

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 European regulation applicable to medical devices is currently set by Regulation (EU) 2017/745 of 5 April 2017, which replaced Directive 93/42/EEC of 14 June 1993, for those devices dated from 26 May 2021.

It should be noted that for certain devices which obtained the CE marking before 26 May 2021, the Directive remains the applicable regulation until the expiry of their CE certificate, however there is an obligation to implement the provisions of Regulation (EU) 2017/745 such as "post-market surveillance".

According to the same logic, Directive 93/42/EEC remains applicable for clinical investigations authorised before 26 May 2021, applying the terms of Regulation (EU) 2017/745 concerning the management of "adverse events".

This Regulation, like the Directive before it, enacts the general principles regarding the design and manufacture of medical devices as well as the management of clinical investigations. It provides 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, which corresponds to the CE marking process. This certification is based on the manufacturer's responsibility only for the least risky devices, and also requires the obtaining of a CE certificate of conformity issued by a notified body which carries out a technical file review for class IIa, IIb and III devices.

These requirements will not be modified by the entry into force, on 26 May 2021, of the new Regulation (EU) 2017/745 of 5 April 2017, which repeals Directive 93/42/EEC, aims to roll out unified and strengthened European regulations, under the terms of 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;
- the addition of general requirements in terms of safety and performance of the devices.

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 for a period of five years on the basis of a file submitted for renewal and reviewed by the notified body.
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, certain operators involved in the distribution of devices must register with the competent authorities, and are likely to be subject to unexpected checks by national health agencies. Critical design and manufacturing subcontractors are also subject to the supervision of the notified body.
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 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) 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 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, US 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. 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 II medical devices benefit from a simplified procedure, known as 510 (k), considering that the device in question already has an equivalent on the American 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 (the "Substantial Equivalent with a predicate device" concept). To demonstrate substantial equivalence, the applicant must provide evidence that its device has the same intended use and is as safe and effective as a device already marketed (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.

US regulations also require the FDA to register the operators involved in the manufacture and marketing of medical devices on the US 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 US 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 arise from the Physician Payment Sunshine Act (the "**Sunshine Act**"), adopted in March 2010 as part of the US "The Patient Protection and Affordable Care" Law and implementation through various regulations adopted by the "US Centers for Medicare & Medicaid Services" (the body that sets the reimbursement terms 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 programmes.

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 2021, 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 Universal 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 Universal Registration Document, the Group is not yet generating revenue. Given the development cycle of its products, the Group plans to generate revenue in 2024 subject to obtaining the CE marking on its Kalios and Artus medical device 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 Universal 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 Universal Registration Document. Furthermore, the materialisation of certain risks described in Chapter 3 *Risk factors* of this Universal 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 Universal 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 Universal 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, Board members 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 Universal Registration Document, the Company is a French corporation (*société anonyme*) governed by prevailing laws and regulations and the Company's bylaws. 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 Universal Registration Document.

12.1.1 Composition of the Board of Directors and the Advisory Board

12.1.1.1 Changes in the composition of the Board of Directors in 2021

In 2021, the composition of the Board of Directors changed as follows:

Departures	• Substainable Development Partner International represented by Jean-François Le Bigot, Board member (Board of Directors meeting of 18 February 2021) • Jean-Michel Malbrancq, Board member (Board of Directors meeting of 18 February 2021) • Fate, represented by Benoit Adelus, Board member (Board of Directors meeting of 18 February 2021) • Christian Latrémouille, Board member (Board of Directors meeting of 8 April 2021) • Véronique Phé, Board member (Board of Directors meeting of 20 July 2021)
Co-options	• Claire Corot, Board member (Board of Directors meeting of 18 February 2021) • Ellen Roche, Board member (Board of Directors meeting of 18 February 2021) • Véronique Phé, Board member (Board of Directors meeting of 8 April 2021) • Soad El Ghazouani Achik, Board member (Board of Directors meeting of 7 December 2021)
Appointments	• None
Renewals	• Michel Finance, Board member (General Meeting of 6 April 2021) and Chairman of the Board of Directors (Board of Directors meeting of 6 April 2021) • Claire Corot, Board member (General Meeting of 6 April 2021) • Ellen Roche, Board member (General Meeting of 6 April 2021) • Christian Latrémouille, Board member (General Meeting of 6 April 2021) • Dominique Carouge, Board member (General Meeting of 6 April 2021)

	• Truffle Capital, represented by Philippe Pouletty, Board member (General Meeting of 6 April 2021) • Daniel Hayoz, Board member (General Meeting of 6 April 2021) • Patrick Coulombier, Board member (General Meeting of 6 April 2021)

The General Meeting of 6 April 2021 renewed the directorship of Mr Michel Finance, 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 Board members of the Company. The Board of Directors co-opted Ms Claire Corot as new Board member 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 Board members 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 Board member of the Company. The Board of Directors co-opted Ms Véronique Phé as new Board member, 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.

Following the resignation of Ms Véronique Phé, acknowledged by the Board of Directors on 20 July 2021, Ms Soad El Ghazouani Achik was co-opted, on 7 December 2021, as a new Board member as her replacement and for the remaining term of office of Ms Véronique Phé, *i.e.* until the end of the General Meeting called to approve the financial statements for the financial year ended 31 December 2023.

12.1.1.2 Composition of the Board of Directors

As at the date of approval of the Universal 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	No

First and last name, business address	Office	Independent	Date of appointment, renewal and term	Committee member
			approve the financial statements for the financial year ending 31 December 2023	
Truffle Capital, represented by Philippe Pouletty 5, rue de la Baume, 75008 Paris, France	Board member	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	Board member	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
Daniel Hayoz Fort St Jacques 139 1752 Villars sur Glane, Switzerland	Board member	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	Board member	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	Board member	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	Board member	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
Soad El Ghazouani Achik 320, avenue Archimède – Les Pléiades III – Bâtiment B – 13100 Aix-en-Provence, France	Board member	Yes	Co-option: 7 December 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

The term of directorship is three years and expires at the end of the Ordinary General Meeting held to approve the financial statements for the previous financial year. Board members may be re-elected without limitation. They can be dismissed at any time.

The Board members' management expertise and experience are the result of various salaried and management positions they have previously held (see section 12.1.5 of the Universal Registration Document).

At the date of approval of the Universal Registration Document, the Board of Directors had eight members, including three women. 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 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 age, gender or professional qualifications and experience.

As part of the co-optations that took place during the 2021 financial year, the Compensation and Governance Committee ensured compliance with the aforementioned diversity policy and therefore with the aforementioned criteria thus ensuring diversity in terms of professional experience and a complementarity of profiles within the Board of Directors.

At the date of approval of the Universal Registration Document, seven Board members are of French nationality and one Board member is of American nationality.

The independence of the Company's Board members is assessed in accordance with the criteria defined by recommendation R3 of the Middlenext Code, *i.e.* to be classified as independent, a Board member must not:

- 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 Board members (see section 19.1.4.1 of this Universal Registration Document) in no way affects their qualification as independent Board members within the meaning of the Corporate Governance Code for small- and mid-cap companies as amended in September 2021 by Middlenext, given: (i) the subscription price paid for said subscription warrants; and (ii) that the amounts at stake are insignificant for the Board members concerned.

At its meeting of 24 March 2022, the Board of Directors carried out the annual assessment of the independence of the Board members with regard to these criteria and, at the end of this review, considered that the following Board members should be qualified as independent: Ms Soad El Ghazouani Achik, Ms Ellen Roche and Mr Dominique Carouge.

12.1.1.3 Composition of the Advisory Board

As at the date of approval of the Universal Registration Document, the Company also had an Advisory Board of observers (whose appointment is specified in section 19.2.2.1 of the Universal 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	Appointment: 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
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 Mr Jean-François Le Bigot, and Fate, represented by Mr 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 Professor Christian Latrémouille's heart surgery experience with innovative prosthesis implants.

It is stipulated that:

- observers are not compensated in respect of their position. Moreover, all other compensation that they could receive would be for services performed;
- Substainable 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 subscription warrants (BSAs) (see section 19.1.4.1);
- Mr Christian Latrémouille is not a shareholder of the Company and holds 34,524 share subscription warrants (see section 19.1.4.1).

12.1.2 Executive Management

As at the date of approval of the Universal Registration Document, Executive Management is ensured by:

Name	Office	Main positions in the Company	Main positions outside the Company	Starting date and end of term of office
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 Executive Management of the Company has been ensured by a Chairman and Chief Executive Officer (Mr Michel Finance) since 20 May 2019.

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 Universal Registration Document, none of the Board members or executive corporate officers of the Company over the last five years:

- has been convicted of fraud;

- has been associated, in his or her capacity as an executive or Board member, 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).

12.1.4 Other corporate offices and functions held

Board members' other current corporate offices and functions held

As at the date of approval of the Universal Registration Document, the other current corporate offices and functions held by the Board members are:

First name, last name, function or position	Current corporate offices held as at the date of approval of the Universal Registration Document
Michel Finance Chairman and Chief Executive Officer and Board member	- 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 Board member	*As permanent representative of Truffle Capital:* - Director of Carbios SA (listed company) - Chairman of the Board of Directors of Diaccurate SA - Co-founder and director of Affluent Medical SA - Co-founder and director of Holistick Medical SASU - Co-founder and director of Deinove SA (Euronext Growth Paris) - Co-founder and director of Skinosive SAS - Co-founder and director of Artedrone SAS - Chairman of the Board of Directors of PK Med SAS - Co-founder and director of Bariatek SAS - Chairman of the Board of Directors of Caranx Medical SAS - Co-founder of Skinnate SAS - Co-founder and Chairman of SpikImm SAS *In a personal capacity:* - Chief Executive Officer and director of Truffle Capital SAS - Manager of Nakostech SARL - Founder and Chairman of the Board of Directors of Abivax SA (listed company) - Director of France Biotech (Association Loi 1901) *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 Board member	- Director of Shanghai MyoPowers Medical Technology Co. Ltd (a company registered in China) - Business consultant and other management consultancy (self-employed)
Daniel Hayoz Board member	- Head of the Next Generation and Research Department at the HFR-Cantonal Hospital of Fribourg - Professor at the Universities of Lausanne (UNIL) and Fribourg (UFR) in the Faculty of Medicine - Director of PKMed - Director of Bariatek
Dominique Carouge Independent Board member	- Chairman of Doreca Conseil SASU - Director of "Les Enfants de Sanofi" association - Director of Diaccurate SA
Claire Corot Board member	- Director of Holistick Medical - Senior Partner at Truffle Capital
Ellen Roche	- Director of Helios Cardiovascular

First name, last name, function or position	Current corporate offices held as at the date of approval of the Universal Registration Document
Independent Director	- Associate professor at the Massachusetts Institute of Technology
Soad El Ghazouani Achik Independent Director	- Chief Executive Officer and director of T-HEART

Other corporate offices and functions held by the Board members during the last five financial years and which have ended to date

As at the date of approval of the Universal Registration Document, the other corporate offices and functions held by the Board members 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 Board member	- Chief Executive Officer (until January 2019) and director (until May 2018) of Theradiag - Director of France Biotech (until December 2021)
Truffle Capital represented by Philippe Pouletty Board member	*As permanent representative of Truffle Capital:* - Member of the Management Committee of Deinobiotics SAS - Director of Vexim SA - Director of Plasmaprime SAS - Director of Neovacs SA (Euronext Growth Paris) - Member of the Management Committee of Kephalios - Member of the Management Committee of LudoPowers - Chairman of Nanosive SASU - Co-founder and director of Carmat SA (Euronext Growth Paris) - Co-founder and director of Pharnext SA (Euronext Growth Paris) - Director of Biokinesis SAS *On a personal basis:* - Member of the Supervisory Board of Innate Pharma SA (Euronext Growth Paris) - Chairman and director of Splicos SAS - Member of the Supervisory Board of Cytomics SA - Director of the Association Centre Chirurgical Marie Lannelongue (a non-profit association) - Honorary Chairman of France Biotech (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 Board member	- Chairman of Iollas Consulting (until January 2019) - Chairman of MyoPowers (Group company) (until May 2018) -
Daniel Hayoz Board member	- Head of the Department of Medicine and Head of Service for Medicine at the HFR-Cantonal Hospital Fribourg - Chairman of the Board of Directors of MyoPowers SA (Switzerland)
Dominique Carouge	- Director of APSA – Aventis Pharma SA - Director of Sanofi North America

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
Independent Board member	- Director of Sanofi Europe - Director of Aventis France - Director of Sanofi Pasteur Mérieux - Director of Sanofi Espoir - Director of SETC (Belgium)
Claire Corot Board member	Head of Research, Innovation and Business Development of Guerbet
Ellen Roche Independent Director	- None.
Soad El Ghazouani Achik Independent Director	- None.

12.1.5 Biographies of Board members, 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 this Universal Registration Document.

- **Dr Philippe Pouletty (representative of Truffle Capital), Board member**

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-President 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: Board member**

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 Director 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: Board member**

Dr Daniel Hayoz is Head of the Department of Medicine and Head of Service for Medicine at 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 Operating Partner at Truffle Capital

- **Mr Dominique Carouge: independent Board member**

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: Board member**

Over the last 30 years, Ms Claire Corot, Senior Partner at Truffle Capital since 2021, 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 Board member**

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.

- **Ms Soad El Ghazouani Achik: independent Board member**

Ms Soad El Ghazouani Achik has more than 25 years of experience in the field of medical devices.
She is currently Chief Executive Officer and co-founder of T-heart, a venture-funded start-up company developing a tricuspid valve replacement by catheter system.
She previously held the position of Chief Executive Officer of Novostia.
Before that, Ms Soad El Ghazouani Achik held several management positions, including Vice-President of Global Marketing at Biosensors, Managing Director of Bioring and Vice-President for the Europe region at Ev3.Ms Soad El Ghazouani Achik has also held several operational management positions for Medtronic, Boston Scientific, Meadox and Hitachi.
She holds an MBA in international business from EM Lyon business school and a biomedical engineering degree.

- **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 for the United States and Latin America regions. 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.

- **Dr Christian Latrémouille: observer**

Dr Christian Latrémouille is a doctor of medicine, specialised in cardiac surgery, and is a university professor at the University of Paris. Dr 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 pre-clinical 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, Dr 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 Universal 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 Universal Registration Document.

To the Company's knowledge, and subject to the agreements between related parties described in Chapter 17 of this Universal 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 of this Universal Registration Document.

The internal regulations of the Company's Board of Directors, applicable since the admission of the Company's shares to trading on the regulated market of Euronext Paris, provides for a procedure for informing and preventing existing or potential conflicts of interest. Accordingly, as from that date, each Board member must (i) inform the Board of Directors, as soon as he or she 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.

Furthermore, to the Company's knowledge, beside the dilutive instruments referred to in section 19.1.4.4 of this Universal 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 Board members or executives referred to in section 12.1 of this Universal 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, at its meeting of 18 February 2020, the Board of Directors set up a procedure for evaluating agreements relating to ordinary 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.

The Audit Committee reported on the implementation of the procedure to the Board of Directors at its meeting of 24 March 2022. The report presented confirmed the normal nature and the current conditions of the agreements entered into by the Company which were examined.

13 COMPENSATION AND BENEFITS

13.1 Compensation of corporate officers

13.1.1 Compensation policy for corporate officers

It is presented below, in accordance with Article L. 22-10-8 of the French Commercial Code, the compensation policy for executive and non-executive corporate officers subject to shareholder approval.

13.1.1.1 General principles concerning 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 Universal Registration Document.

No component 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 submitted for approval by the General Meeting of 24 May 2022 or, in the absence of such approval, to the compensation policy approved by the General Meeting of 6 April 2021.

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 refers:

- **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 Board members 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.

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 15 February 2022 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 the payment of any variable and exceptional compensation of the executive corporate officers may only be made subject to the approval of the shareholders pursuant to Article L. 22-10-34 of the French Commercial Code.

Fixed annual compensation

Chairman and Chief Executive Officer

On the recommendation of the Compensation and Governance Committee and after deliberation of the Board of Directors on 15 February 2022, the annual fixed compensation of the Chief Executive Officer is between €250,000 and €350,000.

In addition, in the event of the appointment of one or several new Chief Executive Officers or Deputy CEO, 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 executive corporate 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.

It is specified that the payment of any variable compensation of executive corporate officers may only be made subject to approval by the General Meeting pursuant to Article L. 22-10-34 of the French Commercial Code.

Chairman and Chief Executive Officer

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 the Chief Executive Officer is subject to performance criteria, the target 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 7 February 2022 and approved by the Board of Directors on 15 February 2022).

For each quantitative criterion, the Board of Directors defines a quantified target.
A formula is used to calculate the amount of the variable portion due by taking into account the level actually achieved in relation to the target.

For each qualitative criterion, the Board of Directors defines a target event to characterise the achievement of the objective.

The achievement of this target will allow for 100% of the variable compensation due in this respect to be obtained. Since the targets determined by the Board of Administrators for each objective were particularly demanding, in the case of performance which exceeds the objective set, the value of the variable part acquired cannot exceed 100%.

In the event of performance which is below the target fixed for each objective, the corresponding variable part is calculated on a straight line basis depending on the rate at which the objective was obtained.

Performance is assessed without compensation between the criteria.

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 criteria are based on operational plans and clinical trials (relating to the progress of the clinical development of the Company's medical devices), presented below:

Criteria	Objectives	Definitions	Weighting
Quantitative criteria	Operational objectives	Management of the Company's financing	30%

	Clinical objectives	Clinical development of the Company's medical devices, in accordance with the action plan and general schedule for each project	40%
Qualitative criteria	Operational objectives	Implementation of the Group's medium- and long-term strategy	30%
TOTAL			100%

For reasons of confidentiality related to the Group's activity, strategy and objectives, the level of achievement required (target) for the quantitative criteria as well as the detail of the qualitative criteria, although pre-established in a precise manner, cannot be made public.

These criteria are always assessed taking into account performance at Group level.

Given the demanding nature of the criteria adopted by the Board of Directors, their achievement rate was 50% for the 2020 financial year and 57.14% for the 2021 financial year.

There is no provision for repayment of part of the annual variable compensation.

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, the Chairman of the Board of Directors may receive conditional compensation paid in the form of stock options, share subscriptions or warrants. However, the total number of shares that may be subscribed to under stock options, share subscriptions or warrants during a financial year may not represent more than 2% of the Company's share capital (undiluted) on the day of their allocation.

Allocations of securities giving access to the share capital subject to financial and non-financial performance conditions may be made to the Chief Executive Officer. However, the total number of shares that the securities giving access to the share capital, allocated during a financial year, may not represent more than 3% of the Company's share capital (undiluted) on the date of their allocation.

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 Board member

The Chairman and Chief Executive Officer does not receive any compensation in his capacity as Board member. In the event of separation of the functions of Chairman and Chief Executive Officer, the Board of Directors may, where appropriate, at its discretion, grant compensation to executive corporate officers in office or appointed during the year in respect of their directorship.

Compensatory payments and benefits due as a result of termination of executive corporate officers

Neither the Chairman of the Board of Directors nor the Chief Executive Officer receives any compensation linked to a forced departure or a non-compete clause.

Benefits in kind

The Chief Executive Officer may have a company car. In the event of separation of the functions of Chairman and Chief Executive Officer, the Chairman of the Board of Directors may receive benefits in kind, upon decision of the Board of Directors, and in particular a company car.

Supplementary pension plan

Neither the Chairman of the Board of Directors nor the Chief Executive Officer has a supplementary pension plan.

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.

The directorships' terms are set out in section 12.1.1 of the Universal 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 Board members is distributed and paid in accordance with the Board of Directors' internal regulations. This breakdown takes into account participation in the work of the Board of Directors 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 Board members at €120,000, until decided otherwise.

Other benefits

Non-executive corporate officers may be repaid for expenses incurred while performing their duties.

They may also receive exceptional compensation for a one-off or special assignments.

13.1.2 Term of office of executive corporate officers – Employment contract for corporate officers

The term of office of the various corporate officers is indicated in Chapter 12 of this Universal Registration Document.

The Company entered into an employment contract with Mr Daniel Hayoz, Board member 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.

No other corporate officer has an employment contract with the Company.

The conditions for dismissal of corporate officers are those defined by law and the bylaws, which can be accessed on the Company's website.

13.2 Components of compensation and benefits of any kind paid or allocated in respect of financial year 2021 to corporate officers

13.2.1 Compensation and benefits paid to executive corporate officers of the Company

In accordance with Article L. 22-10-34 of the French Commercial Code, the General Meeting called to approve the financial statements for the year ended 31 December 2021, will approve the fixed, variable and exceptional components of the total compensation and benefits of any kind paid or allocated to the Chairman and Chief Executive Officer in respect of the 2021 financial year. The General Meeting must explicitly approve the payment of variable or exceptional compensation.

It will be proposed to the Ordinary General Meeting called to approve the financial statements for the year ended 31 December. 2021 to approve the components of compensation paid or awarded in respect of the 2021 financial year to the Chairman and Chief Executive Officer, as set out below, it being recalled that he exercises his duties as Chairman of the Board of Directors without charge.

In respect of the 2021 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 €50,000 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 for a total amount of €11,497. He did not receive any compensation in respect of his office as Chairman of the Board of Directors.

13.2.1.1 The tables below present compensation and benefits of any kind paid to executive corporate officers by the Company or by any Group company during the financial years ended 31 December 2020 and 31 December 2021.

The tables below 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 2020	Financial year 2021
Mr Michel Finance – Chairman and Chief Executive Officer		
Compensation due in respect of the financial year (*for details see table 2)*	305,185	311,497
Value of multi-year variable compensation paid 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)*	180,978	356,248*
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	486,163	705,245

**Valuation of the 272,500 founders' warrants granted to Mr Michel Finance for the 2021 financial year, of which 20% are exercisable subject to a condition of presence over 48 months, i.e. until 2025, and 80% are subject to performance conditions to be met in 2022 and 2023, which cannot be detailed for reasons of confidentiality related to the Group's activities, strategy and objectives.*

It is also specified that 338,175 BSPCEs granted to Mr Michel Finance in respect of previous financial years were recognised as null and void and can no longer be exercised.

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 2020 and 2021 and the compensation received by the same people during the same financial years.

In euros	Financial year 2020		Financial year 2021	
	Amounts allocated(1)	Amounts paid(2)	Amounts allocated(1)	Amounts paid(2)
Mr Michel Finance – Chairman and Chief Executive Officer				
Fixed compensation	250,000	250,000	250,000	250,000
Annual variable compensation	43,750	35,553	50,000**	43,750
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***	11,435	11,435	11,497	11,497
Total	**305,185**	**296,988**	**311,497**	**305,247**

(1) in respect of the financial year (2) during the financial year

***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 2021 financial year was proposed by the Compensation and Governance Committee 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 2021 financial year were set by the Board of Directors on 18 February 2021. They included operational and clinical objectives. These objectives were estimated at 57.14% by the Compensation and Governance Committee at its meeting of 7 February 2022. On the proposal of the Compensation and Governance Committee, the Board of Directors of the Company, on 15 February 2022, awarded Mr Michel Finance gross variable compensation in the amount of €50,000 for 2021. This variable compensation will be paid in one instalment subject to its approval by the General Meeting called to approve the financial statements of 31 December 2021.*

****Benefits in kind correspond to a company car.*

Table 4: Share subscription or purchase options granted to each executive corporate officer by the Company or any Group company during the 2021 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 2021-6 20 September 2021	BSPCE	€356,248	272,500	€6	19 September 2031

Table 5: Share subscription or purchase options exercised during the 2020 financial year by each executive corporate officer

None.

Table 6: Bonus shares granted to each corporate officer during the 2020 financial year

None.

Table 7: Bonus shares granted and made available to each executive corporate officer during the 2020 financial year

None.

Table 8: History of share subscription or purchase options

Share subscription warrants

Please refer to the tables in section 19.1.4.1 “Share subscription warrants” of the Universal Registration Document.

Company founders’ share warrants plan

Please refer to the tables in section 19.1.4.2 “Company founders' share warrants plan” of the Universal Registration Document.

Table 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 2021-1	BSPCE 2021-2	BSPCE 2021-3	BSPCE 2021-4	BSPCE 2021-6
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)	20 July 2021	€6.93	125,000	30,000	70,000	250,000	
	20 September 2021	€6.00					204,000
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 10: Summary of bonus share awards

None.

Table 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		Supplementary 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							

13.2.1.2 Fixed, variable and exceptional components of the total compensation and benefits of any kind paid during or awarded in respect of the past financial year to Michel Finance, Chairman and Chief Executive Officer

Fixed compensation for the 2021 financial year: **€250,000**
This compensation was not increased compared to that of the 2020 financial year.

Variable compensation for the 2021 financial year: €50,000
The variable compensation of Mr Michel Finance for the 2021 financial year could reach up to €87,500, *i.e.* 35% of his annual fixed compensation.

The variable compensation of Mr Michel Finance was based on three operational and clinical objectives (two quantitative and one qualitative, shown in the table below).

For each quantitative criterion, the Board of Directors had defined a quantified target.
A formula is used to calculate the amount of the variable portion due by taking into account the level actually achieved in relation to the target. In the event of a performance exceeding the target set, the value of the variable portion is adjusted upwards within the limit of a maximum set for each target.

For each qualitative criterion, the Board of Directors had defined a target event to characterise the achievement of the objective.

The achievement of this target will allow for 100% of the variable compensation due in this respect to be obtained. Since the targets determined by the Board of Administrators for each objective were particularly demanding, in the case of performance which exceeds the objective set, the value of the variable part acquired cannot exceed 100%.

In the event of performance which is below the target fixed for each objective, the corresponding variable part is calculated on a straight line basis depending on the rate at which the objective was obtained.

Performance is assessed without compensation between the criteria.

As performance was not met for all objectives, the Board of Directors set the achievement rate of the variable portion at 57.14% for the 2021 financial year, i.e. €50,000. The findings of the Board of Directors are summarised in the table below.

Criteria	Objectives	Definitions	Weighting	Attainment rate	% of the variable portion acquired
Quantitative criteria	Operational objectives	Admission of the Company's shares to trading on the Euronext Paris regulated market	45%	75%	33.75%
	Clinical objectives	Progress of the clinical development of the Company's medical devices, in accordance with the action plan and the general schedule of each project	50%	36.79%	18.39%
Qualitative criteria	Operational objectives	Effective management of the Group and partnerships abroad	5%	100%	5%
Total			100%		57.14%

For the 2020 financial year, the rate of achievement of the objectives attached to the variable portion of the compensation of Mr Michel Finance, approved by the Board of Directors, was 50%.

Grant of share subscription or purchase options
Mr Michel Finance was not granted any share subscription or purchase options with respect to the 2021 financial year.

Allocation of bonus shares
Mr Michel Finance was not granted any bonus shares in respect of financial year 2021.

Commitments corresponding to elements of compensation, indemnities or benefits due or likely to be due as a result of the assumption of office or termination of office
The Company has made no commitment corresponding to elements of compensation, indemnities or benefits due or likely to be due as a result of the assumption, termination or change of duties of Mr Michel Finance or subsequent to the exercise of these, in particular retirement commitments and other lifetime benefits.

Benefits in kind
Mr Michel Finance benefited from a company car representing benefits in kind in the amount of €11,497 with respect to the 2021 financial year.

Compensation paid or allocated by a company included in the Company's scope of consolidation
No compensation was paid or allocated to Mr Michel Finance by a company included in the scope of consolidation of the Company within the meaning of Article L. 233-16 of the French Commercial Code.

Compensation as Board member
Mr Michel Finance did not receive any compensation as a Board member of the Company for the 2021 financial year.

Compensation ratios

Ratio between the level of compensation paid to Mr Michel Finance and (i) that of the average compensation on a full-time equivalent basis of permanent and fixed-term employees, present during the financial year, of Affluent Medical and its subsidiaries in France, other than corporate officers, and (ii) the median compensation on a full-time equivalent basis of permanent and fixed-term employees, present for the duration of the financial year, of Affluent Medical and its subsidiaries in France, other than corporate officers, and (iii) the French minimum wage (SMIC):

Table of ratios for I. Paragraph 6 and 7 of Article L. 22-10-9 of the French Commercial Code				
	Financial year 2018	Financial year 2019	Financial year 2020	Financial year 2021
Change (in %) of the Chief Executive Officer's compensation[(1)]	N/A	5.91%	16.16%	2.78%
Change (in %) in the compensation of the Chairman of the Board of Directors	N/A	33.33%	n/a[(3)]	n/a[(3)]
Change (in %) of the average compensation of employees[(2)]	N/A	-9.80%	16.71%	5.73%
Ratio of the Chief Executive Officer's compensation to the average compensation of employees	N/A	628.10%	625.13%	607.67%
Change in the ratio (in %) compared to the previous financial year	N/A	17.42%	-0.47%	-2.79%
Change (in %) of the median compensation of employees[(2)]	N/A	20.15%	3.95%	-0.33%
Ratio of the Chief Executive Officer's compensation to the median compensation of employees	N/A	674.30%	753.45%	776.97%
Change in the ratio (in %) compared to the previous financial year	N/A	-11.85%	11.74%	3.12%
Change (in %) of the minimum wage	1.23%	1.52%	1.20%	1.55%
Ratio of the Chief Executive Officer's compensation to the French minimum wage	N/A	1,400.61%	1,607.68%	1,627.08%
Change in the ratio (in %) compared to the previous financial year	N/A	4.33%	14.78%	1.21%
Company performance				
Change in consolidated revenue	N/A	0	0	0
Change in consolidated net income	N/A	47.48%	-13.68%	3.5%

(1) The Chief Executive Officer's compensation includes the fixed amount paid in year N, the variable portion for year N-1 paid in year N, and the IFRS value of the BSPCE allocation granted in year N in respect of the long-term compensation and benefits in kind.
(2) The employees taken into account in the calculation of the ratio are those of Affluent Medical companies and its subsidiaries in France, *i.e.* the most representative scope of the Group's workforce in France. The compensation of these employees includes the fixed and variable amounts, the valuation (fair value) of the BSPCEs and bonus shares granted and the benefits in kind.
(3) Since 14 May 2020, the functions of Chairman of the Board of Directors and Chief Executive Officer are no longer separated and are held by Mr Michel Finance, who receives no compensation for his duties as Chairman of the Board of Directors.

13.2.2 Compensation and benefits paid to the Company's other corporate officers

Table 3: Table of compensation for directorships and other compensation received by non-executive corporate officers

The following table shows the compensation received by the Company's non-executive corporate officers during the 2020 and 2021 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 2020 financial year	Amounts paid during the 2020 financial year	Amounts allocated in respect of the 2021 financial year	Amounts paid during the 2021 financial year***
Michel Finance				
Board members' compensation	0	0	0	0
Other compensation (including allocation of BSPCEs)	486,163	477,966	705,245	661,495
Truffle Capital represented by Philippe Pouletty				
Board members' compensation	0	0	0	0
Other compensation	0	0	0	0
Patrick Coulombier				
Board members' compensation	10,750	10,750	12,750	0
Other compensation	0	0	0	0
Daniel Hayoz				

Board members' compensation	10,750	10,750	10,500	0
Other compensation***	3,000	3,000	3,000	0
Dominique Carouge				
Board members' compensation	2,500	2,500	17,250	0
Other compensation	0	0	0	0
Christian Latrémouille*				
Board members' compensation	7,750	7,750	10,500	0
Other compensation	0	0	0	0
Fate represented by Benoit Adelus*				
Board members' compensation	0	0	0	0
Other compensation	0	0	0	0
Substainable Development Partner International represented by Jean-François Le Bigot*				
Board members' compensation	0	0	0	0
Other compensation	0	0	0	0
Jean-Michel Malbrancq*				
Board members' compensation	8,750	8,750	0	2,250
Other compensation	0	0	0	0
Vincent Gardès*				
Board members' compensation	3,500	3,500	0	0
Other compensation	0	0	0	0
Reinhard Ambros*				
Board members' compensation	0	0	0	0
Other compensation	0	0	0	0
José Da Gloria*				
Board members' compensation	4,250	4,250	0	0
Other compensation	2,875	2,875	0	0
Thierry Herbreteau*				
Board members' compensation	2,250	2,250	0	0
Other compensation	0	0	0	0

Total	**528,969**	**521,070**	**756,245**	**663,745**

*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 Board members of the Company as at the date of approval of the Universal 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 2020 and 2021 financial years.

*** Board members 'compensation for the 2021 financial year was paid on 18 February 2022. As a result, no compensation for Board members in respect of their duties was paid during the financial year ended 31 December 2021.

**** Corresponds to the compensation received by Mr Daniel Hayoz under the terms of his employment contract (€3,000 per year) (see 13.1.2).

In 2020 and 2021, the compensation of each Board member 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 Board member, and his/her physical presence or attendance *via* videoconferencing. Other compensation corresponds to various assignments carried out (see section 17.2 of the Universal Registration Document) or to participation in the Audit Committee or the Compensation and Governance Committee.

13.3 Sums provisioned or otherwise recognised by the Company for the purposes of payment of pensions, retirement income or other benefits to Board members 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 OPERATING PROCEDURES OF CORPORATE GOVERNANCE 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 Universal 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 stated in the Middlenext Corporate Governance Code, to which the Company refers, the law does not favour any formula and it is for the Company's Board of Directors to choose between the two methods of exercising the executive management of the Company according to 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 shall exercise his/her powers within the scope of the Company's corporate purpose, subject to the powers expressly attributed by law 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.

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 interest, 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, Board

members 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 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. 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 Board member receives all the information required to perform his/her duties and may ask for all documents that he/she deems useful.

14.1.4 Term of office expiry date

Refer to section 12.1.1 of the Universal Registration Document.

In addition, it is specified that the General Meeting of 24 May 2022 will be asked to set the age limit for the Chairman of the Board of Directors at 85 years, in order to ensure consistency with the age limit of Board members and the continuation of the current term of office of the Chairman and Chief Executive Officer.

14.1.5 Conditions for the preparation and organisation of the work of the Board of Directors

General rules

The Board of Directors has internal regulations updated on 18 February 2021 which specify in particular:

- the role and responsibilities of the Board of Directors;
- the rules governing the composition of the Board of Directors and the rules for classifying its members as independent;
- the nature of the duties of the Board members and the rules of ethics to which they are subject;
- the Board of Directors' operating procedures and the rules for determining the compensation of its members.

Board member information

The members of the Board of Directors concluded that they received sufficient information to perform their duties. The Board members receive information and documents relating to the topics on the agenda

of the Board of Directors' meetings several days before the date of the meeting. They have the opportunity to prepare the topics that will be discussed at the meeting. Particularly sensitive and urgent subjects may be discussed without prior distribution of documents or with prior notification of the date of the meeting.

In addition, the Chairman responds to members' requests for additional information and the Board members are also regularly informed between meetings when the Company's news so warrants.

Notice of meeting

The notice period for meetings of the Board of Directors is at least five (5) days on first notice and two (2) days on second notice, with the exception, in both cases, where all the Board members are present (if necessary by videoconference or telecommunication) or represented. It meets as often as the interests of the Company require and at least four (4) times per year. A schedule of meetings is established at the beginning of the financial year according to the timing of the activity and the closing of the accounts, while exceptional meetings may be convened at any time according to the Group's current situation.

Notices of meetings including the agenda are sent before each meeting, and the documents necessary for their preparation are sent separately to the Board members.

Representation of Board members

The Board of Directors may validly deliberate only if at least half of its members are present. In the event of a tie, the Chairman of the meeting does not have the casting vote.

Board guests

The Group Chief Financial Officer attends all meetings of the Board of Directors and all discussions.

Meetings and work of the Board of Directors and average attendance rate

The functioning of the Board of Directors (notice of meetings, quorum, information for Board members) complies with the legal and statutory provisions of the Company. The Board of Directors meets at least four times a year.

The frequency of the Board of Directors 'meetings depends on the financial and legal calendar (communication of half-year and annual results) and on any current issues.

During 2021, the Board of Directors met 14 times. The Company's Statutory Auditors were convened and attended the majority of the meetings of the Board of Directors, in particular those relating to the closing of the annual and half-year financial statements.

The Group Chief Financial Officer took part in these meetings, in particular to present the financial statements and collect all authorisations and provide all explanations enabling the Board of Directors to make informed decisions.

The internal regulations of the Board of Directors updated on 18 February 2021 allow Board members to participate remotely in Board meetings: Board members who attend the meeting of the Board of Directors by videoconference or telecommunication are deemed present for the purposes of calculating the quorum and majority, providing that the means used allows for their identification and effective participation in accordance with the legal and regulatory provisions.

The minutes of the Board of Directors' deliberations are drawn up at the end of each meeting and submitted for approval to all Board members.

The Board of Directors' activities in 2021 focused on the following topics:

- Monitoring of the Group's day-to-day management:
- the review of the annual and half-yearly parent company and consolidated financial statements in the presence of the Statutory Auditors,
- the regular review of the Group's financial position, and more specifically its financing and external growth strategy,
- the preparation of the Annual General Meeting (agenda, draft resolutions, annual management report and other reports or sections included in the annual financial report issued by or approved by the Board of Directors);

- Preparation of the IPO.

Average attendance rate of Board members in 2021:

Michel Finance	Chairman and Chief Executive Officer	100%
Philippe Pouletty	Board member	100%
Patrick Coulombier	Board member	100%
Daniel Hayoz	Board member	100%
Dominique Carouge	Independent Board member	100%
Claire Corot	Director	100%
Ellen Roche	Independent Director	64%
Soad El Ghazouani Achik(1)	Independent Director	0%
Véronique Phé(2)	Independent Director	13%
Jean-François Le Bigot – representative of Substainable Development Partner International(3)	Observer	93%
Benoit Adelus – Fate representative(3)	Observer	57%
Christian Latrémouille(4)	Observer	86%
Total		85%

(1) In office from 7 December 2021. Attendance rate calculated based on one meeting from that date to 31 December 2021, compared to a total of 14 meetings during the financial year.
(2) In office from 8 April to 20 July 2021. Attendance rate calculated based on eight meetings during this period, compared to a total of 14 meetings during the financial year.
(3) In office since 6 April 2021. Attendance rate calculated based on 11 meetings from that date to 31 December 2021, compared to a total of 14 meetings during the financial year.
(4) In office since 8 April 2021. Attendance rate calculated based on 11 meetings from that date to 31 December 2021, compared to a total of 14 meetings during the financial year.

Assessment of the work of the Board of Directors

The Board of Directors assesses its ability to meet the expectations of the shareholders who have entrusted it with the management of the Company, by periodically reviewing its composition, organisation and functioning (which also involves a review of the Board of Directors' committees, and in particular the Audit Committee).

The Board of Directors considers the desirable balance of its composition and that of its committees and periodically examines the appropriateness of its organisation and functioning.

The evaluation has three objectives:

- review the operating procedures of the Board of Directors;
- check that important topics are properly prepared and discussed;
- assess the actual contribution of each Board member to the work of the Board of Directors.

The assessment is carried out according to the following methods:

- once a year, after preparation by the Compensation and Appointments Committee, the Board of Directors discusses its operation;
- shareholders are informed each year in the corporate governance report of the performance of the assessments and, where applicable, any follow-up given.

At its meeting of 24 March 2022, the Board of Directors discussed its functioning and that of its committees during the past year. This assessment concluded that Board members were generally satisfied with its functioning and that of its Committees, as well as its relationship with Executive Management, and the skills of each member. The Board of Directors also decided on areas for improvement for the current year, notably concerning the monitoring of the executive succession plan as well as CSR.

14.2 Service agreements between Board members and the Company or its Subsidiary

To the best of the Company's knowledge, there are no service agreements binding the members of the Board of Directors or executive corporate officers of the Company to the Company or to any of its subsidiaries providing for the granting of benefits at the end of such an agreement.

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 by the same Board of Directors and amended by the Board of Directors on 18 February 2021.

In addition, on 24 March 2022, the Board of Directors decided, in accordance with recommendation R8 of the Middlenext Code and given its size, to convene the Board of Directors in the form of a CSR Committee instead of the creation of a specialist CSR Committee.

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 Chairman of the Audit Committee 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 Universal Registration Document, the members of the Audit Committee are:

- Mr Dominique Carouge (Chairman);
- Ms Claire Corot.

14.3.1.2 Missions – Duties

The Audit Committee monitors matters relating to the preparation and control of accounting and financial reporting 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 of Directors' powers, the Audit Committee is tasked in particular with:

(i) monitoring:
- the process for preparing financial reporting 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 of Directors thereon.

14.3.1.3 Operating methods

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.

The Audit Committee met four times in 2021, with an attendance rate of 100%, and dealt in particular with the following points:

- approval of the financial statements and the adjustment to IFRS standards of Affluent Medical;
- review of expenses incurred during the financial year;
- review of budget items and re-estimation exercises budget;
- review of cash flow and financing requirements.

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 Board members.

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 Universal 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 Missions – Duties

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, operating directors 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 retirement 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 Board member 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 Operation

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.

The Compensation and Governance Committee met three times in 2021, with an attendance rate of 100%, and dealt with all subjects related to its mission, and in particular:

- the co-option and renewal of Board members;
- the independence of the Board members;
- the compensation and compensation policies of the Chairman and Chief Executive Officer and the Board members;
- the compensation of the members of the Executive Committee.

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 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 Board members are invited. They have the same right to information as the Board members.

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, 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 Universal Registration Document, four observers were appointed (refer to section 12.1.2 of the Universal Registration Document).

14.5 Statement related to corporate governance

14.5.1 Corporate Governance Code

As part of its development, the Company has undertaken an overall 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 with the Middlenext Corporate Governance Code for listed companies, as amended in September 2021 (insofar as the principles it contains are compatible with the organisation, size, resources and shareholding structure of the Company).

The Board of Directors took note of all the recommendations of the said Code and the items presented in the "Points of vigilance" sections.

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	Applied	Not applied
R1. Board member ethics	X	--
R2. Conflicts of interest	X	--
R3. Composition of the Board – Presence of independent Board members	X	--
R4. Board member information	X	--
R5. Training of Board members(1)		X
R6. Organisation of the Board and committee meetings	X	--
R7. Establishment of committees(2)		X
R8: Establishment of a specialist Corporate Social Responsibility (CSR) committee(3)		X
R9. Introduction of Board internal regulations(4)	X	--
R10. Selection of each Board member	X	--
R11. Term of directorships	X	--
R12. Compensation of Board members	X	--
R13. Establishment of an assessment of the Board's work	X	
R14. Relations with "shareholders"	X	--
R15. Diversity and equity policy within the Company	X	
R16. Definition and transparency of executive corporate officers' compensation	X	--
R17. Preparation for executives' succession	X	
R18. Concurrent corporate offices and employment contracts	X	--
R19. Severance benefits	X	--
R20. Supplementary retirement plans	X	--
R21. Stock options and allocation of bonus share	X	--
R22. Review of the items for monitoring	X	--

(1) As at the date of this report, no training plan for Board members has been put in place by the Board of Directors. This provides for a review during

the financial year 2022 to assess the advisability of complying with this recommendation.

(2) In view of the update of the Middlenext Code in September 2021 and the strengthening of this recommendation which now provides that the Appointments and/or Compensation Committee is chaired by an independent member, the Company complies with this recommendation except for the chairmanship of the Compensation and Governance Committee, which is chaired by Mr Philippe Pouletty. Although he is not an independent Board member of the Company, given his experience in the same function in several listed companies as well as his in-depth knowledge of the management of biotechnology companies and the issues specific to this sector, his appointment to the position of Chairman of the Compensation and Governance Committee is adapted for the Company.

(3) As at the date of this report, the Board of Directors has not set up a specialist CSR committee. The option of a Board of Directors meeting to form a CSR Committee was favoured.

(4) The internal regulations of the Board of Directors may be consulted at the Company's registered office and on its website.

14.5.2 Succession plan for executive corporate officers

Each year, the Board of Directors reviews the succession plan put in place for the Chairman and Chief Executive Officer, on the recommendations of the Compensation and Governance Committee, in the more or less long term, and in the event of a crisis situation.

14.5.3 Dialogue between executives and shareholders

At the end of the General Meeting, the Board of Directors reviews the results of the votes. It pays particular attention to negative votes by analysing, among other things, how the majority of non-controlling shareholders were expressed. The Board of Directors questions the advisability of changing, in view of the next General Meeting, what may have elicited negative votes and the possibility of a communication on this subject.

14.5.4 Gender balance and equity policy

During its meeting of 24 March 2022, the Board of Directors ensured the existence of a policy aimed at gender balance and equity within the Company and its implementation at every hierarchical level of the company.

To this end, the Human Resources Department was asked to issue its conclusions on said policy, which is described below:

The Group works in favour of diversity and ensures that it does not discriminate on any grounds whatsoever and ensures equal opportunities for all in terms of recruitment, training, compensation, assignment and professional development, according to personal skills and aptitudes. The Group also ensures that all its employees are treated fairly at each hierarchical level.

This is because it believes that respect for these values enables employees to be more professionally and personally fulfilled and more involved when the Group is committed to inclusion, diversity and equality.

It is therefore essential for the Group to create an environment where difference is encouraged and where employees can each make a contribution to the Company's dynamics.

Any employee who experiences or witnesses behaviour that goes against the values of diversity or fairness advocated by the Group is expected to report it to the competent authorised person, who is generally his or her line manager or the Human Resources Director.

The Group can already see that this policy produces better productivity, higher levels of innovation and better decision-making.

The Board of Directors has agreed to review the results of this policy at the end of the current financial year.

14.6 Information on internal control and risk management procedures

14.6.1 Objectives of the Company in terms of internal control and risk management procedures

The purpose of the Company's internal control procedures is to:

- To ensure that the acts of management or execution of operations, as well as the behaviour of staff, fall within the framework defined by the guidelines given for the Company's activities by the corporate bodies, by the applicable laws and regulations, and by the Company's internal values, standards and rules;
- To verify that the accounting, financial and management information communicated to the Company's governing bodies fairly reflects the activity and situation of the Company and its subsidiaries.

One of the objectives of internal control is to prevent and control the risks resulting from the activity of the Company and its subsidiaries and the risks of error or fraud, in particular in the accounting and financial areas (operational risks, financial, compliance or other).

Like any control system, however, it cannot provide an absolute guarantee that these risks are completely eliminated.

14.6.2 Summary description of the procedures implemented

The purpose of internal control is therefore to:

- Ensure that management actions and operations as well as staff behaviour are in line with the guidelines given by the Board of Directors,
- Ensure that operations comply with applicable laws and regulations,
- Prevent and control the risks inherent in the Company's activity as well as the risks of error or fraud, particularly in the accounting and financial fields.

To this end, a summary description of the procedures implemented within our Company is set out below:

14.6.2.1 General organisation of internal control and risk management procedures at Company level

- **Responsibilities**

It is the responsibility of Executive Management to design and implement an internal control system to meet the aforementioned objectives.

The Company's management has decided to gradually implement the means intended to respond to this new system.

A work programme has therefore been defined to formalise all the procedures put in place by the various players in the company.

- **Fields of application**

The internal control framework applies to the Company's management and all its departments. Internal control concerns all functions, whether functional or operational at all levels and is implemented through the involvement of the following directors who represent the organisation of the Company's departments:

- Executive Management: Mr Michel Finance,
- Administrative and Financial Department: Mr Jérôme Geoffroy,

- **Stakeholders**

The main players in internal control within the Company are:

- The Board of Directors,
- Executive Management,
- The Administrative and Financial Department,
- The Audit Committee composed of Mr Dominique Carouge (independent Board member) and Ms Claire Corot.

14.6.2.2 Presentation of summary information on the internal control and risk management procedures implemented by the Company

Due to the size of Affluent Medical and the proximity of management with operational staff, the involvement of Executive Management, members of the Board of Directors and operating directors is strong and revolves around the following key points:

- Clearly established areas of responsibility,
- Principle of delegation and supervision,
- Separation of tasks between authorisation, control, registration and payment functions,
- Distinction between the operators who initiate the transactions and those responsible for their validation, monitoring or settlement,
- Detection controls at all levels, whether purely financial or more technical (intrusions, IT security, fraud, etc.),
- Systematic documentation of visa checks.

Lastly, the Company relies heavily on its human capital around the following areas, which are implemented by Executive Management:

- Raising awareness of ethics and the need for control,
- Employee loyalty policy,
- Accountability and motivation policy,
- Active training and skills assessment policy.

14.6.2.3 Risks related to the preparation of financial and accounting information

The Financial Department is responsible for producing the half-yearly and annual consolidated financial statements.

Half-yearly financial statements are produced for the Group's eight subsidiaries as well as for the consolidation (balance sheet, income statement and notes) by the Company.

Internally, the following are prepared monthly:

- An estimated income statement;
- Cash flow monitoring (bimonthly).

These documents are presented to each Board of Directors if necessary. They are prepared on the basis of the figures provided by the accounting information system, as well as the data provided by the Operations Department.
The Administrative and Financial Department checks the consistency of the information collected and summarises the information in order to report it.

Four people are dedicated to the financial and administrative aspects of the Company and are responsible for the following tasks:

- Accounting management,
- Cash flow monitoring and supplier payments,
- Accounting management of subsidiaries,
- Monitoring of receipts (checks, transfers), bank reconciliations,
- The preparation of annual and half-yearly statements,
- Management control and cost analysis,
- Establishment of the annual budget and analysis of discrepancies with the implementation of corrective actions,
- Tax, social and legal obligations,
- Reporting to shareholders and the stock market,
- Other administrative and financial tasks.

Relations with banks, as well as signatures, are handled directly by the Executive Management and the Administrative and Financial Department.

Lastly, as part of the internal control process, a budgetary and strategic review is carried out every six months not only at the level of the Company but also at the level of each of its subsidiaries.

Also and depending on the local legislation applicable to foreign subsidiaries (Italy, Romania and China), financial and accounting reporting is reviewed as part of the review of the consolidated financial statements by the auditors.

The Group's Co-Statutory Auditors verify the consolidated financial statements with the assistance of the Administrative and Financial Department, accountants and/or local auditors and by conducting their own audits.

Financial and accounting reporting is finalised by the Board of Directors on a half-yearly basis and annually, after having been presented to the Audit Committee.

The Audit Committee ensures the effectiveness of the internal control and financial risk management systems, in addition to monitoring the process of preparing financial reporting.

The entire process of preparing and processing the financial and accounting information described above thus aims to manage and limit the risks in this area.

15 EMPLOYEES

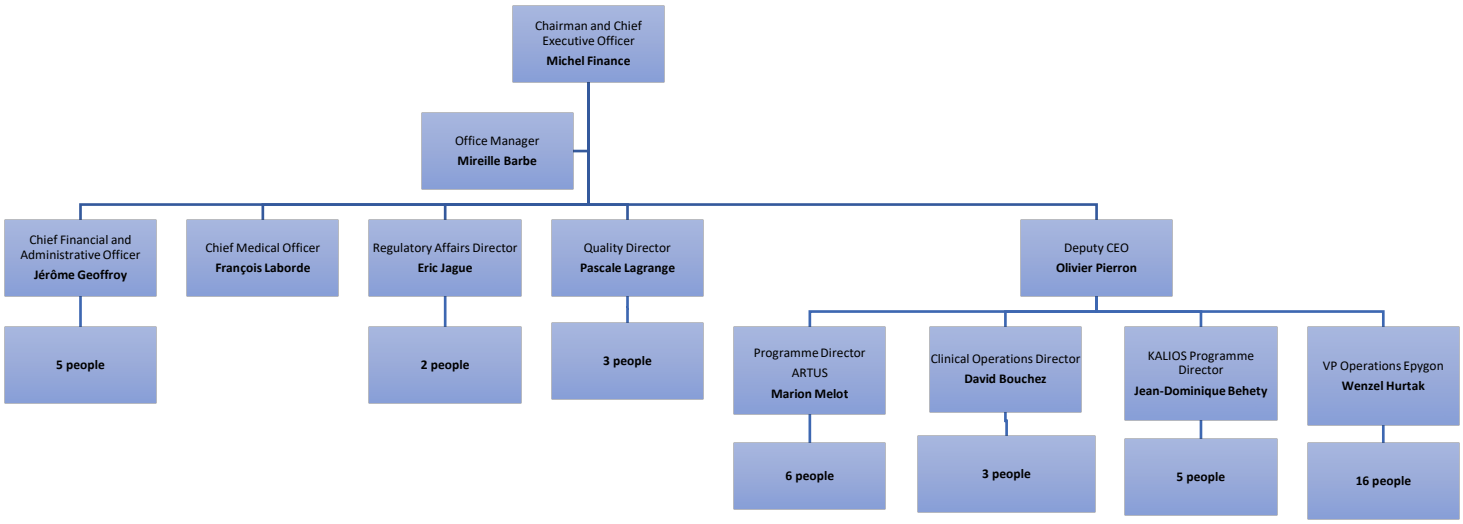
15.1 Number of employees and breakdown by function

The Group's workforce totalled 50 employees at the date of approval of the Universal Registration Document.

As at 31 December 2019, 2020 and 2021, the Group's workforce was broken down as follows:

Workforce at year-end	2019	2020	2021
Affluent Medical *(Holding company)*	10	12	10
Epygon	1	1	1
Epygon Italie	16	17	22
Kardiozis	2	2	2
Kephalios	9	8	9
MyoPowers Medical Technologies France	5	6	6
Medev Europa	-	0	
TOTAL	**43**	**46**	**50**

At the date of approval of the Universal 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 Universal Registration Document.

15.2 Shareholdings and stock options of corporate officers and members of management

At the date of approval of the Universal 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%	523,000	0	523,000	0	2.4%
Patrick Coulombier *Board member*	0	0	0%	36,168	0	36,168	0	0.2%
Daniel Hayoz *Board member*	0	0	0%	123,300	0	123,300	0	0.6%
Truffle Capital *Board member*	0	11,851,753	65.2%	0	0	0	11,851,753	54,5%
Dominique Carouge *Board member*	0	0	0%	0	32,080	32,080	0	0.0%
TOTAL	**0**	**11,851,753**	**65.2%**	**682,468**	**32,080**	**714,548**	**11,851,753**	**57.7%**

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 Universal Registration Document, may give them a stake of 7.85% 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 Incentive 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 as at the date of approval of the Universal Registration Document below shows the breakdown of the Company's share capital and voting rights on a non-diluted basis and on a diluted basis thereafter taking into account a double voting right as provided for in Article 11 of the Company's bylaws.

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]	11,851,753	65.25%	19,524,474	66.64%	11,851,753	54.52%	19,524,474	59.39%
Other financial investors[2]	3,600,551	20.37%	6,953,419	23.73%	3,700,551	17.02%	6,953,419	21.15%
Founders, executives and members of the Board of Directors, the Advisory Board and committees[3]	637,757	3.51%	847,757	2.89%	2,788,518	12.83%	2,998,518	9.12%
Individual	1,888,956	10.50%	1,889,426	6.45%	1,888,956	8.69%	1,889,426	5.75%
Self-auditing	84,785	0.47%	84,785	0.29%	84,785	0.39%	84,785	0.26%
Employees	0	0.00%	940	0.00%	1,424,788	6.55%	1,424,788	4.33%
TOTAL	**18,163,802**	**100.00%**	**29,299,861**	**100.00%**	**21,739,351**	**100.00%**	**32,875,410**	**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, Fate, Kam, Zhu.

Holding Incubatrice Serie I holds 1,774,104 shares representing 9.8% of the share capital and 12.1% of the voting rights on an undiluted basis and 8.2% of the capital and 10.8% on a diluted basis.

Holding Incubatrice Serie II holds 741,922 shares representing 4.1% of the capital and 5.1% of the voting rights on an undiluted basis and 3.4% of the capital and 4.5% on a diluted basis.

(3) Note that this figure includes the 254,607 share subscription warrants (BSAs) and 1,896,154 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 the exercise of the 287,487 share subscription warrants (BSAs) and the 3,284,362 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 AGAs, 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 Universal Registration Document for a detailed presentation of changes in the share capital.

Direct or indirect shareholdings in the share capital pursuant to Articles L. 233-7 and L. 233-12 of the French Commercial Code, brought to the attention of the Company

From 14 June 2021 until the date of approval of the Universal Registration Document, Affluent Medical has not been notified of any legal, regulatory or statutory threshold crossing.[57]

16.2 Shareholdings of corporate officers and transactions carried out by the members of the Board of Directors on the Company's shares

On the date of approval of the Universal Registration Document, Truffle Capital, a legal entity Board member represented by Mr Philippe Pouletty, is the management company of the funds and companies jointly holding, on the date of approval of the Universal Registration Document, 65.2% of share capital and 66.6% of the Company's voting rights.

On the date of approval of the Universal Registration Document, neither the Chairman and Chief Executive Officer nor any other member of the Board of Directors holds an interest in the capital of Affluent Medical.

To the Company's knowledge, no executive or corporate officer, or any person having close personal ties with an executive, has declared having carried out any transactions on the Company's shares, in accordance with Article L. 621-18-2 of the French Monetary and Financial Code, during the financial year ended 31 December 2021.

16.3 Voting rights of main shareholders

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.

16.4 Control of the Company

As at the date of approval of the Universal Registration Document, on the basis of the Position-Recommendation no. 2021-02 "Guide for the preparation of universal registration documents – DOC

[57] *No statement of threshold crossing published by the AMF.*

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.

These entities collectively hold 11,851,753 shares representing 65.2% of the share capital and 66.6% of the voting rights of the Company on an undiluted basis and 11,851,753 shares representing 54.5% of the share capital and 59.4% of the voting rights of the Company 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 Board members on the Company's Board of Directors.

To the best of the Company's knowledge, there were no concerted actions between shareholders at the date of approval of the Universal Registration Document.

16.5 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.

16.6 Pledges of the Company's shares

To the best of its knowledge, the Company does not have any pledge on a significant portion of its capital.

17 TRANSACTIONS WITH RELATED PARTIES

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 entered into agreements with its own subsidiaries. All of these agreements are described in section 6.3.

In addition, information relating to transactions with related parties is provided in Note 23 to the consolidated financial statements, in Section 18.1.1.

17.2 Statutory Auditors 'special reports on related-party agreements for the financial year ended 31 December 2021

AFFLUENT MEDICAL

Special report from the Statutory Auditors on regulated agreements

(General Meeting called to approve the financial statements for the financial year ended 31 December 2021)

This is a translation into English of the Statutory Auditors'special report on regulated agreements 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. It should be understood that the agreements reported on are only those provided for by the French Commercial Code and that the report does not apply to those related-party transactions described in IAS 24 or other equivalent accounting standards.

PricewaterhouseCoopers Audit
63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

EXPERTEA AUDIT
60, boulevard Jean Labro
13016 Marseille

Special report from the Statutory Auditors on regulated agreements

(General Meeting to approve the financial statements for the year ended 31 December 2021)

To the Company's General Meeting
AFFLUENT MEDICAL
320, avenue Archimède
13100 Aix-en-Provence, France

In our capacity as Statutory Auditors of your company, we hereby present our report on regulated 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 evaluate the benefits resulting from these agreements prior to 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

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 in previous years

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.

• Employment contract, medical expert

- Person involved: Mr Daniel Hayoz (Board member)
- Nature and purpose: employment contract between the Company and Mr Daniel Hayoz, Board member.
- Terms and conditions: gross compensation received during the financial year ended 31 December 2021 amounted to €3,000.

This agreement was authorised by the Board of Directors on 9 April 2018.

Signed at…. and […….], on

The Statutory Auditors

PricewaterhouseCoopers Audit	EXPERTEA AUDIT
Thierry Charron	Jérôme MAGNAN

18. FINANCIAL REPORTING ON THE GROUP'S PORTFOLIO, FINANCIAL POSITION AND RESULTS

18.1 Historical financial reporting

18.1.1. Consolidated historical financial reporting for the financial years ended 31 December 2019, 2020 and 2021

18.1.1.1. Consolidated financial statements prepared under IFRS as at 31 December 2021

Consolidated statement of financial position

Consolidated statement of financial position (in thousands of euros)	Notes	31/12/2021	31/12/2020
ASSETS			
Goodwill	3	32,203	32,203
Other intangible assets	4.1	20,695	22,566
Tangible assets (including right-of-use assets)	4.2	2,005	1,781
Shareholdings in equity affiliates	5	-	14
Other non-current financial assets	6	457	351
Total non-current assets		**55,360**	**56,915**
Other current receivables	7	3,265	2,261
Cash and cash equivalents	8	11,410	5,650
Total current assets		**14,675**	**7,911**
Total assets		**70,035**	**64,826**
LIABILITIES AND EQUITY			
Equity			
Capital	9	18,164	15,257
Premiums		80,546	62,683
Translation reserve		22	21
Other items in comprehensive income		10	(22)
Reserves and earnings		(55,207)	(42,649)
Equity – attributable to shareholders of Affluent Medical		**43,535**	**35,290**
Non-controlling interests		-	-
Total shareholders' equity		**43,535**	**35,290**
Non-current financial liabilities	11	16,085	16,248
Non-current lease liabilities	11.4	913	731
Employee benefits commitments	12	96	117
Non-current provisions	13	130	228
Deferred tax liabilities	20	1,973	2,440
Derivative liabilities	11	-	-
Other non-current liabilities		-	7
Total non-current liabilities		**19,197**	**19,771**
Current financial liabilities	11	2,416	3,575
Current lease liabilities	11.4	337	226
Trade payables	14	1,793	2,352
Other current liabilities	14	2,447	2,261
Derivative liabilities	11	310	1,351
Total current liabilities		**7,303**	**9,765**
Total liabilities and equity		**70,035**	**64,826**

Consolidated income statement

Consolidated income statement (in thousands of euros)	Notes	31/12/2021 12 months	31/12/2020 12 months
REVENUE		-	-
Other operating income	16	1,451	824
OPERATING EXPENSES			
Purchases consumed		(2,518)	(3,108)
External expenses	17.1	(5,496)	(3,563)
Personnel expenses	17.2	(4,405)	(4,694)
Taxes and duties		(88)	(67)
Provisions net of reversals		98	(125)
Other current operating income and expenses	17.3	145	46
Depreciation and amortisation	4	(2,420)	(1,907)
CURRENT OPERATING INCOME		**(13,233)**	**(12,594)**
Other non-current operating income and expenses	18	-	-
OPERATING INCOME before share of net income of equity affiliates		**(13,233)**	**(12,594)**
Share of income of equity affiliates	5	(14)	(398)
OPERATING INCOME after share of net income of equity affiliates		**(13,247)**	**(12,992)**
Net borrowing cost	19	(3,055)	(2,165)
Other financial income and expenses	19	4	32
Change in fair value of derivative liabilities	19	1,041	597
Profit (loss) before tax		**(15,257)**	**(14,528)**
Income taxes	20	437	209
Net income (loss) for the period		**(14,820)**	**(14,319)**
Of which attributable to shareholders of Affluent Medical		(14,820)	(14,319)
Of which non-controlling interests		-	-
		31/12/2021	**31/12/2020**
Basic earnings per share (€/share)	21	**(0.88)**	**(1.07)**
Diluted earnings per share (€/share)	21	**(0.88)**	**(1.07)**

Consolidated statement of comprehensive income

Consolidated statement of comprehensive income (in thousands of euros)	31/12/2021 12 months	31/12/2020 12 months
Net income (loss) for the period	**(14,820)**	**(14,319)**
Actuarial differences	32	(2)
Tax effect related to these items	-	-
Items that cannot be reclassified to profit or loss	**32**	**(2)**
Consolidation translation differences	1	(3)
Items that can be reclassified in profit or loss	**1**	**(3)**
TOTAL Other comprehensive income (net of tax)	33	(5)
Consolidated statement of comprehensive income	**(14,787)**	**(14,324)**
Of which attributable to shareholders of Affluent Medical	*(14,787)*	*(14,324)*
Of which non-controlling interests	-	-

Change in consolidated equity

Change in consolidated equity Note	*Capital Affluent Medical SA* *Number of shares*	Share capital	Capital related premiums	Reserves and earnings	Translation reserve	Other items in comprehensive income	Equity – attributable to shareholders of Affluent Medical	Total non-controlling interests	Total shareholder s' equity
					In thousands of euros				
At 31 December 2019	*11,899,967*	**11,900**	**47,701**	**(28,641)**	**24**	**(20)**	**30,964**	**-**	**30,964**
Net income (loss) for the period		-	-	(14,319)	-	-	(14,319)	-	(14,319)
Other items in comprehensive income		-	-	-	(3)	(2)	(5)	-	(5)
Comprehensive income		**-**	**-**	**(14,319)**	**(3)**	**(2)**	**(14,324)**	**-**	**(14,324)**
Conversion of convertible bonds	*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		-	-	959	-	-	959	-	959
Share subscription warrants (BSA)		-	11	-	-	-	11	-	11
At 31 December 2020	***15,256,824***	**15,257**	**62,683**	**(42,649)**	**21**	**(22)**	**35,290**	**-**	**35,290**
Net income (loss) for the period		-	-	(14,820)	-	-	(14,820)	-	(14,820)
Other items in comprehensive income		-	-	-	1	32	33	-	33
Comprehensive income		**-**	**-**	**(14,820)**	**1**	**32**	**(14,787)**	**-**	**(14,787)**
Capital increase through the conversion of debt	*232,558*	233	1,767	-	-	-	2,000	-	2,000
Capital increase	*2,674,420*	2,674	20,326	-	-	-	23,000	-	23,000
Capital increase costs		-	(1,730)	155	-	-	(1,575)	-	(1,575)
Allocation of the share premium to the legal reserve		-	(2,500)	2,500	-	-	-	-	-
Share-based compensation		-	-	42	-	-	42	-	42
Net movements in treasury shares		-	-	(372)	-	-	(372)	-	(372)
Net gains and losses on treasury shares		-	-	(63)	-	-	(63)	-	(63)
At 31 December 2021	***18,163,802***	**18,164**	**80,546**	**(55,207)**	**22**	**10**	**43,535**	**-**	**43,535**

Consolidated cash flow statement

Consolidated cash flow statement Amounts in thousands of euros	Notes	31/12/2021 12 months	31/12/2020 12 months
Cash flows from operating activities			
Net income (loss) for the period		**(14,820)**	**(14,319)**
Elimination of amortization of intangible and tangible assets, provisions and reversals of provisions	4, 13	2,332	2,465
Gains or losses on disposal of assets		(20)	-
Spreading of grants		(305)	(264)
Share-based payment expense	10	42	959
Interest expense, accrued interest, impact of amortised cost and accretion of advances		3,037	2,039
Change in fair value of derivatives	11.3	(1,041)	(597)
Share of income of equity affiliates	5	14	398
Income tax expense (including deferred tax)	20	(437)	(209)
Gross cash flow before net borrowing cost and taxes		**(11,198)**	**(9,528)**
(-) Change in working capital requirement		**(1,136)**	**612**
Including increase (decrease) in other non-current financial assets	6	(40)	(20)
Including increase (decrease) in other receivables	7	(1,002)	1,728
Including increase (decrease) in trade payables	14	(558)	(1,352)
Including increase (decrease) in tax and social security debts	14	696	240
Including increase (decrease) in other liabilities	14	(232)	17
Taxes paid		**(30)**	**(20)**
Cash flows from operating activities		**(12,364)**	**(8,936)**
Cash flows from investing activities			
Acquisitions of tangible assets	4.2	(334)	(304)
Sale price of assets sold		174	-
Cash flows from investing activities		**(160)**	**(304)**
Cash flows from financing activities			
Capital increase net of capital increase costs		21,425	7,456
Receipt of advances and conditional grants	11.1	2,529	2,755
Bank borrowings	11.2	795	2,140
Issue of convertible bonds, net of fees		-	4,000
Repayments of convertible bonds		(5,164)	(1,952)
Gross financial interest paid		(521)	(715)
Other movements related to the pre-financing of the research tax credit	11.5	-	(711)
Repayment of lease liabilities	11.4	(283)	(222)
Other cash flows from financing activities (liquidity contract)		(500)	-
Share subscription warrants (BSA)		-	11
Cash flows from financing activities		**18,281**	**12,762**
Impact of exchange rate fluctuations		-	-
Increase (decrease) in cash		**5,757**	**3,522**
Opening cash and cash equivalents		5,648	2,126
Closing cash and cash equivalents		11,405	5,648
Increase (decrease) in cash		**5,757**	**3,522**

Cash and cash equivalents (including Bank overdrafts)	**Notes**	**31/12/2021**	**31/12/2020**
Cash and cash equivalents	8	11,410	5,650
Bank overdrafts	8	(5)	(2)
Closing cash and cash equivalents (including Bank overdrafts)		**11,405**	**5,648**

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 reporting 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: Information on the Company and its business

The information below constitutes the notes to the consolidated financial statements prepared under IFRS for the financial year ended 31 December 2021 with comparative information for the financial year ended 31 December 2020.

The consolidated financial statements of Affluent Medical SA were approved by the Board of Directors on 24 March 2022 and authorised for publication.

1.1 The Company and its business

Affluent Medical is a French player in MedTech founded by Truffle Capital with the aim of becoming one of the European leaders in the treatment of heart and vascular diseases, which are the leading cause of death worldwide, and of urinary incontinence, which today affects one in four adults.
Affluent Medical develops 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 2023.

Registered office address: 320, avenue Archimède – Les Pléiades III – Bâtiment B
13100 Aix-en-Provence, France
Trade and Companies Register 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 and sub-subsidiaries is hereinafter referred to as the "Group".

1.2 Significant events during the financial year ended 31 December 2021

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 État Coronavirus" guarantee fund of up to 90.00%. The Company has an option to extend the amortisation and repayment period of the loan to up to five years after the initial maturity date provided for in the contract.

April 2021:
The Company entered into the following:

- on 15 April 2021, a State-guaranteed loan of €0.2 million with BNP Paribas with a deferred repayment of one year (principal and interest) and amortisation of the loan for four years;
- on 23 April 2021, a State-guaranteed loan of €0.2 million with Bpifrance with a deferred repayment of one year (principal and interest) and amortisation of the loan of four years.

The Ordinary and Extraordinary General Meeting of 6 April 2021 notably:

- decided to amend the terms and conditions of the Kreos share subscription warrants (BSAs), which may thus give entitlement, by conversion, to a maximum of 40,000 ordinary shares and decided to set the maximum nominal amount of the capital increases that may be carried out as a result of the exercise of the Kreos warrants at €400 thousand;
- decided to convert all of the Company's 11,207,401 A shares.

On 6 April 2021, the holders of A shares met for a General Meeting and approved the conversion of all of the 11,207,401 A shares into ordinary shares of the Company, on the basis of one (1) A share for every (1) ordinary share, with effect from the first listing date of the shares on the Euronext Paris regulated market.

June 2021:

On 9 June 2021, Affluent Medical announced the success of its IPO on the regulated market of Euronext Paris. In this context, the Company carried out a capital increase of €25 million with the issue of 2,906,978 new ordinary shares at a price of €8.60 per share. Following this transaction, the number of shares increased to 18,163,802. Taking into account the IPO price of €8.60 per share, the market capitalisation of Affluent Medical stands at approximately €156 million.

September 2021

On 16 September 2021, Affluent Medical announces the success of the first adjustment of the Kalios mitral ring in a patient with postoperative recurrence of severe mitral insufficiency. This adjustment, which was carried out without surgery in July 2021, has improved the prognosis of the patient who is currently under scheduled medical follow-up without limitation to his ordinary activities.

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 2021 and 31 December 2020 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 2021.

The accounting principles and methods used by the Company are described below. In certain cases, IFRS allow the choice between the application of a reference treatment or another authorised treatment.

Principles applied to the preparation of the financial statements

The Company's consolidated financial statements have been prepared in accordance with the historical cost principle, 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 raisings of capital;
- issue of convertible and non-convertible bonds;
- loans guaranteed by the State;
- repayable advances and subsidies;
- the repayment of research tax credit receivables by the State;
- the IPO on the regulated market of Euronext Paris concomitant with a capital increase.

The Company will need additional funds to pursue its development plan and this may also depend on achieving development milestones, obtaining favourable clinical results and/or obtaining regulatory approvals or achieving commercial success.

At the date of closing of these financial statements, the Board of Directors believes that the Company will be able to cover the financing needs of the transactions planned until the end of September 2022 on the basis of the following information:

- Consolidated net cash and cash equivalents at 31 December 2021 (including current bank overdrafts), which amounted to €11,410 thousand;
- The projected collection of the research tax credit for the financial year 2021 for an amount of €1,044 thousand;

- Cash flow consumption forecasts by the Company for 2022;
- The repayment of the bond issue of €1 million to Head Leader (see Note 11.3).

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 September 2022.

As such, the Company continues to actively study various solutions to continue financing its business and development. These solutions could, without being restrictive, involve carrying out capital increases, setting up bonds and obtaining public 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.

Accounting methods

The accounting principles used are identical to those used for the preparation of the annual IFRS consolidated financial statements for the year ended 31 December 2020, except for the application of the following new standards, amendments to standards and interpretations adopted by the European Union, mandatory for the Company at 1 January 2021:

- Amendments to IFRS 4 – *Insurance contracts – deferred from the application of IFRS 9*, published by the IASB on 25 June 2020 and published in the Official Journal of the European Union on 16 December 2020;
- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 – *Interest rate benchmark reform – phase 2*, published by the IASB on 27 August 2020 and published in the Official Journal of the European Union on 14 January 2021;
- Amendments to IFRS 16 – *Covid-19 rent concessions beyond 30 June 2021*, published by the IASB on 31 March 2021 and published in the Official Journal of the European Union on 31 August 2021;
- IFRS IC decision dated 20 April 2021 – *Attributing benefit to periods of service (IAS 19 – Employee benefits)*.

These new standards, amendments and interpretations adopted by the European Union had no significant impact on the Company's financial statements (see Note 2.2).

The standards, amendments to standards and interpretations published by the IASB and not yet adopted by the European Union are as follows:

- Amendments to IAS 1 – *Presentation of financial statements: classification of liabilities as current or non-current – deferral of effective date*, published by the IASB on 23 January 2020 and on 15 July 2020, respectively, the application of which is mandatory as from 1 January 2023;
- Amendments to IAS 1 – *Presentation of the financial statements and IFRS Practice Statement 2: Disclosure of accounting policies*, published by the IASB on 12 February 2021, with application mandatory from 1 January 2023;
- Amendments to IAS 8 – *Accounting policies, changes in accounting estimates and errors*: Definition of accounting estimates published by the IASB on 12 February 2021, with application mandatory from 1 January 2023;

- Amendments to IAS 12 – *Income tax*: Deferred tax relating to assets and liabilities arising from a single transaction published by the IASB on 7 May 2021, with application mandatory from 1 January 2023; and
- Amendments to IFRS 17 – *Insurance contracts*: initial application of IFRS 17 and IFRS 9 – comparative information published by the IASB on 9 December 2021, with application mandatory from 1 January 2023.

The Company does not anticipate any significant impact of these standards, amendments to standards and interpretations on its financial statements at the date of adoption.

Standards, amendments to standards and interpretations adopted by the European Union but not yet mandatory for the 2021 annual financial statements are as follows:

- Amendments to IFRS 3 – *Business combinations*, IAS 16 – *Tangible assets* 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 and in the Official Journal of the European Union on 2 July 2021, with application mandatory from 1 January 2022;
- IFRS 17 – *Insurance contracts* published by the IASB on 18 May 2017 including the amendments to IFRS 17 published by the IASB on 25 June 2020 and published in the Official Journal of the European Union on 23 November 2021, the application of which is mandatory from 1 January 2023.

The Group has chosen not to apply in advance the standards, amendments and interpretations adopted by the European Union but whose early application would have been possible, and which will come into force after 31 December 2021.

2.2 Change in accounting method

The consolidated financial statements have been prepared by applying the change in accounting method relating to the decision of the IFRS Interpretations Committee ("IFRS IC") of 20 April 2021 *Attributing benefit to periods of service (IAS 19 – Employee benefits)*.

In the financial statements previously published, the method used measured the obligation and then recognise the expense on a straight-line basis over the employee's career within the Company. The commitment corresponded to a proportion of the rights acquired by the employee at the time of retirement.

The IFRS IC decision must be applied when:

- rights are granted subject to presence in the Company on the retirement date (with loss of all rights in the event of early departure),
- rights depend on seniority, but are capped after a certain number of years of service, with the ceiling capped well before retirement – for some employees at least.

In its decision, the IFRS IC considers that given that no rights are acquired in the event of departure before retirement age and that rights are capped after a certain number of years of service, the pension expense should be recognised over the years conferring rights to employees on the departure date.

The methodological difference was deemed immaterial by the Company and therefore did not result in retrospective accounting. The impact of the change in method of €31 thousand on 1 January 2021 was recorded in other comprehensive income for the 2021 financial year.

With the exception of the new texts identified in Note 2.1 above, the Company did not make any changes in accounting methods for the financial year ended 31 December 2021.

2.3 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 affect those returns through its power over the entity.

Subsidiaries are fully consolidated from the date on which the Group acquires control. They are deconsolidated from the date on which control ceases to be exercised.

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:

	Country	31/12/2021			31/12/2020		
		% Group interest	% control	Method	% Group interest	% control	Method
AFFLUENT MEDICAL SA	France	**Parent company**					
EPYGON SAS	France	100.00%	100.00%	FC	100.00%	100.00%	FC
KEPHALIOS SAS	France	100.00%	100.00%	FC	100.00%	100.00%	FC
KARDIOZIS SAS	France	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
EPYGON ITALIE SRL	Italy	100.00%	100.00%	FC	100.00%	100.00%	FC
MEDEV EUROPA SRL (1)	Romania	100.00%	100.00%	FC	100.00%	100.00%	FC
SHANGHAI EPYGON MEDICAL TECHNOLOGY	China	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

Company without operational activity created in 2020.
FC: Full consolidation
E: Equity method

2.4 Presentation currency

The Group's financial statements are prepared in euros (EUR).

2.5 Conversion method

2.5.1 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.

2.5.2 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 currency 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)	**31/12/2021**		**31/12/2020**	
	Average rate	Closing rate	Average rate	Closing rate
Romanian Leu LEI/RON	4.9215	4.9490	4.8383	4.8683
Yuan Ren Min Bi – RMB	7.6282	7.1947	7.8747	8.0225

2.6 Use of judgments 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 book value 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 expenses:

- Development expenses 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;

- The recoverable amount of the technologies developed internally and the estimated useful life of the technology (see Notes 4.1 and 4.3);

- Allocation of share subscription warrants ("BSAs") and founders' share warrants ("BSPCEs") 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 described in Note 10;

- 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;

- 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;

- Determination of the fair value of convertible bonds (Financing CB and 2019 CB) and non-convertible bonds with share subscription 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;

- 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;

- 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 and 11.1.3.

2.7 Impact of the Covid-19 health crisis on the consolidated financial statements as at 31 December 2021

Activities were affected by Covid-19 in 2020 and 2021. 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.
In 2020, the Company benefited from partial activity measures to minimise the impacts of these delays. In this regard, the Company received €52 thousand in compensation for short-time working hours, which was deducted from personnel expenses. During the 2021 financial year, the Company did not receive any new compensation in this respect.

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 2021 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). 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).

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 cash-generating units, generally corresponding to a company:

Goodwill (amount in thousands of euros)	**31/12/2021**	**31/12/2020**
EPYGON SAS	10,722	10,722
KARDIOZIS SAS	5,422	5,422
KEPHALIOS SAS	8,698	8,698
MYOPOWERS MEDICAL TECHNOLOGIES FRANCE	7,361	7,361
Total	**32,203**	**32,203**

There were no indications of impairment during the periods presented in accordance with IAS 36**.**

The Group carried out annual impairment tests on goodwill (€32,203 thousand at the end of the reporting periods).
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 2021 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 at 31 December 2021, based on internal valuations, the Group concluded that the recoverable amount of the CGUs tested exceeded their book value. 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 book value.

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.

4.1 Intangible assets

Accounting principles

Research and development expense

Research expenses are systematically recognised as expenses.

According to IAS 38, development expenses are recognised as intangible assets only if all of the following criteria are met:

a) Technical feasibility 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 personnel expenses incurred to generate the asset.

The expenses are 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 expenses 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 at 1 January 2019. The Company has decided not to retrospectively apply IFRS 3 (see Note 2).

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 expenses	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 (Amounts in thousands of euros)	Patents and similar rights	Software and other intangible assets	Total
Gross value			
Statement of financial position at 31 December 2019	**28,512**	**159**	**28,671**
Acquisition	-	-	-
Disposal and reclassification	-	-	-
Statement of financial position at 31 December 2020	**28,512**	**159**	**28,671**
Acquisition	-	-	-
Disposal and reclassification	-	-	-
Statement of financial position at 31 December 2021	**28,512**	**159**	**28,671**
Amortisations			
Statement of financial position at 31 December 2019	**4,150**	**79**	**4,229**
Increase	1,849	27	1,876
Decrease	**-**	**-**	**-**
Statement of financial position at 31 December 2020	**5,999**	**106**	**6,104**
Increase	1,844	27	1,871
Decrease	-	-	-
Statement of financial position at 31 December 2021	**7,843**	**133**	**7,976**
NET BOOK VALUE			
Statement of financial position at 31 December 2019	**24,362**	**80**	**24,442**
Statement of financial position at 31 December 2020	**22,513**	**53**	**22,566**
Statement of financial position at 31 December 2021	**20,669**	**26**	**20,695**

Patents and similar rights consist of technologies developed in-house, details of which are given below:

INTERNALLY DEVELOPED TECHNOLOGIES (Amounts in thousands of euros)	31/12/2021	31/12/2020
Gross values		
EPYGON	9,786	9,786
KARDIOZIS	2,223	2,223
KEPHALIOS	8,207	8,207
MYOPOWERS	8,280	8,280
Total	**28,496**	**28,496**

Amortisations		
EPYGON	2,586	1,946
KARDIOZIS	574	427
KEPHALIOS	2,138	1,598
MYOPOWERS	2,538	2,018
Total	**7,836**	**5,990**
Net book value		
EPYGON	7,200	7,840
KARDIOZIS	1,649	1,796
KEPHALIOS	6,069	6,609
MYOPOWERS	5,742	6,262
Total	**20,660**	**22,507**

4.2 Tangible assets

Accounting principles

Tangible assets 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 liabilities".

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.

TANGIBLE ASSETS (Amounts 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)	Assets in progress	Total	Of which rights-of-use
Gross value											
Statement of financial position 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 at 31 December 2020	**1,219**	**1,155**	**94**	**84**	**15**	**247**	**15**	**105**	**-**	**2,934**	**1,448**
Acquisition	600	304	213	9	18	2	-	-	18	1,198	865
Disposal and reclassification	(508)	(173)	-	-	-	-	-	-	-	(681)	(508)
At 31 December 2021	**1,311**	**1,286**	**307**	**93**	**33**	**249**	**15**	**105**	**18**	**3,451**	**1,805**
Amortisations											
Statement of financial position 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 at 31 December 2020	**455**	**512**	**23**	**65**	**8**	**46**	**6**	**37**	**-**	**1,153**	**529**
Increase	209	213	37	9	6	25	3	44	-	546	299
Decrease	(235)	(19)	-	-	-	-	-	-	-	(254)	(235)
Statement of financial position at 31 December 2021	**429**	**707**	**60**	**74**	**14**	**71**	**9**	**81**	**-**	**1,445**	**593**
Net book value											
Statement of financial position at 31 December 2019	**832**	**584**	**78**	**25**	**13**	**154**	**12**	**49**	**-**	**1,746**	**983**
Statement of financial position at 31 December 2020	**763**	**643**	**71**	**19**	**8**	**201**	**9**	**68**	**-**	**1,781**	**918**
Statement of financial position at 31 December 2021	**882**	**579**	**247**	**19**	**19**	**178**	**6**	**58**	**18**	**2,006**	**1,212**

Rights-of-use

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 2020, the Company renewed the lease for its premises in Besançon and set up new vehicle leases.

In 2021, the Company notably:

- expanded its premises in Italy for an impact of +€275 thousand;
- leased laboratory equipment and IT equipment for an impact of +€231 thousand;
- extended the lease for the Besançon site (MyoPowers site) for an impact of +€73 thousand;
- signed a new lease for the Aix-en-Provence site by Affluent Medical (gross value of €233 thousand) and noted the end of the lease agreement for the company Kephalios on this same site (in the amount of €311 thousand gross and €116 thousand in accumulated depreciation (*i.e.* a net value of €195 thousand).

4.3 Impairment of tangible and intangible assets

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 book value 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 estimated 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 2021, unchanged compared to 31 December 2020, see Note 3) 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 2021 and 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 at 31 December 2021 and 31 December 2020, based on internal valuations, the Group concluded that the recoverable amounts of the CGUs tested exceeded their book value. 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 book value.

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 at 31 December 2021 amounts to €20,660 thousand and to €22,507 thousand at 31 December 2020 (see Note 4.1).

Minor delays in the implementation of the Company's clinical programmes in 2021 and 2020 due to the Covid-19 health crisis (see Note 2.6) were not considered an indication of impairment.

Accounting principles

Under the equity method, the investment in a joint venture is initially recognised at acquisition cost and subsequently adjusted for the share of profit or loss attributable to owners of the Group and other comprehensive income. Any dividends received are recorded as a reduction of the net book value of the investment.

Joint venture contracts

In 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 Mainland 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 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 INVESTMENTS IN EQUITY AFFILIATES (Amounts in thousands of euros)	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total investments in equity affiliates
Statement of financial position 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 at 31 December 2020	**14**	**-**	**14**
Share of income of equity affiliates	(14)	-	(14)
Translation differences	-	-	-
Statement of financial position at 31 December 2021	**-**	**-**	**-**

The data relating to joint ventures are as follows:

DATA ON JOINT VENTURES (Amount in thousands of euros)	31/12/2021			31/12/2020		
	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total
Revenue	-	-	**-**	-	-	**-**
Operating income	(911)	(819)	**(1,731)**	(633)	(868)	**(1,501)**
Net income (loss)	(911)	(819)	**(1,731)**	(633)	(868)	**(1,501)**
Percentage held	**40.00%**	**40.00%**	**40.00%**	**40.00%**	**40.00%**	**40.00%**
Theoretical share of net income of equity affiliates	(365)	(328)	(692)	(253)	(347)	(601)
Share of net income of equity affiliates (1)	(14)	-	(14)	(253)	(145)	(398)

(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 book value 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.

On the basis of the balance sheet items of the two joint ventures available at 31 December 2020, and in view of the expenses incurred by the two joint ventures during the 2021 financial year, the Company decided to use an equivalence value of zero at 31 December 2021.

DATA ON JOINT VENTURES (Amount in thousands of euros)	31/12/2020		
	JV SHANGHAI EPYGON	JV SHANGHAI MYOPOWERS	Total
ASSETS			
Non-current assets	**2**	**1**	**4**
Inventories	-	-	**-**
Trade receivables	-	-	**-**

Other current receivables	1	1	**1**
Cash and cash equivalents	258	176	**434**
Total current assets	259	177	**435**
Total assets	**261**	**178**	**439**
LIABILITIES AND EQUITY			
Equity	34	(498)	**(464)**
Non-current liabilities	-	-	-
Current liabilities	227	676	**903**
Total liabilities and equity	**261**	**178**	**439**
Theoretical equity value of the Group in shareholders' equity	**14**	**(199)**	**(186)**
Equity value retained by the Group in shareholders' equity	**14**	**-**	**14**

Note 6: Financial assets

Accounting principles

As at 31 December 2020 and 31 December 2021, 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 2020 and 31 December 2021.

Profits or losses arising from changes in the value of financial assets at fair value through profit or loss are presented in the "Net finance income (expense)" 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	Liquidity contract	Total
Statement of financial position at 31 December 2019	**256**	**17**	**58**	-	**331**
Increases	-	-	25	-	25
Decreases	-	-	(5)	-	(5)
Statement of financial position at 31 December 2020	**256**	**17**	**78**	-	**351**
Increases	-	-	54	500	554
Decreases	-	-	(15)	(433)	(448)
Statement of financial position at 31 December 2021	**256**	**17**	**117**	**67**	**457**

Security deposits were made when the non-convertible bonds were set up with KREOS Capital. They amounted to €256 thousand at 31 December 2021 as at 31 December 2020 (see Note 11.3.1).

Following its IPO on the Euronext Paris market, the Company signed a liquidity contract with a specialised institution to limit the intra-day volatility of the Affluent Medical share.
In this context, the Company has entrusted this institution with €400 thousand to take buy or sell positions on the Company's shares. The shares acquired under this contract are recognised as treasury shares at their acquisition cost.
The result of the disposal of these treasury shares is recorded in shareholders' equity.
The cash reserve related to the liquidity contract is presented in "other non-current financial assets".
On 27 August 2021, the Company announced the contribution of an additional €100 thousand to the liquidity contract awarded to Kepler Cheuvreux.

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)	31/12/2021	31/12/2020
Research tax credit (1)	1,044	509
Value added tax (2)	1,642	1,038
Prepaid expenses (3)	335	175
Advances and payments on account	37	115
Miscellaneous	207	425
Total other current receivables	**3,265**	**2,261**

(1) Research tax credit (RTC)

- 2021 RTC: €1,044 thousand, expected to be repaid in the second half of 2022;
- 2020 RTC: €509 thousand, repaid in the second half of 2021.

(2) Value added tax

- As part of the progress of expenses in the launch of the Group's products, the Company recognises a VAT credit at the various closings presented;
- In addition, during the financial year ended 31 December 2021, the Company incurred numerous costs related to the IPO, which generated VAT credits as at 31 December 2021.

(3) Prepaid expenses are related to the Group's day-to-day business and mainly concern fees.

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)	31/12/2021	31/12/2020
Bank accounts	11,410	5,650
Cash equivalents	-	-
Total cash and cash equivalents	**11,410**	**5,650**

Note 9: Capital

Composition of share capital

COMPOSITION OF SHARE CAPITAL	31/12/2021	31/12/2020
Capital (in thousands of euros)	18,164	15,257
Number of shares	18,163,802	15,256,824
of which ordinary shares	18,163,802	4,049,422
of which preferred A shares	-	11,207,402
Nominal value (in euros)	€1.00	€1.00

The number of Company shares does not include share subscription warrants ("BSA"), founders' share warrants ("BSPCE") granted to employees, executives, Board members and external service providers and not yet exercised.

Change in share capital

During the 2021 financial year, the Company carried out several capital increases in cash:

- issue of 2,906,978 new ordinary shares for an amount of €25 million on 9 June 2021 (€2,907 thousand of share capital and €22,093 thousand of issue premium);
- of which the conversion of the €2 million KREOS bond issue into capital, by the issuance of 232,558 new ordinary shares for an amount of €233 thousand.

Preferred A shares

As part of the Company's initial public offering, preferred A shares will be automatically converted into ordinary shares when the Company's securities are listed 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.

Following the Company's initial public offering on the regulated market of Euronext Paris, the Company signed a liquidity contract on 14 June 2021 in order to limit the intra-day volatility of the Company's share. In this context, the Company has entrusted Kepler Cheuvreux with €400 thousand to take buy or sell positions on the Company's shares.
On 27 August 2021, the Company announced the contribution of an additional €100 thousand to the liquidity contract awarded to Kepler Cheuvreux.

At 31 December 2021, under this contract, 65,037 treasury shares were recognised as a deduction from shareholders' equity and €67 thousand in respect of the cash account were recorded as non-current financial assets.

Issue fees

Ancillary costs directly attributable to the issuing of shares or stock options are recognised, net of tax, as a deduction from equity.

As part of the Company's IPO and the concomitant capital increase, the Company generated costs of €2.91 million. These costs were deducted from the issue premium in the amount of €1.73 million (of which €155 thousand had already been recognised at 31 December 2020) and the balance of €1.18 million was recognised as expenses for 2021.

Dividends

The Company did not pay any dividends during the years presented.

Note 10: 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 (BSAs)

The table below summarises the data relating to the plans issued as well as the assumptions used for valuation in accordance with 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 **BSA 2018-3** 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 12 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 12 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 at 30 September 2019, for 20% as at 31 December 2020 and for 50% as at 31 December 2021.
The plan **BSA 2020-1** has a vesting period of 48 months: one quarter after 12 months of their allocation then one forty-eighth over the following 36 months.

Change in the number of warrants outstanding

Number of outstanding options						
Type	**Date of grant**	**31/12/2020**	**Issued**	**Exercised**	**Lapsed**	**31/12/2021**
BSA 2018-1	09/04/2018	1,644	-	-	-	1,644
BSA 2018-2	09/04/2018	84,549	-	-	(18,789)	65,760
BSA 2018-4	23/10/2018	65,760	-	-	(8,905)	56,855
BSA 2018-5	23/10/2018	32,500	-	-	(32,500)	-
BSA 2020-1	08/07/2020	32,080	-	-	-	32,080
Total		**216,533**	**-**	**-**	**(60,194)**	**156,339**

The vesting conditions (performance conditions and service conditions) defined for each share subscription warrant (BSA) plan have not changed since 31 December 2020.

10.2 Founders' share warrants (French BSPCE)

The table below summarises the data relating to 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
BSPCE 2021-1	20/07/2021	125,000	10 years	€6.93	6 years	34.08%	-0.66%	276
BSPCE 2021-2	20/07/2021	30,000	10 years	€6.93	6 years	34.08%	-0.66%	66
BSPCE 2021-3	20/07/2021	70,000	10 years	€6.93	6 years	34.08%	-0.66%	155
BSPCE 2021-4	20/07/2021	250,000	10 years	€6.93	6 years	34.08%	-0.66%	552
BSPCE 2021-5	20/09/2021	30,000	10 years	€6.00	6 years	34.08%	-0.58%	66
BSPCE 2021-6	20/09/2021	476,500	10 years	€6.00	6 years	34.08%	-0.58%	865

There is no issue of **BSPCE** 2020-1.
The plan **BSPCE** 2018-1 has no vesting period: all founders' 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 12 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 at 30 September 2019, 18.44% as at 31 December 2019 and 28.37% as at 31 December 2021.
The plan **BSPCE 2018-4** has a vesting period of 48 months: one quarter after 12 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 at 31 December 2019, and 16.67% as at 31 December 2020, 16.67% as at 30 June 2021 and 50% as at 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 12 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 12 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 at 31 December 2021 related to the implementation of financing agreements and 50% as at 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 at 31 December 2021 are related to the implementation of financing agreements, and 26.46% as at 31 December 2022 are related to the achievement of specific milestones in the development of clinical trials, and 8.57% as at 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 at 31 December 2021, 40% as at 30 June 2022 and 20% as at 31 December 2022.
The **BSPCE 2021-1** plan has a vesting period for 66.6% 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 33.3% subject to performance conditions linked to the achievement of specific milestones in the development of clinical trials, of which 2.4% as at 30 September 2022, 9.3% as at 31 December 2022, 3.0% as at 31 March 2023, 3.3% as at 30 September 2023, 10.0% as at 31 December 2023, 1.6% as at 31 December 2024 and 3.7% as at 31 December 2025.
The **BSPCE 2021-2** plan has a vesting period spread over 48 months: one quarter after 12 months of their allocation then one forty-eighth over the following 36 months.
The **BSPCE 2021-3** plan has a vesting period for 50.0% 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 50.0% subject to performance conditions linked to the achievement of specific milestones in the development of clinical trials, 12.5% as at 30 June 2022, 12.5% as at 30 June 2023, 8.3% as at 31 December 2023, 8.3% as at 31 December 2024 and 8.3% as at 31 December 2025.
The **BSPCE 2021-4** plan has a vesting period for 33.3% 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 66.6% subject to performance conditions linked to the achievement of specific milestones in the development of clinical trials, of which 12.7% as at 31 December 2022, 5.0% as at 31 March 2023, 12.7% as at 31 December 2023, 16.0% as at 31 December 2024 and 20.3% as at 31 December 2025.
The **BSPCE 2021-5** plan has a vesting period of 36 months: one third after 12 months of their allocation then one thirty-sixth over the following 24 months.
The **BSPCE 2021-6** plan has a vesting period for 20.0% 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 54.0% subject to performance conditions linked to the achievement of specific milestones in the development of clinical trials as at 31 December 2022 for 26.0% subject to market conditions as at 31 March 2023.

Change in the number of founders' share warrants (BSPCEs) outstanding

Number of outstanding options						
Type	**Date of grant**	**31/12/2020**	**Issued**	**Exercised**	**Lapsed**	**31/12/2021**
BSPCE 2018-1	09/04/2018	1,339,866	-	-	(59,184)	1,280,682
BSPCE 2018-2	09/04/2018	838,435	-	-	(460,315)	378,120
BSPCE 2018-3	09/04/2018	359,627	-	-	(359,627)	-
BSPCE 2019-1	10/07/2019	137,500	-	-	(100,000)	37,500
BSPCE 2019-2	10/07/2019	300,600	-	-	(250,500)	50,100
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	-	-	(37,500)	37,500
BSPCE 2020-4	07/12/2020	134,935	-	-	(87,675)	47,260
BSPCE 2020-5	07/12/2020	75,000	-	-	(30,000)	45,000
BSPCE 2021-1	07/12/2020	-	125,000	-	-	125,000
BSPCE 2021-2	07/12/2020	-	30,000	-	-	30,000
BSPCE 2021-3	07/12/2020	-	70,000	-	-	70,000
BSPCE 2021-4	07/12/2020	-	250,000	-	-	250,000
BSPCE 2021-5	07/12/2020	-	30,000	-	-	30,000
BSPCE 2021-6	07/12/2020	-	476,500	-	-	476,500
Total		**3,687,663**	**981,500**	**-**	**(1,384,801)**	**3,284,362**

The vesting conditions (performance conditions and service conditions) defined for each founders' share warrant (BSPCE) plan have not changed since 31 December 2020.

10.3 Allocation of bonus shares (AGA)

The **AGA2021-1** plan of 20 July 2021 has a one-year vesting period followed by a two-year holding period.

The table below summarises the data relating to 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)**
AGA2021-1	20/07/2021	4,050	N/A	N/A	N/A	N/A	N/A	28

Change in the number of AGAs outstanding

Number of outstanding options						
Type	**Date of grant**	**31/12/2020**	**Issued**	**Exercised**	**Lapsed**	**31/12/2021**
AGA2021-1	20/07/2021	-	4,050	-	350	3,700
Total		**-**	**4,050**	**-**	**350**	**3,700**

10.4 Expenses recognised in accordance with IFRS 2 during the periods presented

The Company recorded an expense relating to share-based compensation of €42 thousand as at 31 December 2021 and €959 thousand as at 31 December 2020.
The cumulative expense amounts to €4,993 thousand as at 31 December 2021 and €4,951 thousand as at 31 December 2020.

Note 11: Loans and financial liabilities

Accounting principles

Unless otherwise indicated, loans and financial liabilities are measured at amortised cost calculated using the effective interest rate method in accordance with IFRS 9.
The portion of financial liabilities at less than one year is presented under "Current financial liabilities".

CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amounts in thousands of euros)	31/12/2021	31/12/2020
Repayable advances and innovation loan	13,113	9,489
State-guaranteed loans	2,970	2,155
Bond loan	-	4,593
Other loans and liabilities	2	9
Non-current financial liabilities	**16,085**	**16,248**
Non-current lease liabilities	913	731
Non-current derivative liabilities	-	-
Total non-current financial liabilities	**16,998**	**16,978**
Repayable advances and innovation loan	-	-
State-guaranteed loans	-	-
Pre-financing of research tax credit receivables	-	-
Bond loan	2,410	3,573
Other loans and liabilities	-	-
Bank overdrafts	6	2
Current financial liabilities	**2,416**	**3,575**
Current lease liabilities	337	226
Current derivative liabilities	310	1,351
Total current financial liabilities	**3,063**	**5,152**
Total financial liabilities	**20,061**	**22,131**

Redemption value/balance sheet value reconciliation

(amounts in thousands of euros)	Redemption value		Bifurcation of derivative liabilities	Accrued interest	Amortised cost	Book value at 31/12/2021
	31/12/2020	31/12/2021				
Lease liabilities	957	1,250	-	-	-	1,250
Repayable advances	9,593	13,175	-	-	(61)	13,113
State-guaranteed loans	2,140	2,935	-	35	-	2,970
Pre-financing of the RTC	-	-	-	-	-	-
Kreos bond loan	5,532	1,367	-	-	3	1,370
Financing convertible bond (CB) issue	-	-	-	-	-	-
2018 CBs bond loan	-	-	-	-	-	-
2019 CBs bond loan	4,034	1,000	(1,364)	187	1,217	1,040
Derivative liabilities	1,351	310	-	-	-	310
Other loans and liabilities	10	2	-	-	-	2
Current bank overdrafts	2	6	-	-	-	6
Total financial liabilities	**23,556**	**20,045**	**(1,364)**	**222**	**1,159**	**20,061**

(amounts in thousands of euros)	Redemption value		Bifurcation of derivative liabilities	Accrued interest	Amortised cost	Book value at 31/12/2020
	31/12/2019	31/12/2020				
Lease liabilities	1,013	957	-	-	-	957
Repayable advances	6,032	9,593	-	-	42	9,489
State-guaranteed loans	-	2,140	-	15	-	2,155
Pre-financing of the RTC	669	-	-	-	-	-
Kreos bond loan	7,484	5,532	-	-	(49)	5,481
Financing convertible bond (CB) issue	3,304	-	-	-	-	-
2018 CBs bond loan	3,152	-	-	-	-	-
2019 CBs bond loan	4,009	4,034	(1,364)	-	14	2,684
Derivative liabilities	1,264	1,351	-	-	-	1,351
Other loans and liabilities	48	10	-	-	-	10
Current bank overdrafts	1	2	-	-	-	2
Total financial liabilities	**26,976**	**23,556**	**(1,364)**	**15**	**(77)**	**22,131**

Statement of changes in financial liabilities

CURRENT AND NON-CURRENT FINANCIAL LIABILITIES (Amounts in thousands of euros)	31/12/2020	Collection	Repayment	Impact of amortised cost	New financial liability for rights-of-use	Exit from IFRS 16 contracts	Fair value	Accrued interest	Conversion	Transfers between non-current and current liabilities	31/12/2021
Non-current lease liabilities	731	-	-	-	833	-	-	-	-	(651)	**913**
Repayable advances and innovation loan	9,489	2,529	-	19	-	-	-	1,076	-	-	**13,113**
State-guaranteed loans	2,155	795	-	-	-	-	-	19	-	-	**2,970**
Bond loan	4,593	-	(2,164)	52	-	-	-	-	(2,000)	(481)	-
Derivative liabilities	-	-	-	-	-	-	(41)	-	-	41	-
Other loans and liabilities	9	-	-	-	-	-	-	(8)	-	-	**2**
Non-current financial liabilities	**16,977**	**3,324**	**(2,164)**	**70**	**833**	**-**	**(41)**	**1,088**	**(2,000)**	**(1,091)**	**16,998**
Current lease liabilities	226	-	(283)	-	21	(278)	-	-	-	651	**337**
Pre-financing of the RTC	-	-	-	-	-	-	-	-	-	-	-
Bond loan	3,573	-	(3,000)	1,203	-	-	-	153	-	481	**2,410**
Derivative liabilities	1,351	-	-	-	-	-	(1,000)	-	-	(41)	**310**
Other loans and liabilities	-	-	-	-	-	-	-	-	-	-	-
Bank overdrafts	2	4	-	-	-	-	-	-	-	-	**6**
Current financial liabilities	**5,152**	**4**	**(3,283)**	**1,203**	**21**	**(278)**	**(1,000)**	**153**	**-**	**1,091**	**3,063**
Total financial liabilities	**22,129**	**3,328**	**(5,448)**	**1,273**	**854**	**(278)**	**(1,041)**	**1,241**	**(2,000)**	**-**	**20,061**

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 INNOVATION LOANS (Amounts in thousands of euros)	BPI Innovation AFFLUENT MEDICAL	Project MIVANA – EPYGON	Project MIVANA – KEPHALIOS	Project PIAVE ARTUS – MYOPOWERS	Total
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
At 31 December 2020	**919**	**3,317**	**1,259**	**3,994**	**9,489**
(+) Collection	-	-	-	2,529	2,529
Accrued interest	-	448	104	524	1,076
Financial expenses	19	-	-	-	19
At 31 December 2021	**938**	**3,765**	**1,362**	**7,048**	**13,113**

Breakdown of repayable advances and innovation loans by maturity, in redemption value

MATURITIES OF REPAYABLE 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
At 31 December 2021	**1,000**	**3,763**	**1,362**	**7,047**	**13,175**
Share at less than one year	100	-	-	-	**100**
Share between one and five years	800	2,319	892	6,188	**10,199**
Share at more than five years	100	1,447	470	859	**2,876**

11.1.1 BPI Innovation loan

On 8 April 2020, the Company entered into a contract with Bpifrance for a loan of €1,000 thousand 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 €1,000 thousand 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).

Under IFRS, the fact that the loan bears the payment of a lower annual interest than the market amounts to considering that the Company has benefited from a loan at a rate more favourable than market conditions. The difference between the amount of the loan at historical cost and that of the loan discounted at a marginal debt ratio (3.10%) is considered as a grant received from the State.

11.1.2 Repayable advance for "MIVANA project"

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 an agreement with Bpifrance 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";
- grants of a maximum of €3,122 thousand (including €1,957 thousand for AFFLUENT MEDICAL Group companies).

The aid granted by Bpifrance breaks down into grants and repayable advances.
At this stage, the delays observed in the conduct of clinical trials had negligible effects on the calculation of accrued interest.

Contract between EPYGON and Bpifrance

EPYGON received a total of €2,319 thousand in connection with this agreement 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 (one payment);
- €800 thousand at 30 June 2023 (one payment);
- €1,100 thousand at 30 June 2024 (one payment);
- €1,350 thousand at 30 June 2025 (one payment).

During the 2021 financial year, Epygon renegotiated with Bpifrance in order to reschedule the repayments initially planned. Bpifrance agreed to postpone the final repayment date by 18 months, according to the following calendar:

- €500 thousand at 31 December 2023 (one payment);
- €800 thousand at 31 December 2024 (one payment);
- €1,100 thousand at 31 December 2025 (one payment);
- €1,350 thousand at 31 December 2026 (one payment).

The contract between Bpifrance and EPYGON provides for 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 at 31 December 2021, 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 €1,495 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 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 (one payment);
- €250 thousand at 30 June 2023 (one payment);
- €350 thousand at 30 June 2024 (one payment);
- €450 thousand at 30 June 2025 (one payment).

During the 2021 financial year, KEPHALIOS renegotiated with Bpifrance in order to reschedule the repayments initially planned. Bpifrance agreed to postpone the final repayment date by 18 months, according to the following calendar:

- €100 thousand at 31 December 2023 (one payment);
- €250 thousand at 31 December 2024 (one payment);
- €350 thousand at 31 December 2025 (one payment);
- €450 thousand at 31 December 2026 (one payment).

In addition to the provisional fixed repayment schedule, KEPHALIOS must pay an annuity 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 at 31 December 2021, based on KEPHALIOS revenue forecasts, the Company has made an estimate of the additional payments. The debt was recognised at amortised cost by recognising €499 thousand of accrued interest.

11.1.3 Repayable advance for “PIAVE ARTUS project”

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 grant for €201 thousand and a repayable advance for €7,796 thousand.

The Company received a total of €6,188 thousand in connection with this contract and met the conditions for success of key step 1.

The repayment schedule is as follows: €2,055 thousand per year from 1 September 2023 to 1 September 2026 (four instalments).

In May 2021, the company renegotiated with BPI in order to postpone the due dates of the next key steps as well as the start of the repayment of the advance.
Thus, key step 4 has been postponed by six months to 30 June 2023 (this stage corresponds to the CE or FDA marking and the finalisation of the programme).
The repayment start date of the advance has been postponed to 31 December 2024 and should follow the following repayment schedule:

- €1,949 thousand as at 1 January 2025 (one payment);
- €1,949 thousand as at 1 January 2026 (one payment);
- €1,949 thousand as at 1 January 2027 (one payment);
- €2,451 thousand as at 1 January 2028 (one payment).

As part of the implementation of the repayable advance for the PIAVE ARTUS project (see Note 11.1.4), the Company will have to pay, in addition to the projected fixed repayment schedule, if applicable, an annuity 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 2021, based on revenue forecasts, the Company has made an estimate of the additional payments. The debt was recognised at amortised cost by recognising €864 thousand of accrued interest.
At this stage, the delays observed in the conduct of clinical trials had negligible effects on the calculation of accrued interest.

11.2 State-guaranteed loans

Accounting principles

The Group benefits from State-guaranteed loans (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 State-guaranteed loans to strengthen its cash position in the current context of the Covid-19 pandemic.

As at 31 December 2021, the PGE were classified as non-current financial liabilities.

Change in State-guaranteed loans

CHANGE IN STATE-GUARANTEED LOANS (Amounts in thousands of euros)	BNP Paribas		Société Générale			CIC	Bpifrance	Total
	Affluent Medical		Epygon	Kardiozis	Kephalios	MyoPowers	Affluent Medical	
At 31 December 2019	-	-	-	-	-	-	-	-
(+) Collection	1,000	-	90	160	890	-	-	2,140
(-) Repayment	-	-	-	-	-	-	-	-
(+/-) Accrued interest	8	-	1	1	6	-	-	15
At 31 December 2020	**1,008**	**-**	**91**	**161**	**896**	**-**	**-**	**2,155**
(+) Collection	-	200	-	-	-	395	200	795
(-) Repayment	-	-	-	-	-	-	-	-
(+/-) Accrued interest	7	3	-	1	5	4	-	20
At 31 December 2021	**1,015**	**203**	**91**	**162**	**900**	**399**	**200**	**2,970**

Breakdown of State-guaranteed loans by maturity, in redemption value

MATURITIES OF LOANS GUARANTEED BY THE STATE, IN REDEMPTION VALUE (Amounts in thousands of euros)	BNP Paribas		Société Générale			CIC	Bpifrance	Total
	Affluent Medical		Epygon	Kardiozis	Kephalios	MyoPowers	Affluent Medical	
At 31 December 2021	**1,015**	**203**	**91**	**162**	**900**	**399**	**200**	**2,970**
Share at less than one year	170	-	11	20	113	-	-	**314**
Share between one and five years	845	186	80	142	787	382	179	**2,601**
Share at more than five years	-	17	-	-	-	17	21	**55**

11.2.1 State-guaranteed loans: BNP Paribas

On 6 April 2020, AFFLUENT MEDICAL contracted a loan guaranteed by the French State with optional amortisation over five years with French bank BNP Paribas under the following conditions:

- Amount of the financing: €1,000 thousand;
- 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 State guarantee, under the "FDG État 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 a repayment over four years. The applicable annual interest rate is 1% with a guarantee cost of €21 thousand.
On 15 April 2021, AFFLUENT MEDICAL contracted a loan guaranteed by the French State with optional amortisation over five years with French bank BNP Paribas under the following conditions:

- Amount of the financing: €200 thousand;
- Term: 12 months;
- Annual interest rate: 0.00%;
- Repayment: an annual payment of the principal and interest in arrears after a deferred period of 12 months.

This loan benefits from a State guarantee, under the "FDG État Coronavirus" guarantee fund, of up to 90%.
The Company intends to request an additional grace period of 12 months and repayment over four years.

11.2.2 State-guaranteed loans: Société Générale

On 5 June 2020, EPYGON contracted a loan guaranteed by the State with optional amortisation over five years with French bank 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 State guarantee, under the "FDG État Coronavirus" guarantee fund, of up to 90%.
In March 2021, the company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 0.58% with a cost of the State guarantee premium of €2 thousand.

On 5 June 2020, KARDIOZIS contracted a State-guaranteed loan with optional amortisation over five years with French bank 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 State guarantee, under the "FDG État Coronavirus" guarantee fund, of up to 90%.
In March 2021, the company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 0.58% with a cost of the State guarantee premium of €3 thousand.

On 5 June 2020, KEPHALIOS contracted a State-guaranteed loan with optional amortisation over five years with French bank 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 State guarantee, under the "FDG État Coronavirus" guarantee fund, of up to 90%.
In March 2021, the company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 0.58% with a cost of the State guarantee premium of €19 thousand.

11.2.3 State-guaranteed loans: CIC

On 5 February 2021, MYOPOWERS contracted a State-guaranteed loan with optional amortisation over five years with French bank CIC under the following conditions:

- Amount of the financing: €395 thousand;
- Term: 12 months;
- Annual interest rate: 0.00%;
- Repayment: an annual payment of the principal and interest in arrears after a deferred period of 12 months.

This loan benefits from a State guarantee, under the "FDG État Coronavirus" guarantee fund, of up to 90%.
In November 2021, the company negotiated an additional amortisation period of 12 months which will be followed by a repayment over four years. The applicable annual interest rate is 0.70% with a cost of the State guarantee premium of €8 thousand.

11.2.4 State-guaranteed loans: Bpifrance

On 6 May 2021, AFFLUENT MEDICAL contracted a State-guaranteed loan with optional amortisation over five years with French bank Bpifrance under the following conditions:

- Amount of the financing: €200 thousand;
- Term: 12 months;
- Annual interest rate: 2.35%;
- Repayment: an annual payment of the principal and interest in arrears after a deferred period of 12 months.

This loan benefits from a State guarantee, under the "FDG État Coronavirus" guarantee fund, of up to 90%.
The company intends to request an additional grace period of 12 months and repayment over 4 years.

11.3 Bonds and convertible bonds

Change in bond loans

CHANGE IN BOND LOANS (Amounts in thousands of euros)	KREOS bond loan	Financing CBs 2018	2018 CBs	2019 CBs – Truffle Innovation + Biomed	2019 CBs – Head Leader	Total
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	25	14	338
(-) Repayment	(1,952)	-	-	-	-	(1,952)
(+/-) Accrued interest	-	88	84	79	34	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*
At 31 December 2020	**5,481**	**-**	**-**	**-**	**2,684**	**8,167**
(+) Impact of amortised cost	51	-	-	-	1,203	1,254
(-) Repayment	(2,164)	-	-	-	(3,000)	(5,164)
(+/-) Accrued interest	-	-	-	-	153	153
(+/-) Conversion	(2,000)	-	-	-	-	(2,000)
At 31 December 2021	**1,370**	-	-	-	**1,040**	**2,410**

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 – and €164 thousand in respect of the conversion option for the derivative liability of the 2019 CB – see Note 11.3.4). The net impact on shareholders' equity as at 31 December 2020 amounted to a negative €493 thousand.

On 11 June 2021, the KREOS bond issue was converted into capital for an amount of €2,000 thousand, *i.e.* the issue of 232,558 new ordinary shares. Following this conversion, the loan was subject to a new schedule.

Breakdown of bonds by maturity date, in redemption value

MATURITIES OF BOND LOANS, IN REDEMPTION VALUE (Amounts in thousands of euros)	KREOS bond loan	Financing CBs 2018	2018 CBs	2019 CBs – Truffle Innovation + Biomed	2019 CBs – Head Leader	Total
At 31 December 2021	**1,367**	**-**	**-**	**-**	**1,000**	**2,367**
Share at less than one year	1,367	-	-	-	1,000	**2,367**
Share between one and five years	-	-	-	-	-	**-**
Share at more than five years	-	-	-	-	-	**-**

11.3.1 KREOS non-convertible bond loan

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 loan 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 (BSA 2018-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 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 (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 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 presented in "Other non-current financial assets".
Each BSA 2018-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 BSA 2018-KREOS warrants and the date of exercise, less a discount of 20%.
The exercise period of each share subscription warrant 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 in the Shareholders' Agreement; or iii) the fifth anniversary of the Company's IPO.

Accounting treatment

In accordance with IFRS 9, non-convertible debt is measured using the amortised cost method.
At 31 December 2019, the debt was valued at €7.2 million.

After analysis, the share subscription warrants attached to Tranche A (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.

The fair value has been determined by using the Black&Scholes pricing model with the following main assumptions:

Share subscription warrants issued to KREOS	**Tranche A**			
	Upon issue (26/10/2018)	**31/12/2019**	**31/12/2020**	**31/12/2021**
Number of share subscription warrants	65,574	65,574	65,574	65,574
Strike price	€4.71	€4.71	€4.71	€4.71
Contractual term	5.05	3.87	5.37	5.00
Volatility	34.92%	36.57%	45.98%	39.29%
Risk-free rate	-0.19%	-0.51%	-0.75%	-0.48%
Value of the derivative (in thousands of euros)	**147**	**138**	**178**	**157**
Change in fair value over the period (in thousands of euros)		**(10)**	**40**	**(21)**

Share subscription warrants issued to KREOS	**Tranche B**			
	Upon issue (01/06/2019)	**31/12/2019**	**31/12/2020**	**31/12/2021**
Number of share subscription warrants	65,574	65,574	65,574	65,574
Strike price	€4.71	€4.71	€4.71	€4.71
Contractual term	4.46	3.87	5.37	5.00
Volatility	36.57%	36.57%	45.98%	39.29%
Risk-free rate	-0.51%	-0.51%	-0.75%	-0.48%
Value of the derivative (in thousands of euros)	**144**	**138**	**178**	**157**
Change in fair value over the period (in thousands of euros)		**(6)**	**40**	**(21)**

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.

As part of the Company's IPO, Kreos Capital subscribed for Company shares in the amount of €2 million through debt conversion. Accordingly, following this transaction and the rescheduling of certain monthly maturities, a new debt repayment schedule was put in place.

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 3,000,000 convertible bonds for a total of €3 million.
On 19 June 2020, all convertible bonds were redeemed in new shares, generating the issue of 599,218 shares.

The convertible bonds have the following characteristics:

- 3,000,000 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 CBs 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.

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 €5,000,000 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 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 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 2018 Convertible Bond Loan

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 2019 Convertible Bond Loan

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 2,300,000 convertible bonds (CBs) for the benefit of TRUFFLE Biomedtech Crossover Fund, 1,700,000 for the benefit of Truffle Innov FRR France and 4,000,000 CBs 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:

- 8,000,000 CBs with a nominal value of €1 each were issued at par with a maturity of 60 months, *i.e.* until 10 December 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 CBs – Head Leader	**Upon issue (10/16/2020)**	**31/12/2020**	**31/12/2021**
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	€4.00
Expected term	5	0.42	N/A
Volatility	41.09%	0.00%	N/A
Risk-free rate	-0.81%	0.00%	N/A
Value of the derivative (in thousands of euros)	**1,364**	**1,000**	**-**
Change in fair value over the period (in thousands of euros)		**(364)**	**(1,000)**

(1) According to the agreement, the strike price is reduced by 20% in the event of the securities being floated on a regulated market.

On 25 February 2021, Head Leader Limited notified the Company of its request for the redemption of convertible bonds (CBs) in the event of the listing of the Company's shares for trading on the Euronext Paris regulated securities market. This additional repayment of around €4.1 million (including accrued interest) will be made in the months following completion of admission of the Company's shares to trading on the Euronext Paris regulated market.

Following the success of the IPO in June 2021, the repayment of the Head Leader debt became certain, resulting in the lapse of the conversion option. Consequently, the fair value of the derivative liability is zero. The change in its fair value during the period was recorded in the income statement for €1.0 million. Unamortised expenses (at the IPO date) on the debt component are spread between the IPO date and the date of the end of effective repayment on 28 January 2022.
The Company redeemed the bond in tranches of €1 million each month between October 2021 and January 2022.
At 31 December 2021, a nominal amount of €1 million remained for the 2019 bond to be repaid to Head Leader.

11.4 Debt related to lease liabilities

Change in lease liabilities

CHANGE IN LEASE LIABILITIES (Amount in thousands of euros)	Lease liabilities
At 31 December 2019	**1,013**
(+) Increase	167
(-) Repayment	222
At 31 December 2020	**957**
(+) Increase	854
(-) Repayment	(283)
(-) Early exit from contract	(278)
At 31 December 2021	**1,250**

During the 2021 financial year, lease liabilities increased by €262 thousand after deduction of repayments for the period, corresponding to the following items:

- renewal of the Aix-en-Provence commercial lease and the transfer of ownership between Kephalios and Affluent Medical (exit of the lease for Kephalios in the amount of negative €202 thousand (€311 thousand in gross value and €109 thousand in depreciation) (cumulative) and signature of the lease by Affluent Medical with an impact of €233 thousand);
- extension of the Besançon lease (site of the MyoPowers subsidiary) with impact of +€73 thousand;
- various industrial and IT equipment leased for €231 thousand;
- new premises leased in Italy for €275 thousand.

Breakdown of financial liabilities by maturity, in redemption value

CURRENT AND NON-CURRENT LEASE LIABILITIES (Amount in thousands of euros)	Lease liabilities
At 31 December 2021	**1,250**
Share at less than one year	337
Share between one and five years	692
Share at more than five years	221

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.

In 2021, the Group applied the change in accounting method for calculating pension obligations in line with the IFRS IC decision presented in Note 2.2.

EMPLOYEE BENEFITS COMMITMENTS (Amounts in thousands of euros)	**31/12/2021**	**31/12/2020**
Italian employees	78	58
French employees	18	59
Employee benefits commitments	**96**	**117**

12.1 Italian employees

The main actuarial assumptions used to assess retirement benefits are as follows:

ACTUARIAL ASSUMPTIONS FOR RETIREMENT BENEFITS – Italy	31/12/2021	31/12/2020
Retirement age	Age 67	
Discount rate (IBOXX Corporates AA)	0.98%	0.33%
Mortality table	ISTAT SIM/F 2019 table	
Salary adjustment rate	3.90%	3.60%
Turnover	3.00%	

The provision for retirement commitments has changed as follows:

EMPLOYEE BENEFITS COMMITMENTS (Amounts in thousands of euros)	31/12/2021	31/12/2020
Opening of the period	**258**	**45**
Cost of services rendered	19	20
Financial cost	-	-
Benefits paid	(2)	(7)
Actuarial differences	3	(0)
Close of the period	**78**	**58**

12.2 French employees

The main actuarial assumptions used to assess retirement benefits are as follows:

ACTUARIAL ASSUMPTIONS FOR RETIREMENT BENEFITS – France		31/12/2021	31/12/2020
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)		0.98%	0.33%
Mortality table		INSEE 2019	
Salary adjustment rate		2.00%	
Turnover	Kephalios	Medium	
	Other French entities	High	
Social security charges rate		45%	

The provision for retirement commitments has changed as follows:

EMPLOYEE BENEFITS COMMITMENTS (Amounts in thousands of euros)	31/12/2021	31/12/2020
Opening of the period	**59**	**41**
Cost of services rendered	(6)	15
Financial cost	-	-
Compensation paid	-	-
Actuarial differences	(35)	3
Changes in scope	-	-
Close of the period	**18**	**59**

Note 13: Provisions

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 will 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.

	31/12/2020				
PROVISIONS (Amounts in thousands of euros)	**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**

	31/12/2021				
PROVISIONS (Amounts in thousands of euros)	**Amount at start of the period**	**Provisions**	**Reversals**	**Changes in scope**	**Amount at end of the period**
Provisions for risks	-	-	-	-	**-**
Provisions for litigation	228	55	(153)	-	**130**
Provisions for risks and contingencies	**228**	**55**	**(153)**	**-**	**130**

The Group has set aside a provision of €125 thousand for industrial tribunal disputes that arose in 2020.

During the 2021 financial year, the Company recognised allocations of €55 thousand in connection with labour disputes and provision reversals of €153 thousand corresponding to the end of disputes present at 31 December 2020.

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. It asserts that the development of the Artus medical device reproduces, according to the company, 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 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 an amount of €50 thousand, which has been paid.
Since the decision of 4 June 2020, the proceedings on the merits have resumed: Implantica Marketing Limited has reiterated its claims for damages mentioned above by submissions dated 11 January 2021.

On 8 February 2021, the Implantica patent expired.

The procedure is still ongoing at the closing date of the financial statements.

At 31 December 2020 and 31 December 2021, the Company did not record any provisions for risks and charges in respect of this dispute.

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)	31/12/2021	31/12/2020
Trade payables and related accounts	1,793	2,352
Tax and social security payables	2,137	1,441
Current deferred income	9	350
Current tax liability	31	32
Other debts	69	138
Non-Group current accounts	200	300
Total other current liabilities	**4,239**	**4,613**
Non-current deferred income	-	9
Total other non-current liabilities	**-**	**9**

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.

Note 15: Financial assets and liabilities

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 CBs 2018 and 2019 CB, (see Notes 11.3.2 and 11.3.4) and in respect of share subscription warrants attached to the Kreos non-convertible bond issue (see Note 11.3.1).

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)	31/12/2021		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	457	457	-	457
Other current receivables	3,265	3,265	-	3,265
Cash and cash equivalents	11,410	11,410	11,410	-
Total of balance sheet headings concerning an asset item	**15,132**	**15,132**	**11,410**	**3,722**
Current financial liabilities	2,416	2,416	-	2,416
Current lease liabilities	337	337	-	337
Non-current financial liabilities	16,085	16,085	-	16,085
Non-current lease liabilities	913	913	-	913
Other current liabilities	2,447	2,447	-	2,447
Derivative liabilities	310	310	310	-
Total of balance sheet headings concerning a liability item	**22,508**	**22,508**	**310**	**22,198**

Note 16: Other operating income

OTHER OPERATING INCOME (Amounts in thousands of euros)	31/12/2021	31/12/2020
Research tax credit (RTC)	1,101	380
Grants	350	444
Total other operating income	**1,451**	**824**

Other operating income includes:

- research tax credits for French companies amounting to €1,101 thousand at 31 December 2021 and €380 thousand at 31 December 2020. This increase is explained by the financing of grants and repayable advances received from BPI, which are deducted from the calculation basis of the research tax credit; and
- subsidies spread over the duration of the expenses incurred as part of the project with Bpifrance in the amount of €45 thousand at 31 December 2021 and €36 thousand at 31 December 2020 (see Note 11.1.1) and MIVANA and PIAVE ARTUS development projects (see Notes 11.1.2 and 11.1.3) in the amount of €305 thousand at 31 December 2021 (of which €272 thousand for the MIVANA project and €33 thousand for the PIAVE ARTUS project) and €408 thousand at 31 December 2020.

Note 17: Operating expenses

Operating expenses dedicated to R&D, pre-clinical and clinical activities, regulatory affairs and quality, and excluding general administrative expenses, represent approximately 81% of the Company's total expenses.

17.1 External expenses

External expenses (Amounts in thousands of euros)	31/12/2021	31/12/2020
Fees	(3,440)	(2,969)
Fees relating to the IPO	(1,155)	-
Missions and receptions	(215)	(128)
Maintenance and repairs	(223)	(152)
Advertising, publications, public relations	(20)	(21)
IPO advertisements	(25)	-
Rentals and rental expenses	(64)	(58)
Insurance premiums	(64)	(48)
Studies, research, subcontracting, documentation and seminars	(23)	(9)
Miscellaneous	(267)	(178)
Total external expenses	**(5,496)**	**(3,563)**

As part of its initial public offering in June 2021, the Group incurred expenses which were partially deducted from the share premium and the remainder was recognised in external expenses (see Note 9). This breakdown was made after analysing the nature of each invoice recorded in respect of this IPO

and the concomitant capital increase. Following this analysis, €1,180 thousand in costs were recognised in external expenses for the 2021 financial year.

17.2 Personnel expenses

Personnel expenses (Amounts in thousands of euros)	31/12/2021	31/12/2020
Employee compensation	(3,110)	(2,782)
Social security charges	(1,241)	(976)
Retirement commitments	(11)	(29)
Short-time working compensation	-	52
Share-based payments	(42)	(959)
Total personnel expenses	**(4,405)**	**(4,694)**

The Company's average headcount was 48 as at 31 December 2021 compared to 42 as at 31 December 2020.

17.3 Other current operating income and expenses

Other current operating income and expenses (Amounts in thousands of euros)	31/12/2021	31/12/2020
Net book value of assets sold	(154)	-
Income from assets sold	174	-
Other miscellaneous expenses and income	125	46
Other current operating income and expenses	**145**	**46**

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 2020 and 2021.

Note 19: Net finance income (expense)

Accounting principles

Net finance income (expense) includes all:

- Expenses related to the financing of the Company: interest paid, amortised costs of financial liabilities, accretion of repayable advances;
- Changes in the fair value of derivative liabilities.

Foreign exchange gains and losses are also recognised in net finance income (expense).

Breakdown of financial income and expenses

FINANCIAL INCOME AND EXPENSES (Amounts in thousands of euros)	31/12/2021	31/12/2020
Net borrowing cost	**(3,055)**	**(2,165)**
Income from cash and cash equivalents	-	-
Interest expenses	(3,036)	(2,129)
Effect of accretion	(19)	(36)
Other financial income and expenses	**1,045**	**629**
Foreign exchange income	-	1
Change in fair value of derivative liabilities (1)	1,041	597
Other	4	30
Net finance income (expense)	**(2,010)**	**(1,536)**

The interest expense under IFRS 16 amounted to €41 thousand in 2021 and €37 thousand in 2020.

(1) See Note 11.3.1 “KREOS non-convertible bond loan” and 11.3.4 “Convertible Bond Loan 2019”.

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 tax is 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 book value 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 €85,279 thousand as at 31 December 2021.

The income tax rate applicable to Affluent Medical is the current rate in France, *i.e.* 26.5%. 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 2021.

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)	**31/12/2021**	**31/12/2020**
Net income (loss)	(14,820)	(14,319)
Neutralisation		
Share of equity affiliates	(14)	(398)
Consolidated tax	437	209
Tax credits	1,101	380
Profit (loss) before tax	**(16,344)**	**(14,509)**
Current tax rate	26.50%	28.00%
Theoretical tax at the current rate	**4,331**	**4,063**
Permanent differences	(73)	181
Share-based payments	(11)	(269)
Non-capitalised tax loss, adjusted for deferred taxation	(3,812)	(3,770)
Effect of tax rate differences	3	4
Other	(1)	(0)
Income taxes	**437**	**209**
Effective tax rate	2.9%	1.5%

Type of deferred tax

NATURE OF DEFERRED TAX (amounts in thousands of euros)	31/12/2021	31/12/2020
Other temporary differences	93	181
Deferred tax loss in France	21,320	19,176
Total items that are deferred tax assets	**21,413**	**19,357**
Valuation difference on technologies developed in-house	(4,946)	(6,001)
Other temporary differences	(2,173)	(1,515)
Total deferred tax liabilities	**(7,119)**	**(7,516)**
Total deferred tax items	**14,294**	**11,841**
Unrecognised deferred tax assets	(16,267)	(14,282)
Deferred tax assets (liabilities), net	**(1,973)**	**(2,440)**

Loss carried forwards

LOSS CARRIED FORWARDS AS BASE (amounts in thousands of euros)	31/12/2021	31/12/2020
France	85,279	68,487
Italy	-	-
Total	**85,279**	**68,487**
Of which activated	11,893	17,481

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 and founders' 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	31/12/2021	31/12/2020
Net income for the year (in thousands of euros)	(14,820)	(14,319)
Weighted average number of shares outstanding over the period	16,873,582	13,360,416
Weighted average number of shares for diluted earnings over the period	16,873,582	13,360,416
Basic earnings per share (€/share)	(0.88)	(1.07)
Diluted earnings per share (€/share)	(0.88)	(1.07)

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 2021, the Company's dilutive instruments consisted of:

- share subscription warrants attached to KREOS non-convertible bonds, see Note 11.3.1;
- BSAs, BSPCEs and AGA shares granted to employees, members of the Board of Directors, external service providers, see Notes 10.1 and 10.2.

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 expense are located in France and Italy, and in China through the Joint Ventures.

The Group's non-current assets amounted to €55,338 thousand as at 31 December 2021 broken down geographically as follows: €54,164 thousand in France, €1,174 thousand in Italy and €0 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)	31/12/2021	31/12/2020
Fixed compensation	253	253
Variable compensation paid	88	36
Consulting fees	-	2
Benefits in kind	11	11
Directors' fees	55	48
Share-based payments	(85)	540
TOTAL	**322**	**890**

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).

The 2019 CB 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).

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 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 and 11.1.3) 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 2021:

(Amounts in thousands of euros)	Project MIVANA – EPYGON	Project MIVANA – KEPHALIOS	Project PIAVE ARTUS – MYOPOWERS
Effective interest rates used to calculate accrued interest	13.21%	12.62%	6.78%
Effective interest rates if revenue assumptions increased by 10 points	13.34%	13.30%	6.82%
Impact on accrued interest as at 31 December 2021	€16 thousand	€29 thousand	€4 thousand

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 book value 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 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 2021, the Company's cash amounted to €11,410 thousand, compared to €5,650 thousand as at 31 December 2020. 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 €12,364 thousand and negative €8,936 thousand respectively for the financial years ended 31 December 2021 and 2020. As at 31 December 2021, the Company's net loss amounted to €14,820 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 September 2022.

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 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 2021 were prepared on a going concern basis (see Note 2.1). 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 2021 12 months		Financial year 2020 12 months	
(Amounts excl. tax in thousands of euros)	**PWC**	**EXPERTEA**	**PWC**	**EXPERTEA**
Statutory audit assignment				
Affluent Medical	72	298	45	22
Fully consolidated subsidiaries	49	-	50	-
Services other than the certification of financial statements (1)	150	18		
Sub-total	**271**	**47**	**95**	**22**
Other services rendered				
- Tax	-	-	-	-
- Other	-	-	-	-
Sub-total	**-**	**-**	**-**	**-**
Total	**271**	**47**	**95**	**22**

(1) Services other than the certification of financial statements, covering mainly services required under capital increases and the work done for the Company's listing on the stock exchange.

Note 27: Post-closing events

In February 2022, the Group signed an amendment to the PGE loans contracted with BPI and BNP for €0.2 million each, opting for an additional deferred repayment of 12 months, then amortisation over 4 years, thus setting the maturity date of the BNP loan on 15 April 2027, with a rate of 0.75%, and that of the BPI at a rate of 3.35% on 31 May 2027.

Consequences of the conflict in Ukraine

The war in Ukraine launched by Russian forces on 24 February 2022 will have significant economic and financial consequences worldwide.

The sanctions imposed on Russia will have considerable impact on companies with operations or business relations with Russia.

As at 31 December 2021, the Group had no activity or business relationship with Russia.

However, the Group's activities could be impacted by the direct or indirect consequences of the conflict, which it is not possible to quantify with precision at this time.

The Group could be exposed in several ways:

- Supply problems, particularly for metals (titanium, etc.), polymers or electronics;
- Increase in product development costs in line with the surge in raw materials and energy.

18.1.1.2 Consolidated financial statements prepared under IFRS as at 31 December 2019 and 2020

The Universal Registration Document incorporates by reference the consolidated financial statements prepared in accordance with IFRS for the financial years ended 31 December 2020 and 31 December 2019, presented in the registration document approved by the AMF on 12 April 2021 under approval number I. 21-007. These financial statements were the subject of an audit report issued by the Company's Statutory Auditors.

18.1.1 Change of accounting reference date

N/A

18.1.2 Accounting standards

The Group's consolidated financial statements have been prepared in accordance with IFRS international accounting standards.

18.1.3 Change in accounting standards

N/A

18.1.4 Date of latest financial reporting

Financial year ended 31 December 2021

18.2 Interim and other financial reporting

N/A

18.3 Statutory Auditors 'report on the consolidated financial statements at 31 December 2021

PricewaterhouseCoopers Audit
63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

EXPERTEA AUDIT
60, boulevard Jean Labro
13016 Marseille

Report of the Statutory Auditors on the consolidated financial statements

Year ended 31 December 2021

This is a free translation into English of the Statutory Auditors' report issued in French and is provided solely for the convenience of English speaking readers. This report includes information specifically required by European regulations or French law. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

To the General Meeting
AFFLUENT MEDICAL
320, avenue Archimède
13100 Aix-en-Provence, France

Opinion

In compliance with the engagement entrusted to us by your General Meeting, we audited the accompanying consolidated financial statements of AFFLUENT MEDICAL for the year ended 31 December 2021.

We certify that the consolidated financial statements are, in accordance with IFRS as adopted by the European Union, regular and fair and give a true and fair view of the results of operations for the past financial year as well as of the financial position and assets at the end of the financial year of the group consisting of the persons and entities included in the consolidation scope.

The opinion expressed above is consistent with the content of our report to the Audit Committee.

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 performed our audit task in compliance with the independence rules laid down in the French Commercial Code and by the Code of Ethics for the profession of Statutory Auditors over the period from 1 January 2021 to the date on which our report is issued. In particular, we have not provided any services prohibited by Article 5, paragraph 1, of Regulation (EU) 537/2014.

Justification of assessments – Key audit matters

Due to the global crisis related to the Covid-19 pandemic, the consolidated financial statements for this year have been prepared and audited under specific conditions. Indeed, this crisis and the exceptional measures taken in the context of the health emergency have multiple consequences for companies, particularly on their activity and their financing, as well as increased uncertainties about their future prospects. Those measures, such as travel restrictions and remote working, have also had an impact on the companies' internal organisation and on audit performance.

It is in this complex and evolving context that, in accordance with the provisions of Articles L. 823-9 and R. 823-7 of the French Commercial Code relating to the justification of our assessments, we bring to your attention the key points of the audit relating to the risks of material misstatement that, in our professional judgment, were the most significant for the audit of the consolidated financial statements of the year, as well as our responses to those risks.

These assessments were made in the context of the audit of the consolidated financial statements taken as a whole and the formation of our opinion expressed above. We do not express an opinion on the items of these consolidated financial statements taken in isolation.

Goodwill and intangible assets

Risk identified

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 difference between the acquisition cost of the securities and the total measurement of the assets and liabilities identified at the acquisition date constitutes goodwill. Technologies developed in-house were also provided. At 31 December 2021, goodwill amounted to €32.2 million (*i.e.* 46% of the total balance sheet) and technologies to €20.7 million.

Goodwill is subject to annual impairment testing and technologies are tested for impairment as soon as there is an indication of loss in value according to the methods described in Notes 3 "*Goodwill*" and 4.3 "*Impairment of intangible and property, plant and equipment*" to the consolidated financial statements.

The impairment test consists of comparing the net book value of the asset tested with its recoverable amount, which corresponds to its fair value less costs to sell or its value in use, if this is higher.

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 selling costs.

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.

Minor delays in the implementation of the Company's clinical programs in 2021 and 2020 due to the Covid-19 health crisis (see Note 2.7 to the consolidated financial statements "*Impact of the Covid-19 health crisis on the consolidated financial statements as at 31 December 2021*") were not considered to indicate impairment of technologies.

We considered that the valuation of goodwill constitutes a key point of our audit given its significant nature, the reliance on management judgement when assessing underlying assumptions such as the estimated development cycle of clinical trials, the discount rate or the perpetual growth rate and the sensitivity of the valuation to these assumptions.

Audit procedures implemented in response to this risk

We examined the methods used to implement the goodwill valuation test.

We assessed the reasonableness and relevance of the business plans used by management to estimate the progress and cost of the studies, the commercial forecasts as well as the probabilities of clinical success, based on available information.

We performed a sensitivity analysis of the fair value to a change in these main assumptions.

We assessed the appropriateness of the information provided in the notes to the consolidated financial statements.

Financing

Risk identified

Affluent Medical is a group developing next-generation minimally invasive medical devices in the field of urology and structural heart. The company has launched significant research and development (R&D) expenditures and is still anticipating significant financing needs to be able to continue its clinical studies.

Based on the financing lines obtained and its current cash position, management considers that the company has sufficient cash to finance its working capital requirement until the end of September 2022. As mentioned in the "Going concern" paragraph of Note 2.1 "*Principles applied to the preparation of the financial statements*" to the consolidated financial statements, management has therefore approved the consolidated financial statements for the year ended 31 December 2021 by adopting the principle of going concern despite the losses accumulated since the creation of the company.

Various financing solutions are envisaged and could, without being restrictive, take the form of private placements with investors, capital increases, setting up a bond loan and securing public funding.

Insofar as its financing needs are significant and the Group is dependent on the progress and results of its research programs, the decisions of its other strategic partners, the awarding of grants and market interest for such investments, we considered financing and going concern a key point of our audit.

Audit procedures implemented in response to this risk

We reviewed the method used to prepare the company's cash flow forecasts and carried out a critical review of the cash flow forecasts.

We assessed the reasonableness of the key underlying assumptions such as R&D expenses, other operating expenses and the appropriateness of the discount rate used, particularly in the context of the current crisis, and assessed management's ability to prepare reliable forecasts by comparing current forecasts with forecasts from previous years and by examining, where applicable, the causes of any differences identified.

We assessed the impact of a change in assumptions on cash flow forecasts.

We examined the consistency of these assumptions with the latest cash flow forecasts drawn up by management as approved by the Board of Directors.

We reviewed the refinancing projects presented to the Board of Directors and satisfied ourselves that the refinancing arrangements and amounts proposed would enable the company to meet its commitments over the next 12 months.

We assessed whether the information given in the notes on maintaining the going concern principle was appropriate for the closing of the financial statements at 31 December 2021.

Research tax credit (RTC)

Risk identified

As the Group has an R&D activity, it benefits from the research tax credit.

As described in the paragraph "Research tax credit (RTC)" in Note 7 "*Other receivables*", research tax credits are granted by the French State to the Group's French companies in order 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 repaid for the excess portion.

The research tax credit may be audited by the French tax authorities.

During the 2021 financial year, the Group obtained the payment of the research tax credit of €0.5 million relating to the expenses for 2020 and recognised in accrued income a receivable of €1.0 million for the 2021 expenses.

We considered the research tax credit to be a key point of our audit given the eligibility conditions of the costs included in the calculation base as well as the methods for determining the amount to be received due to the complexity of the rules and legislation.

Audit procedures implemented in response to this risk

On the basis of sampling, we have:

- reconciled the eligible expenses on the basis of the texts in force with the corresponding supporting documents;

- verified the eligibility and amount of the salary costs allocated by the company to R&D;

- compared estimated research tax credits recorded in previous periods with the amounts actually received in order to assess the reliability of the process implemented by management to calculate the amount of the research tax credit.

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.

Other verifications or information laid down in legislation or regulations

Format of presentation of the consolidated financial statements intended to be included in the annual financial report

In accordance with professional standards on the Statutory Auditors' work relating to the annual and consolidated financial statements presented in the single European electronic reporting format, we have also verified compliance with this format defined by the Commission Delegated Regulation (EU) 2019/815 of 17 December 2018 for presentation of the annual financial statements intended to be included in the annual financial report mentioned in I of Article L. 451-1-2 of the French Monetary and Financial Code, prepared under the responsibility of the Chairman and Chief Executive Officer. With regard to the consolidated financial statements, our procedures include verifying that the mark-up of these financial statements complies with the format defined by the aforementioned regulation.

Based on our work, we conclude that the presentation of the consolidated financial statements intended to be included in the annual financial report complies, in all material respects, with the single European electronic reporting format.

It is not our responsibility to verify that the consolidated financial statements that will be included by your company in the annual financial report filed with the AMF correspond to those on which we carried out our work.

Nomination of the Statutory Auditors

We were appointed Statutory Auditors of AFFLUENT MEDICAL by your General Meeting of 6 February 2018 in respect of PricewaterhouseCoopers Audit and 30 December 2020 in respect of Expertea.

At 31 December 2021, PricewaterhouseCoopers Audit was in the fourth uninterrupted year of its mission and Expertea in its second year, including one year since the company's shares were admitted for trading on a regulated market.

Responsibilities of management and those charged with governance for the consolidated financial statements

It is the responsibility of management to prepare consolidated financial statements presenting a true and fair view in accordance with IFRS as adopted by the European Union and to implement the internal control that it deems necessary for the preparation of consolidated financial statements that are free from material misstatements, 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 the company is expected to be liquidated or to cease operations.

The Audit Committee is responsible for monitoring the process of preparing financial reporting and monitoring the effectiveness of the internal control and risk management systems, as well as the internal audit system as regards the procedures for preparing and processing of accounting and financial reporting.

The consolidated financial statements were approved by the Board of Directors.

Statutory Auditors’ responsibilities for the audit of the consolidated financial statements

Objectives and audit procedure

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.
Furthermore, he or she:

- 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 or her 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 or her 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 reporting of the entities or business activities within the Group to express an opinion on the consolidated financial statements. The Statutory Auditor is responsible for the direction, supervision and performance

of the audit of the consolidated financial statements and for the opinion expressed on these consolidated financial statements.

Report to the Audit Committee

We submit a report to the Audit Committee which presents the scope of the audit work and the work program implemented, as well as the conclusions arising from our work. We also draw to its attention, any significant weaknesses identified by us in internal control as regards the preparation and processing of accounting and financial reporting.

Among the elements communicated in the report to the Audit Committee are the risks of material misstatement, which we consider to have been the most significant for the audit of the consolidated financial statements of the financial year and which therefore constitute the key points of the audit. It is our responsibility to describe these key points in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) 537/2014 confirming our independence, within the meaning of the rules applicable in France such as they are set in particular by Articles L. 822-10 to L. 822-14 of the French Commercial Code and in the Statutory Auditors' Code of Ethics. Where appropriate, we meet with the Audit Committee to discuss the risks to our independence and the safeguarding measures applied.

Prepared in Neuilly-sur-Seine and Marseille, on [date] March 2022

The Statutory Auditors

PricewaterhouseCoopers Audit	EXPERTEA AUDIT
Thierry Charron	Jérôme Magnan

18.4 Parent company financial statements at 31 December 2021

BALANCE SHEET

Assets			At 31/12/2021 Gross Amount	At 31/12/2021 Depr. or Allow.	At 31/12/2021 Net amount	At 31/12/2020
Uncalled subscribed capital						
Fixed assets	Intangible fixed assets	Start up costs				
		Research and development costs				
		Franchises, patents and similar assets	1,575	1,431	143	668
		Goodwill (1)				
		Other intangible fixes assets				
		Intangible assets in progress				
		Advance payments on intangible fixed assets				
		TOTAL	**1,575**	**1,431**	**143**	**668**
	Tangible fixed assets	Land				
		Buildings				
		Industrial fixtures and equipment				
		Other tangible fixed assets	13,068	1,900	11,168	2,069
		Tangible fixed assets in progress	17,898		17,898	
		Advance payments on tangible fixed assets				
		TOTAL	**30,967**	**1,900**	**29,067**	**2,069**
	Financial fixed assets	Investments measured using the equity method				
		Other investments	83,034,657		83,034,657	83,034,657
		Loans to group and related companies				
		Investments held in portfolio for the long term				
		Other investments	420,960	50,899	370 060	
		Loans	75,913		75 913	47,945
		Other financial assets	96,492		96 492	6,235
		TOTAL	**83,628,023**	**50,899**	**83 577 124**	**83,088,839**
		Total fixed assets	**83,660,566**	**54,231**	**83,606 ,335**	**83,091,577**
Current assets	Inventories	Raw materials and supplies				
		Work in progress (goods)				
		Work in progress (services)				
		Finished goods and by-production				
		Merchandise				
		TOTAL				
	Advances to suppliers					
	Receivables	Trade accounts receivable	6,699,319		6,699,319	4,508,604
		Other receivables	10,032,778		10,032,778	1,338,270
		Unpaid called capital				
		TOTAL	**16,732,097**		**16,732,097**	**5,846,875**
	Other	Marketable securities				
		(of which own shares :)				
		Cash instruments				
		Available funds	10,671,268		10,671,268	5,024,290
		TOTAL	**10,671,268**		**10,671,268**	**5,024,290**
Prepaid expenses			114,089		114,089	172,934
		Total current assets	**27,517,455**		**27,517,455**	**11 044 100**
Deferred charges						
Premiums on redemption of borrowings						
Exchange rate differences assets						
		TOTAL ASSETS	**111,178,022**	**54,231**	**111,123,791**	**94,135,678**
Deferrals:		(1) Including lease rights (2) Of which the portion at less than one year (gross) of financial assets (3) Including receivables at more than one year (gross)			75,913	

Retention of title clause		Fixed assets		Inventories		Trade receivables	

Liabilities		At 31/12/2021	At 31/12/2020
Shareholders' funds	Share capital (of which paid up : 18 163 802)	18,163,802	15 256 824
	Share premiums (mergers, contributions)	80,546,104	62 683 436
	Revaluation variance		
	Equity reserve		
	Reserves		
	Legal reserves	2,500,001	
	Statutory reserves		
	Tax regulated reserves		
	Other reserves		
	Profit and loss account brought forward	-748,956	-643 623
	Previous results not yet alloted		
	Result for the financial year (profit or loss)	168,101	-105 333
	Net worth before allocation	**100,629,052**	**77 191 303**
	Investment grants Special provision for tax purposes		
	Total	**100,629,052**	**77,191,303**
Other funds	Subordinated equity Advances subject to covenants		
	Total		
Provisions	Provisions for risks		35,000
	Provisions for future costs		
	Total		**35,000**
Liabilities	Financial liabilities		
	Convertible debenture loans	1,187,202	4,040,024
	Other debenture loans		
	Borrowing from credit institution (2)	3,515,982	7 277 884
	Other borrowings (3)	3,669,251	3 662 426
	Total	**8,372,436**	**14 980 335**
	Advances received on orders (1)		
	Trade accounts payable and related liabilities	522,034	664,363
	Taxes and social debts	1,531,690	1,239,650
	Liabilities related to fixed assets		
	Other debts	68,577	25 025
	Cash instruments		
	Total	**2,122,302**	**1,929,039**
	Deferred income		
	Total liabilities and income recorded in advance	**10,494,738**	**16,909,374**
	Exchange rate differences liabilities		
	TOTAL LIABILITIES	**111,123,791**	**94,135,678**

	Leasing for buildings			
	Leasing for other equipment			
	Non expired discounted notes receivable			
	Payables and deferred income, except (1)	at more than one year	1,726,317	7,940,115
		less than a year	8,768,421	8,969,259
	Forwards: (2) Of which bank overdrafts and credit balances			
	(3) of which participating loans			

INCOME STATEMENT

			France	Export	From 01/01/2021 At 31/12/2021 12 months	From 01/01/2020 At 31/12/2020 12 months
Operating income (1)	Sales of purchased goods					
	Sales of manufactured goods					
	Sales of services		5,756,836		5,756,836	3,938,911
	Net sales		**5,756,836**		**5,756,836**	**3,938,911**
	Changes in stock of manufactured goods and work in progress					
	Production of fixed assets capitalised					
	Partial profits on long term contracts					
	Trading incentive grants					
	Write-back of depreciation, provisions and transferred charges				65,591	64,273
	Other income				7	92
		Total			**5,822,434**	**4,003,277**
Operating expenses (2)	Goods Purchases					
	Changes in inventory					
	Raw materials and other supplies	Purchases				
		Changes in inventory				
	Other purchases and expenses (3)				3,239,588	1,450,547
	Taxes				43,226	36,943
	Wages and salaries				1,194,350	1,153,145
	Social security charges				486,846	454,909
	Depreciation and Provisions	• on fixed assets	Depreciation		1,235	1,176
		• on current assets: provisions	Provisions			
		• for risks and future costs: provisions				35,000
	Other expenses				63,769	52,833
		Total			**5,029,018**	**3,184,556**
		Operating result	A		**793,416**	**818,720**
Joint venture oper.	Profit attributed or loss transferred		B			
	Loss attributed or profit transferred		C			
Financial income	From shares in group companies (4)					59,756
	From other investments (4)				3,960	2,884
	Interests and similar incomes (4)				26,338	43,191
	Write-back of provisions and transferred charges				67,407	
	Exchange gain					
	Net profit on disposals of current financial investments					
		Total			**97,706**	**105,832**
Financial expenses	Increase of provisions against financial assets				118,307	
	Interests payable and similar charges (5)				629,714	1,029,886
	Exchange loss					
	Net losses on disposals of current financial investments					
		Total			**748,022**	**1,029,886**
		Net financial result	D		**-650,315**	**-924,054**
RESULT OF ORDINARY OPERATIONS BEFORE CORPORATE TAX ON PROFIT (±A+B-C±D)			E		**143 101**	**-105,333**
Exceptional income	On operating items					
	On capital items				25,000	
	Write-back of provisions and transferred charges					
		Total			**25,000**	
Exceptional expenses	On operating items					
	On capital items					
	Depreciation and provisions					
		Total				

Net exceptional result	F	**25,000**	
Employees' profit sharing plan	G		
Corporate tax on profit	H		
PROFIT OR LOSS (± E ± F - G -H)		**168,101**	**(105,333)**
Referrals			
(1) O / w Operating income relating to prior years after-tax impact of error corrections			
(2) O / w Operating expenses relating to prior years after-tax impact of error corrections			
(3) Including - fees from furniture leasing - real estate leasing fees		59,855	59,855
(4) Of which income from related entities			
(5) Of which interest from related entities			

1. Significant events of the year

1.1 Main events

Capital transactions

Following an IPO in June 2021, the Company carried out a €25 million capital increase in cash.

Debt conversion

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 for a maximum total amount of €8 million.
As part of the Company's IPO, Kreos Capital subscribed for Company shares in the amount of €2 million through debt conversion. Accordingly, following this transaction and the rescheduling of certain monthly maturities, a new debt repayment schedule was put in place.
This loan repayable monthly matures in November 2022.

Convertible bonds

A bond issue of €8 million was launched in December 2019 (2019 CBs). Head Leader Limited (China), partner of Affluent Medical in its two joint ventures in Shanghai, contributed €4 million. 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 repayment of €4 million (accrued interest not included) was made in the amount of €3 million over 2021. The repayment of the balance took place at the end of January 2022.

Borrowings

In March 2020, the Company took out a loan guaranteed by the French State with optional amortisation over five years, with BNP Paribas for an amount of €1 million, for a period of 12 months, after a deferral period of one year, at a rate of 0%.
By amendment dated 4 February 2021, the Company opted for an additional deferred repayment of 12 months, then amortisation over four years, thus setting the maturity date of the loan on 6 April 2026, at a rate 1%. The first deadline will be in May 2022.

In April 2021, the Company took out two other State-guaranteed loans with BNP and BPI, for €0.2 million each, at zero interest, for a period of one year, maturing in April 2022. The contract provides for optional repayment of the loan, with deferral for a maximum period of five years after the maturity date.

Cash advance

Affluent Medical and its subsidiaries signed a cash management agreement for a period of ten years, renewable automatically and for successive five-year periods. The interest rate applicable to the sums made available is 0.5%.

Operational activity

Despite the health crisis, Affluent Medical continued to roll out its development program, and in particular its pre-clinical and clinical studies.

The main milestones achieved are as follows:

- Success of the first post-operative adjustment of the Kalios mitral ring;
- Authorisation of the competent Spanish and Italian authorities for the launch of the Minerva pilot clinical study;
- Authorisation of the competent Czech authorities for the launch of the pivotal clinical study DRY ARTUS;
- Start of the pre-clinical study for new sizes of the Epygon mitral valve;
- Freeze design of the MyoPowers system;
- Preparation of the pre-clinical study on MyoPowers;
- Initiation of the FIH MINERVA clinical study with the Epygon valve;
- Renewal of ISO 13486 certificates for Epygon, Kephalios and MyoPowers;
- Strengthening of the MyoPowers operational team;
- Extension of the R&D sites in Aix-en-Provence, Besançon and Colleretto Giacosa in Italy, the latter two being equipped with clean rooms.

Governance and management

Reinforcement of the management team with the arrival of Eric Jague as Regulatory Affairs Director.

Going concern

The Company focuses on the invention and development of new medical devices. The Company's loss-making position is not unusual given the stage of development of its products.

The Company has successfully financed its activities to date mainly through the IPO, fundraising, the issuance of convertible and non-convertible bonds and the arrangement of loans.

The Company's financial statements at 31 December 2021 were prepared on a going concern basis.

The Board of Directors continues to actively study various solutions to continue financing its business and its development beyond its liquidity horizon.

These solutions could, without being restrictive, involve private placements to investors, capital increases, setting up bonds and obtaining public financing.

Covid-19 health situation

In 2021, activities were affected by Covid-19.
It should be noted that the Company followed government recommendations by implementing teleworking, but did not use the partial activity system in 2021.

The Company signed a teleworking agreement following a referendum held in November 2021, two days a week for all volunteer employees.

Due to the coronavirus, the Group had to deal with delays in its clinical study programs due to the mobilisation of hospitals to contain the health crisis:

- in the patient recruitment process for the pivotal European study of the Kalios medical device, leading to a slowdown in patient recruitment and thus an extension of the planned duration of the study by approximately one year with the recruitment of around fifty patients delayed. The follow-up of the implanted patients as well as the adjustments with the Kalios medical device could be carried out normally;
- in patient identification as part of the preparation of the clinical study on Epygon and Artus medical devices.

In addition to the above, the consequences of the health crisis linked to the Covid-19 pandemic contributed to postponing deadlines and increasing the cost of the programme of pre-clinical and clinical studies on the Artus, Kalios and Epygon medical devices:
delays in obtaining marketing authorisations from the administrative and regulatory authorities

- supply delays due to the global shortage of certain supplies and equipment needed to manufacture medical devices;
- delays in the manufacture of devices internally or at suppliers' sites following the infection of qualified personnel or contact of such personnel;
- delays or difficulties in launching clinical trials, including difficulties in recruiting and training investigators and clinical site staff, but also in opening new sites in current countries or in new countries;
- the mobilisation of healthcare staff usually dedicated to conducting clinical studies to respond to Covid-19 emergencies;
- 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 measures taken with regard to the Covid-19 pandemic.

1.2 Significant events after the balance sheet date

In February 2022, the Company signed an amendment to the PGE loans contracted with BPI and BNP for €0.2 million each, opting for an additional deferred repayment of 12 months, then amortisation over four years, thus setting the maturity date of the BNP loan on 15 April 2027, with a rate of 0.75%, and that of the BPI at a rate of 3.35% on 31 May 2027.

Consequences of the conflict in Ukraine

The war in Ukraine launched by Russian forces on 24 February 2022 will have significant economic and financial consequences worldwide.
The sanctions imposed on Russia will have considerable impact on companies with operations or business relations with Russia.

As at 31 December 2021, the Company had no activity or business relationship with Russia.

However, the Company's activities could be impacted by the direct or indirect consequences of the conflict, which it is not possible to quantify with precision at this time.

The Company could be exposed in several ways:
• Supply problems, particularly for metals (titanium, etc.), polymers or electronics;
• Increase in product development costs in line with the surge in raw materials and energy.

1.3 Accounting principles, rules and methods

The annual financial statements were approved in accordance with the provisions of the French Commercial Code and ANC Regulation 2014-03.

The general accounting conventions have been applied in compliance with the principle of prudence, in accordance with the basic assumptions: going concern, consistency of accounting methods from one financial year to another, independence of financial years, in accordance with the general rules of preparation and presentation of annual financial statements.

The parent company financial statements were prepared on a going concern basis, taking into account the financing acquired and available and the support of the majority shareholder.

2. Information on balance sheet and income statement items

2.1 Fixed assets

2.1.1 Statement of fixed assets (gross)

Fixed assets		Start of the year	Increases	Decreases	Value at year-end
Intangible	Start-up and development costs – **TOTAL I**	-	-	-	-
	Other intangible asset items – **TOTAL II**	1,575	-	-	1,575
Tangible	Land	-	-	-	-
	Construction on clean soil	-	-	-	-
	Construction on third-party land	-	-	-	-
	General installations, fixtures and fittings of buildings	-	-	-	-
	Plant and equipment	-	-	-	-
	General installations, fixtures and fittings	3,259	-	-	3,259
	Transport equipment	-	-	-	-
	Office equipment and IT furniture	-	9,810	-	9,810
	Reusable containers and miscellaneous	-	-	-	-
	Tangible assets in progress	-	17,899	-	17,899
	Advances and prepayments	-	-	-	-
Total III		3,259	27,709	-	30,968
Financial	Investments valued by equity method	-	-	-	-
	Other investments	83,034,658	-	-	83,034,658
	Other long-term investments	-	574,407	153,446	420,961
	Loans and other financial assets	54,181	692,938	574,714	172,405
TOTAL IV		83,088,839	1,267,345	728,160	83,628,024
GENERAL TOTAL (I + II + III + IV)		83,093,673	1,295,054	728 160	83,660,566

2.1.2 Depreciation of fixed assets

SITUATIONS AND MOVEMENTS DURING THE AMORTISATION YEAR					
DEPRECIABLE FIXED ASSETS		Amount of depreciation at the beginning of the financial year	Increases: allocations for the year	Decreases: amortisation of discontinued assets and reversals	Amount of depreciation at the end of the financial year
Start-up and development costs – **TOTAL I**		-	-	-	-
Other intangible assets – **TOTAL II**		906	525	-	1,431
Land		-	-	-	-
Buildings	On clean ground	-	-	-	-
	On third-party land	-	-	-	-
	General installations, fixtures and fittings of buildings	-	-	-	-
Plant and equipment		-	-	-	-
Other tangible assets	General installations, fixtures and fittings	1,189	652	-	1,841
	Transport equipment	-	-	-	-
	Office and IT equipment, furniture	-	59	-	59
	Reusable containers and miscellaneous	-	-	-	-
Total III		1,189	711	-	1,900
GENERAL TOTAL. (I + II + III)		2,095	1,236	-	3,331

2.1.2.1 Depreciation and amortisation periods

Depreciation is calculated on a straight-line basis over the expected useful life.

* Industrial equipment: 5 years
* IT equipment: 3 years

The depreciation period used is the useful life for assets that cannot be broken down at the outset.
At the balance sheet date, the Company assessed, based on the internal and external information at its disposal, whether the assets may have significantly lost value.

2.1.3 Financial assets

- Equity interests

Equity interests are valued at their acquisition cost. Impairment is recognised when the inventory value is lower than the gross value. Inventory value is estimated on the basis of the share of the net book value, revalued, if necessary, to take into account profitability generated by the company concerned or the recoverable value of the securities.

2.1.4 Information on subsidiaries and associates

A. Detailed information on subsidiaries and associates

Subsidiaries **(+ 50% share capital held)**	**Capital** **Res. and carry forward before allocation**	**Share %** **Dividends**	**Book value of shares held** Gross Net	**Revenue excluding taxes** **Results**	**Loans/advances not repaid** **Sureties**
EPYGON 320, avenue Archimède 13100 Aix-en-Provence, France 530 455 238 80037	Capital : €540,119.00	100%	Actions: €27,891,206.00	Revenue excluding tax: €25,169.64 Result: -€6,905,913.41	Current account in debt: €6,049,152.65
KARDIOZIS 320, avenue Archimède 13100 Aix-en-Provence, France 532 628 336 00028	Capital €293,997.00	100%	Actions: €10,212,832.44	Revenue excluding tax: €100,165.67 Result: -€400,979.05	Current account in debt: €1,059,677.93
KEPHALIOS 320, avenue Archimède 13100 Aix-en-Provence, France 531 557 650 00029	Capital €508,395.00	100%	Actions: €22,087,349.20	Revenue excluding tax: €6,514.00 Result: -€3,392,112.18	Current account in debt: €2,773,686.07
MYOPOWERS MEDICAL TECHNOLOGIES FRANCE 18, rue Alain Savary 25000 Besançon	Capital €3,633,091.00	100%	Actions: €22,843,270.02	Revenue excluding tax: €37,071.90 Result:	Current account in credit: €3,669,251.24

799 927 355 00039				-€5,260,647.49	

2.1.5 Receivables

Names	Amount
ACCRUED INTEREST	
Financial assets	8,292
Group equity investments	-
Non-group equity investments	-
Receivables	-
Partners	-
Marketable securities	-
OTHER PRODUCTS	
Invoices to be issued	6,697,087
RRR to be obtained, credit notes to be received	-
Personnel	-
Social security	-
State	-
Miscellaneous	-
TOTAL	6,705,379

The amount of invoices to be issued corresponds to the service provision contracts signed with the subsidiaries.

2.2 Asset impairment

Line items (a)	Situations and movements: (b)			
	A	B	C	*D*
	Impairment at the beginning of the financial year	Increases: allocations for the year	Decreases: reversals during the financial year	Impairment at end of year (c)
Tangible assets	-	-	-	-
Intangible assets	-	-	-	-
Financial assets	-	118,308	67,408	*50,900*
Inventories	-	-	-	

Receivables	-	-	-	-
Other	-	-	-	-
TOTAL	-	*118,308*	*67,408*	*50,900*

The impairment of financial assets relates to the treasury share account.

2.3 Equity

2.3.1 Share capital

	Number of shares	Capital value
Position at the beginning of the financial year	15,256,824	€15,256,824
Movements:		
09/06/2021: 2021 IPO finding	2,906,978	€2,906,978
Position at the end of the financial year:	18,163,802	€18,163,802

2.3.2 Change in equity

Names	N-1	+	-	N
Capital	15,256,824	2,906,978	-	18,163,802
Reserves, premiums and spreads	62,683,436	22,093,033	1,730,363	83,046,106
Retained earnings	-643,623	-	105,333	-748,957
Result	-105,333	273,434	-	168,101
Investment grants	-	-	-	-
Regulated provisions	-	-	-	-
Other	-	-	-	-
TOTAL	77,191,304	25,273,445	1,835,697	100,629,052

The decrease of €1,730,363 on the “Reserves, premiums and differences” line corresponds to the allocation of IPO-related costs to the issue premium.

2.4 Liabilities and provisions

2.4.1 Provisions

	Situations and movements: (b)

	A	B	C	D
Line items (a)	Provisions at the beginning of the financial year	Increases: allocations for the year	Decreases: reversals during the financial year	Provisions at the end of the financial year (C)
Regulated provisions	-	-	-	-
Provisions for risks	35,000	-	35,000	-
Provisions for expenses	-	-	-	-
TOTAL	35,000	-	35,000	-

2.4.1.1 Provisions for risks and contingencies

Nature of Provisions	Amount at beginning of year	Increase: Allowances for the year	Decreases: reversals during the financial year	Amount at end of year
Provision for disputes	35,000	-	35,000	0
Provisions for guarantees given to customers	-	-	-	-
Provisions for losses on forward markets	-	-	-	-
Provisions for fines and penalties	-	-	-	-
Provisions for foreign exchange losses	-	-	-	-
Provisions for pensions and similar obligations	-	-	-	-
Provisions for taxes (1)	-	-	-	-
Provisions for the renewal of fixed assets *	-	-	-	-
Provisions for major maintenance	-	-	-	-
Provisions for social security contributions and tax on paid leave *	-	-	-	-
Other provisions for risks and charges	-	-	-	-
TOTAL	35,000	-	35,000	-

2.5 Maturity of receivables and payables at year-end

STATEMENT OF RECEIVABLES	Gross amount	At 1 year or less	At more than one year

FIXED ASSETS	Receivables from equity interests		-	-	-
	Loans		75,913	75,913	-
	Other financial assets		96,493	75,420	21,073
CURRENT ASSETS	Doubtful or disputed customers		-	-	-
	Other trade receivables		6,699,319	6,699,319	-
	Receivables representing securities loaned or pledged *	Provisions for impairment previously recognised *	-	-	-
	Personnel and related accounts		-	-	-
	Social security and other social organisations		-	-	-
	State and other public bodies	Income tax expense	-	-	-
		Value added tax	147,489	147,489	-
		Other taxes and similar payments	-	-	-
		Miscellaneous	-	-	-
	Group and partners		9,882,518	9,882,518	-
	Miscellaneous debtors (including receivables relating to securities repurchase agreements)		2,771	2,771	-
Prepaid expenses			114,090	114,090	-
TOTAL			17,018,593	16,997,520	21,073

Loans granted during the year	27,967
Repayments obtained during the year	-

STATEMENT OF DEBTS		Gross amount	Less than 1 year at most	More than 1 year and more than 5 years	More than 5 years
Convertible bond loans		1,187,202	1,187,202	-	-
Other bond loans		-	-	-	-
Loans and other borrowings from financial institutions	at 1 year maximum at the outset	3,125	3,125	-	-
	more than 1 year originally	3,512,858	1,786,540	1,626,317	100,000
Miscellaneous loans and borrowings		-	-	-	-
Trade payables and related accounts		522,035	522,035	-	-
Personnel and related accounts		213,529	213,529	-	-

Social security and other social organisations		169,660	169,660	-	-
State and other public bodies	Income tax expense	-	-	-	-
	Value added tax	1,116,562	1,116,562	-	-
	Guaranteed bonds	-	-	-	-
	Other taxes	31,939	31,939	-	-
Debts on fixed assets and related accounts		-	-	-	-
Group and partners		3,727,251	3,727,251	-	-
Other debts (of which relating to securities repurchase agreements)		10,577	10,577	-	-
Debt representing securities borrowed or pledged as collateral		-	-	-	-
Prepaid income		-	-	-	-
TOTAL		10,494,739	8,768,422	1,626,317	100,000

Loans subscribed during the year	400,000
Loans repaid during the year	7,164,493 *
Amount of various loans and debts contracted with individual partners at closing	58,000

2.6 Accrued expenses

Names	Amount
PAYABLE LEAVE	
Provision for leave	51,674
Provisioned social security charges	22,560
Provisioned tax expenses	-
ACCRUED INTEREST	
Borrowings and similar debt	188,652
Share payables groups	-
Share payables excluding groups	-
Debt from joint ventures	-
Suppliers	-
Partners	-
Banks	3,125
Bank overdrafts	-
OTHER EXPENSES	
Invoices to be received	213,822
RRR to be granted, credit notes to be issued	-
Employee participation	-
Personnel	161,855
Social security	81,717
Other tax expenses	11,832
Miscellaneous	-
TOTAL	735,237

2.7 Income statement

2.7.1 Revenue breakdown

	France	Export and community	Total
Sales of goods	-	-	-
Production sold:	-	-	-
• Assets			
• Services	5,756,836	-	5,756,836
Net revenue	**5,756,836**	**-**	**5,756,836**

Revenue was generated under the service agreement signed in 2018 with the subsidiaries.

3. Tax information

3.1 Income tax

3.1.1 Breakdown

		Current income (expense)	Exceptional income (expenses)
Profit (loss) before tax		143,101	25,000
Tax at the rate of:	-	-	-
Tax on LTVP		-	-
Income after tax		**143,101**	**25,000**

4. Information on transactions and commitments to executives

Directors: **(Gross amounts in euros)**	**Amount of directors' fees allocated for 2021**
Patrick Coulombier	12,750*
Jean-Michel Malbrancq	2,250*
Christian Latrémouille	10,750
Dominique Carouge	17,250*
Véronique Phé	1,500
Daniel Hayoz	10,500
Ellen Roche	6,750
TOTAL	61,750

** Including the Audit or Compensation Committee*

Board members 'compensation is paid in the form of directors' fees. The maximum annual amount of directors' fees was set at €120,000 by the General Meeting of 6 April 2021.
In 2021, gross compensation of the administrative bodies (directors' fees, Audit Committee and Compensation and Governance Committee) amounted to €60,250.

By decision of the Board of Directors on 20 April 2018, the scale applicable to the payment of directors' fees is as follows:
- Physical contribution: €2,000;
- Participation conf. call: €750.

A maximum amount of €120,000 may be distributed among Board members who are members of committees of the Board of Directors, according to their attendance at meetings. The maximum amount that may be allocated to a Board member as compensation for the Board of Directors only is set at €15,000 (excluding any compensation that may be paid to it for specific assignments).

The gross amounts detailed in the table below were allocated during the year to Board members as directors' fees for the 2021 financial year:

5. Information on off-balance sheet transactions and commitments

5.1 Retirement commitments and similar benefits

Calculation methodology

The purpose of the actuarial valuation is to produce an estimate of the present value of Affluent Medical's obligations in terms of retirement benefits provided for in the collective agreement.

These indemnities are not recognised as a provision in the Company's financial statements but constitute an off-balance sheet commitment.

This amount is determined at the various balance sheet dates on the basis of an actuarial valuation based on the use of the projected unit credit method, taking into account staff turnover and mortality probabilities.

In accordance with the latest update of ANC recommendation 2013-02 of 7 November 2013 amended on 5 November 2021, the Company has decided to adopt the new method for allocating benefit entitlements for its defined benefit plans under which an indemnity is only due if the employee is still working in the Company on the date of his or her retirement. The amount of this indemnity depends on length of service and is capped at a certain number of consecutive years of service.

This change in method resulted in a reduction of €0.5 thousand in the amount of the off-balance sheet commitment in respect of the retirement indemnity on 1 January 2021 (compared to €26 thousand on 31 December 2020).

Actuarial assumptions

The main actuarial assumptions used to assess retirement benefits are as follows:

ACTUARIAL ASSUMPTIONS	31/12/2021	31/12/2020
Retirement age	Voluntary departure between the ages of 65 and 67	
Collective agreements	Executive: Metallurgy Industries (management) 3025 Non-executive: Metallurgy (Industries) 3126	
Discount rate (IBOXX Corporates AA)	0.98%	0.33%
Mortality table	INSEE 2019	INSEE 2019
Salary adjustment rate	2.00%	
Turnover	High	
Social security charges rate	45.00%	

Calculated commitments

Commitments calculated for retirement benefits break down as follows:

EMPLOYEE BENEFITS COMMITMENTS	31/12/2021	31/12/2020

(Amounts in euros)		
Employee benefits commitments	497	26,192

5.2 Finance lease commitments

	Land	Buildings	Installations, equipment and tooling	Other	Total
Original value			**€357,354**		
Depreciation: ● Cumulations in previous financial years			€28,680		
● Provision for the year			€46,495		
TOTAL			75,175		
Fees paid: ● Cumulations in previous financial years			€39,742		
● Financial years			€54,970		
TOTAL			94,711		
Fees remaining to be paid: ● Less than 1 year at most			€103,746		
● More than 1 year and not more than 5 years			€216,333		
● More than 5 years			0		
TOTAL			320,079		
Amount paid during the financial year			**€59,855**		

6. Workforce information

The average number of employees excluding the Chairman and Chief Executive Officer was 9.04 for the financial year at 31 December 2021, compared with 5.86 at 31 December 2020.

7. Other information

AFFLUENT MEDICAL has signed the following agreements with its subsidiaries:
- A service agreement dated 9 April 2018;
- A cash management agreement dated 5 November 2018;
- An agreement with Kephalios SAS to provide premises free of charge in March 2018.

8. Statutory Auditors' fees

STATUTORY AUDITORS' FEES (Amounts excl. tax in thousands of euros)	Financial year 2021 (12 months)		Financial year 2020 (12 months)	
	PWC	EXPERTEA	PWC	EXPERTEA
Statutory audit assignment	72	29	45	22
Services other than the certification of financial statements	150	18		
Sub-total	**222**	**47**	**45**	**22**
Other services rendered				
- Tax	-	-	-	-
- Other	-	-	-	-
Sub-total	**-**	**-**	**-**	**-**
Total	**222**	**47**	**45**	**22**

(1) Services other than the certification of financial statements, covering mainly services required under capital increases and the work done for the Company's listing on the stock exchange.

18.5 Statutory Auditors' report on the parent company financial statements at 31 December 2021

PricewaterhouseCoopers Audit
63, rue de Villiers
92208 Neuilly-sur-Seine Cedex

EXPERTEA AUDIT
60, boulevard Jean Labro
13016 Marseille

Report of the Statutory Auditors on the annual financial statements

Year ended 31 December 2021

This is a free translation into English of the Statutory Auditors' report issued in French and is provided solely for the convenience of English speaking readers. This report includes information specifically required by European regulations or French law. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

To the General Meeting
AFFLUENT MEDICAL
320, avenue Archimède
13100 Aix-en-Provence, France

Opinion

In compliance with the engagement entrusted to us by your General Meeting, we audited the accompanying annual financial statements of AFFLUENT MEDICAL for the year ended 31 December 2021.

We certify that the annual financial statements are, in accordance with French accounting rules and principles, regular and fair and give a true and fair view of the results of operations for the past financial year as well as the financial position and assets of the company at the end of the year.

The opinion expressed above is consistent with the content of our report to the Audit Committee.

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 annual financial statements" section of our report.

Independence

We performed our audit task in compliance with the independence rules laid down in the French Commercial Code and by the Code of Ethics for the profession of Statutory Auditors over the period from 1 January 2021 to the date on which our report is issued. In particular, we have not provided any services prohibited by Article 5, paragraph 1, of Regulation (EU) 537/2014.

Justification of assessments – Key audit matters

Due to the global crisis related to the Covid-19 pandemic, the annual financial statements for this year have been prepared and audited under specific conditions. Indeed, this crisis and the exceptional measures taken in the context of the health emergency have multiple consequences for companies, particularly on their activity and their financing, as well as increased uncertainties about their future prospects. Those measures, such as travel restrictions and remote working, have also had an impact on the companies' internal organisation and on audit performance.

It is in this complex and evolving context that, in accordance with the provisions of Articles L. 823-9 and R. 823-7 of the French Commercial Code relating to the justification of our assessments, we bring to your attention the key points of the audit relating to the risks of material misstatement that, in our professional judgment, were the most significant for the audit of the annual financial statements for the year, as well as our responses to those risks.

These assessments were made in the context of the audit of the annual financial statements taken as a whole and the formation of our opinion expressed above. We do not express an opinion on the elements of these annual financial statements taken in isolation.

Equity interests

Risk identified

Equity interests for which the net amount shown in the balance sheet at 31 December 2021 was €83,034,657 are valued at their acquisition cost.

As indicated in Note 2.1.3 "*Financial assets*" to the annual financial statements, an impairment loss is recognised when the inventory value is lower than the gross value. Inventory value is estimated on the basis of the share of the net book value, revalued, if necessary, to take into account profitability generated by the company concerned or the recoverable value of the securities.

We considered the valuation of equity interests to be a key point of our audit given the material nature of the equity interests in the total balance sheet (nearly 75%), and the degree of management judgement in determining the main assets, underlying assumptions and the sensitivity of the valuation to those assumptions.

Audit procedures implemented in response to this risk

On the basis of the information provided to us, our work consisted in assessing the reasonableness of these estimates, which are the basis of the inventory values. In particular, we analysed the consistency of the business plans selected to estimate the progress, study cost, commercial forecasts, the appropriateness of the discount rate used and the probabilities of clinical success.

Financing

Risk identified

Affluent Medical is a holding company with subsidiaries that develop next-generation minimally invasive medical devices in the field of urology and structural heart. These subsidiaries have undertaken significant research and development (R&D) expenditures and are still anticipating significant financing needs in order to continue their clinical studies. They are financed through the cash flow of Affluent Medical.

Based on the financing lines obtained and its current cash position, management considers that the company has sufficient cash to finance its working capital requirements and its subsidiaries until the end of September 2022. As mentioned in the "Going concern" paragraph of Note 1.1 "*Main events*" to the annual financial statements, management has therefore approved the company's annual financial statements for the financial year ended 31 December 2021 in accordance with the going concern principle despite the losses accumulated since the creation of the company.

Various finance solutions are envisaged and could, without being restrictive, take the form of private placements with investors, capital increases, setting up a bond loan and securing public funding.

Insofar as the company is dependent on the progress and results of research programs in its subsidiaries, the decisions of its other strategic partners, the awarding of grants and the interest of the financial markets for such investments, we considered financing and going concern a key point of our audit.

Audit procedures implemented in response to this risk

We obtained an understanding of the method used to prepare the cash flow forecasts for the Company and its subsidiaries and carried out a critical review of these cash flow forecasts.

We assessed the reasonableness of the key underlying assumptions such as R&D expenses, other operating expenses and the appropriateness of the discount rate used, particularly in the context of the current crisis, and assessed management's ability to prepare reliable forecasts by comparing current forecasts with forecasts from previous years and by examining, where applicable, the causes of the differences identified.

We assessed the impact of a change in assumptions on cash flow forecasts.

We examined the consistency of these assumptions with the latest cash flow forecasts drawn up by anagement as approved by the Board of Directors.

We reviewed the refinancing projects presented to the Board of Directors and satisfied ourselves that the refinancing arrangements and amounts proposed would enable the company to meet its commitments over the next 12 months.

We assessed whether the information given in the notes on maintaining the going concern principle was appropriate for the closing of the financial statements at 31 December 2021.

Specific verifications

In accordance with professional standards applicable in France, we have also performed the specific verifications required by law and regulations.

Information given in the management report and in the other documents on the financial position and the annual financial statements sent to shareholders

We have no matters to report as to the fair presentation and the consistency with the financial statements of the information given in the management report of the Board of Directors and in the other documents on the financial position and the annual financial statements sent to the shareholders.

We attest to the fair presentation and the consistency with the annual financial statements of the information relating to payment terms mentioned in Article D. 441-6 of the French Commercial Code.

Corporate governance report

We certify the existence, in the Board of Directors' corporate governance report, of the information required by Articles L. 225-37-4, L. 22-10-10 and L. 22-10-9 of the French Commercial Code.

With regard to the information provided in application of the provisions of Article L. 22-10-9 of the French Commercial Code on compensation and benefits paid or allocated to corporate officers as well as on the commitments granted to them, we verified their consistency with the financial statements or with the data used to prepare these financial statements and, where applicable, with the information collected by your company from the companies controlled by it that are included in the scope of consolidation. On the basis of this work, we certify the accuracy and fair presentation of this information.

Concerning the information relating to the elements that your company considers likely to have an impact in the event of a takeover or exchange offer, provided in accordance with the provisions of Article L. 22-10-11 of the French Commercial Code, we have verified their compliance with the documents from which they originate and which were provided to us. Based on this work, we have no matters to report on this information.

Other information

In accordance with the law, we have ensured that the various information relating to the identity of the holders of the share capital or voting rights has been provided to you in the management report.

Other verifications or information laid down in legislation or regulations

Format of presentation of the annual financial statements intended to be included in the annual financial report

In accordance with professional standards on the Statutory Auditors' work relating to the annual and consolidated financial statements presented in the single European electronic reporting format, we have also verified compliance with this format defined by the Commission Delegated Regulation (EU) 2019/815 of 17 December 2018 for presentation of the annual financial statements intended to be included in the annual financial report mentioned in I of Article L. 451-1-2 of the French Monetary and Financial Code, prepared under the responsibility of the Chairman and Chief Executive Officer.

Based on our work, we conclude that the presentation of the annual financial statements intended to be included in the annual financial report complies, in all material respects, with the single European electronic reporting format.

It is not our responsibility to verify that the annual financial statements that will be included by your company in the annual financial report filed with the AMF correspond to those on which we carried out our work.

Nomination of the Statutory Auditors

We were appointed Statutory Auditors of AFFLUENT MEDICAL by your General Meeting of 6 February 2018 in respect of PricewaterhouseCoopers Audit and 30 December 2020 in respect of Expertea.

At 31 December 2021, PricewaterhouseCoopers Audit was in the fourth uninterrupted year of its mission and Expertea in its second year, including one year since the company's shares were admitted for trading on a regulated market.

Responsibilities of management and those charged with governance for the annual financial statements

It is the responsibility of management to prepare annual financial statements presenting a true and fair view in accordance with French accounting principles and to implement the internal control that it deems necessary for the preparation of annual financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the annual 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 the company is expected to be liquidated or to cease operations.

The Audit Committee is responsible for monitoring the process of preparing financial reporting and monitoring the effectiveness of internal control and risk management systems, as well as any internal audit system as regards the procedures for preparing and processing accounting and financial reporting.

The annual financial statements were approved by the Board of Directors.

Statutory Auditors’ responsibilities for the audit of the annual financial statements

Objectives and audit procedure

Our role is to issue a report on the annual financial statements. Our objective is to obtain reasonable assurance about whether the annual 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 Furthermore, he or she:

- identifies and assesses the risks of material misstatement of the annual 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 or her 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 internal control;

- evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the annual 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 annual financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein;

- evaluates the overall presentation of the annual financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

Report to the Audit Committee

We submit a report to the Audit Committee that presents the scope of the audit work and the work program implemented, as well as the conclusions arising from our work. We also draw to its attention, any significant weaknesses identified by us in internal control as regards the preparation and processing of accounting and financial reporting.

Among the elements communicated in the report to the Audit Committee are the risks of material misstatement, which we consider to have been the most significant for the audit of the annual financial statements of the financial year and which therefore constitute the key points of the audit. It is our responsibility to describe these key points in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) 537/2014 confirming our independence, within the meaning of the rules applicable in France such as they are set in particular by Articles L. 822-10 to L. 822-14 of the French Commercial Code and in the Statutory Auditors 'Code of Ethics. Where appropriate, we meet with the Audit Committee to discuss the risks to our independence and the safeguarding measures applied.

Prepared in Neuilly-sur-Seine and Marseille, on [date] March 2022

The Statutory Auditors

PricewaterhouseCoopers Audit	EXPERTEA AUDIT
Thierry Charron	Jérôme Magnan

18.6 Financial reporting *pro forma*

N/A

18.7 Dividend policy

18.7.1 Dividend policy

The Company is positioned as a growth stock and does not intend, as at the date of approval of the Universal Registration Document, to adopt a regular dividend payment policy.

18.7.2 Dividends paid over the last three financial years

In respect of the last three financial years, the Company has not distributed any dividends.

18.8 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 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 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 €50,000 which has been paid. 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 were scheduled in 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 Universal 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.

18.9 Significant change in financial position of the Group

N/A

18.10 Other information

18.10.1 Information relating to the Company's payment terms (Articles L. 441-6-1 and D. 441-4 of the French Commercial Code)

	Article D.441-4 I.-1° Factures reçues non réglées à la date de clôture de l'exercice dont le terme est échu						Article D.441-4 I.-1° Factures émises non réglées à la date de clôture de l'exercice dont le terme est échu					
	0 jour (indicatif)	1 à 30 jours	31 à 60 jours	61 à 90 jours	91 jours et plus	Total (1 jour et plus)	0 jour (indicatif)	1 à 30 jours	31 à 60 jours	61 à 90 jours	91 jours et plus	Total (1 jour et plus)
1. Tranches de retard de paiement à la date de clôture												
Nombre de factures concernées	66					11	0					4
Montant total T.T.C. En € des factures concernées	175 217	80 603	0	0	0	80 603	-1 728	3 960	0	0	0	3 960
Pourcentage du montant T.T.C. des achats de l'exercice	4,40%	2,02%	0,00%	0,00%	0,00%	2,02%						
Pourcentage du montant T.T.C. de l'exercice							-0,03%	0,06%	0,00%	0,00%	0,00%	0,06%
2. Factures exclues du (A) relatives à des dettes et créances litigieuses ou non comptabilisées												
Nombre des factures exclues	8											
Montant total des factures exclues	52 393											
(C) Délais de paiement de référence utilisés (contractuel ou délai légal - article L.441-6 ou article L,443-1 du Code de Commerce)												
Délais de paiement utilisés pour le calcul des retards de paiement	☐ Délais contractuels : (préciser) X Délais légaux : En cas de retard de paiement il vous sera facturé un intérêt sur la base de 3 fois le taux d'intérêt légal à compter du jour suivant la date d'échéance et une indemnité forfaitaire de 40€ pour frais de recouvrement (Article L441-6 du code du commerce).						☐ Délais contractuels : (préciser) voir les conditions générales du client X Délais légaux : En cas de retard de paiement il vous sera facturé un intérêt sur la base de 3 fois le taux d'intérêt légal à compter du jour suivant la date d'échéance et une indemnité forfaitaire de 40€ pour frais de recouvrement (Article L441-6 du code du commerce).					

18.10.2 Financial results of the Company over the last five financial years (Articles R. 225-81, R. 225-83 and R. 225-102 of the French Commercial Code)

The table below shows the Company's financial results since its creation in financial year 2018.

Results of AFFLUENT MEDICAL over the last five financial years

Nature of information	2018	2019	2020	2021
I. Financial position at year-end				
a) Share capital				
b) Number of shares				
c) Number of convertible bonds	6,152,671	10,407,778	4,040,024	-
II. Comprehensive income (loss) from actual operations				
a) Revenue excluding tax	1,998,855	3,076,461	3,938,911	5,756,936
b) Profit before taxes, depreciation, amortisation and provisions				
c) Income tax				
d) Profit after tax, depreciation, amortisation and provisions				
e) Amount of profits distributed	-	-	-	-
III Earnings from operations reduced to one share				

a) Profit after tax but before depreciation, amortisation and provisions	-0.045	-0.001	-0.007	0.009
b) Profit after tax, depreciation, amortisation and provisions				
c) Dividend paid per share	-	-	-	-
IV Personnel				
a) Number of employees	3	4	6	9
b) Total payroll				
c) Amount paid in respect of employee benefits (social security, works, etc.)	154,684	360,339	454,909	486,846

18.10.3 Proposed appropriation of earnings

The Company's income, prepared in accordance with French accounting standards at 31 December 2021, shows a profit of €168,101.28, which we propose to allocate in full to the "Retained earnings" account.

18.10.4 Non-tax deductible expenses

Pursuant to Article 223 *quater* of the French General Tax Code, the sumptuary expenses and non-deductible charges referred to in Article 39-4 of this code amounted to €31,834 for the financial year ended 31 December 2021.

6. ADDITIONAL INFORMATION

6.1. Share capital

6.1.1. Share capital amount

On the date of approval of the Universal Registration Document, the share capital amounts to €18,163,802 divided into 18,163,802 shares with a par value of €1 each, fully paid-up, all of the same category.

6.1.2. Non-equity securities

Refer to section 19.1.4 "*Convertible securities, exchangeable securities or securities with warrants*" of the Universal Registration Document.

6.1.3. Acquisition by the Company of its own shares

Shares held as at 31 December 2021

The Combined General Meeting of 6 April 2021 authorised, under its nineteenth resolution, the Board of Directors to implement for a period of eighteen (18) months as at the date of the Meeting, a share buyback programme pursuant to the provisions of Articles L. 225-209 *et seq.* of the French Commercial Code, subject to the condition precedent of the admission of the Company's shares to the regulated market of Euronext in Paris. The main terms of this authorisation are as follows:

Maximum number of shares that may be purchased: 10% of the total number of shares comprising the share capital on the date of repurchase by the Company, it being specified that (i) when the shares are purchased under a liquidity contract, the number of shares taken into account in the calculation of the 10% limit corresponds to the number of shares purchased less the number of shares resold during the term of the authorisation and (ii) when they are purchased for retention and subsequent delivery in payment or exchange in the context of a merger, spin-off or contribution, the number of shares acquired may not exceed 5% of its share capital.

Purpose of share buybacks:

- the management and liquidity of the Company's shares through an investment services provider acting independently under a liquidity contract in accordance with an ethics charter recognised by the French Financial Markets Authority (*Autorité des Marchés Financiers* – AMF); and/or
- to fulfil obligations related to stock option programmes, bonus share allocations, employee savings plans or other share allocations to employees and executives of the Company or companies related to it; and/or
- to deliver shares upon the exercise of rights attached to securities giving access to the share capital; and/or
- to cancel all or some of the shares thus purchased, subject to the adoption by the Extraordinary General Meeting of the 24th resolution below and in the terms indicated therein; and/or
- to carry out any transaction in accordance with the current regulations; and/or
- more generally, to carry out any purpose that may be authorised by law or any market practice that may be accepted by the market authorities, it being specified that, in such a case, the Company would inform its shareholders by means of a press release.

Maximum purchase price (excluding fees and commissions): 300% of the price per new share used for the IPO (excluding acquisition costs) (as this price will be mentioned in the Company's press release relating to the final characteristics of the public offering of Company shares and their admission to trading on the regulated market of Euronext in Paris).

Maximum amount of funds that can be used to buy back shares: €5 million

Shares bought back in this way may be cancelled.

The Board of Directors implemented the share buyback programme authorised by the General Meeting of 6 April 2021, through the implementation of a liquidity contract, in accordance with the ethics charter recognised by the AMF, entered into with the brokerage firm Kepler Cheuvreux, to which the sum of €4 million has been credited to the liquidity account.

At 31 December 2021, the Company held 65,037 of its own shares, representing 0.43% of its share capital, allocated in full to the liquidity contract to which €67,128.08 in cash were also allocated.

During the financial year ended 31 December 2021, the Company acquired 87,590 shares at an average price of €6.55, and sold 22,553 shares at an average price of €6.29.

These shares were not reallocated to other purposes provided for by the share buyback program.

During the financial year ended 31 December 2021, the Company did not buy back any shares outside its liquidity contract.

New share buyback programme

It is proposed that the General Meeting of 24 May 2022 authorise the Board of Directors, for a period of eighteen months as at the date of the Meeting, to implement a share buyback programme under the framework of the provisions of Article L. 22-10-62 of the French Commercial Code and Regulation (EU) 596/2014 of 16 April 2014 on market abuse and in accordance with the AMF General Regulation conditions described below:

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 contract 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: €12.

Maximum amount of funds that may be allocated to the buyback: €5,000,000.

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.

6.1.4. Convertible securities, exchangeable securities or securities with warrants

The shares giving access to the Company's share capital as at the date of the Universal Registration Document are presented in the tables below:

6.1.4.1. 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 2018	9 April 2018	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
Exercise price of the BSAs	€5	€5	€6.10	€6.10	€5.89	(*Note 6*)
Exercise conditions	Entirely exercisable on their issue date *(1)*	Exercisable based on a vesting schedule *(2)*	Exercisable based on a vesting schedule *(3)*	Exercisable based the achievement of objectives (*4*)	Exercisable based on a vesting schedule *(5)*	(*6*)
Number of BSAs cancelled or null and void	105,216	65,760	8,905	65,000	0	65,574 (*Note 6*)
Number of BSAs outstanding	1,644	65,760	56,855	0	32,080	131,148 (*Note 6*)
Total number of shares that may be subscribed when the BSAs are exercised	1,644	65,760	56,855	0	32,080	169,779 (*Note 6*)

(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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

The corporate officer as at the date of awarding of the BSA-2018-1 is Mr Christian Latrémouille who is no longer a corporate officer of the Company as at the date of approval of the Universal Registration Document.

(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 share subscription warrants 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 at 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 provider 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: Mr Christian Latrémouille, Mr José Da Gloria, Mr Thierry Hebreteau and Mr Reinhard Ambros who are no longer corporate officers of the Company as at the date of approval of the Universal Registration Document.

(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 at 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 provider 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 Mr Jean-Michel Malbrancq who is no longer a corporate officer of the Company as at the date of approval of the Universal Registration Document.

(4) Each BSA-2018-5 share subscription warrant 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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(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 at 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 provider 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 Mr Dominique Carouge.

(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 Universal 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 400,000 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 Universal 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.

At the date of approval of the Universal Registration Document, the total number of BSAs amounts to 338,776 giving entitlement to 377,407 new shares of the Company.

Only a portion of the BSAs of the various plans presented above are exercisable on the date of the Universal 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 BSA Kreos 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.

6.1.4.2. 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	657,601	1,159,025	112,500	250,500	0
Number of BSPCEs outstanding	1,280,682	378,120	0	37,500	50,100	200,400
Total number of shares that may be subscribed when the BSPCEs are exercised	1,280,682	378,120	0	37,500	50,100	200,400

(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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(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 at 30 April 2019).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(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 at 30 April 2019).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-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 13495 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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(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 at 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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

	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	(*1*)	(*2*)	(*3*)	(*4*)
Number of BSPCEs cancelled or null and void	0	37,500	87,675	30,000
Number of BSPCEs outstanding	226,300	37,500	47,260	45,000
Total number of shares that may be subscribed when the BSPCEs are exercised	226,300	37,500	47,260	45,000

(1) 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 at 31 December 2021).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(2) 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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(3) 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 provider agreement entered into with the Company or the termination of all duties of an employee or manager within the Group).

(4) 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).

	BSPCE 2021-1	BSPCE-2021-2	BSPCE-2021-3	BSPCE 2021-4	BSPCE-2021-5	BSPCE 2021-6
Dates of the decisions of the General Meeting	6 April 2021					
Date of the decisions of the Board of Directors	20 July 2021				20 September 2021	
Total number of BSPCEs authorised	10% of the share capital on the grant date (common ceiling with share subscription warrants, bonus shares and stock options issued under the delegations put in place at the General Meeting of 6 April 2021)					
Total number of BSPCEs granted	125,000	30,000	70,000	250,000	30,000	476,500
Number of BSPCEs subscribed	125,000	30,000	70,000	250,000	30,000	476,500
Total number of shares that may be issued when the BSPCEs are exercised, including the number that may be subscribed by:	125,000	30,000	70,000	250,000	30,000	476,500
Corporate officers	0	0	0	0	30,000	272,500
Non-corporate officers	125,000	30,000	70,000	250,000	0	204,000
Start date for the exercise of the BSPCEs	For 66.67%, at the end of the first anniversary of the date of the Board of Directors' award decision For 33.33% on the date of the achievement of the objectives set by the Board of Directors	At the end of the first anniversary of the date of the Board of Directors' grant decision	For 50%, at the end of the first anniversary of the date of the Board of Directors' award decision For 50% on the date of the achievement of the objectives set by the Board of Directors	For 33.33%, at the end of the first anniversary of the date of the Board of Directors' award decision For 66.67% on the date of the achievement of the objectives set by the Board of Directors	At the end of the first anniversary of the date of the Board of Directors' grant decision	For 20%, at the end of the first anniversary of the date of the Board of Directors' award decision For 80% on the date of the achievement of the objectives set by the Board of Directors
Expiry date	10 years from the Board of Directors' grant decision (*i.e.* midnight on 19 July 2031)				10 years from the Board of Directors' grant decision (*i.e.* midnight on 19 September 2031)	
Exercise price of the BSPCEs	€6.93				€6.00	
Exercise conditions	(*1*)	(*2*)	(*3*)	(*4*)	(*5*)	(*6*)
Number of BSPCEs cancelled or null and void	0	0	0	0	0	0
Number of BSPCEs outstanding	125,000	30,000	70,000	250,000	30,000	476,500
Total number of shares that may be subscribed when the BSPCEs are exercised	125,000	30,000	70,000	250,000	30,000	476,500

(1) Each BSPCE-2021-1 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2021-1 founders' share warrant provide that the BSPCE-2021-1 may be exercised under the following conditions:

- for 66.67% of the BSPCE 2021-1 founders' share warrant (the "Vesting BSPCE-2021-1"), according to the following schedule:
  (i) the last day of the calendar month in which the date of the first anniversary of the Vesting Start Date falls, up to one quarter (1/4) of the total number of Vesting BSPCE-2021-1 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number); then
  (ii) the last day of each calendar month following the date referred to in paragraph (i), up to one forty-eighth ($1/48^{th}$) of the total number of Vesting BSPCE-2021-1 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number; except for the last instalment, where the entire balance of the Vesting BSPCE-2021-1 not yet exercisable at that date, will become so).

  As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-2021-1 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions:
- up to 33.33% of the BSPCE-2021-1 founders' share warrant (the "Performance BSPCE-2021-1"), in the event of the achievement of certain objectives determined by the Board of Directors and notified to each Beneficiary in the award letter.

The BSPCE-2021-1 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-2021-1 founders' share warrants);
- 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);
- failure to exercise prior to the expiry of the term of validity of the BSPCE-2021-1 founders' share warrant.

(2) Each BSPCE-2021-2 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2021-2 founders' share warrant provide that the BSPCE-2021-2 may be exercised according to the following schedule:
  (i) the last day of the calendar month in which the date of the first anniversary of the Vesting Start Date falls, up to one quarter (1/4) of the total number of BSPCE-2021-2 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number); then
  (ii) the last day of each calendar month following the date referred to in paragraph (i), up to one forty-eighth ($1/48^{th}$) of the total number of BSPCE-2021-2 founders' share warrant allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number; except for the last instalment, where the entire balance of the BSPCE-2021-2 not yet exercisable at that date, will become so).
  As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-2021-2 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.

The BSPCE-2021-2 founders' share warrants exercisable on a given date will become null and void in the following scenarios:
- 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);
- failure to exercise prior to the expiry of the term of validity of the BSPCE-2021-2 founders' share warrant.

(3) Each BSPCE-2021-3 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2021-3 founders' share warrant provide that the BSPCE-2021-3 may be exercised under the following conditions:
- up to 50% of the BSPCE-2021-3 founders' share warrant (the "Vesting BSPCE-2021-3"), according to the following schedule:

(i) the last day of the calendar month in which the date of the first anniversary of the Vesting Start Date falls, up to one quarter (1/4) of the total number of Vesting BSPCE-2021-3 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number); then

(ii) the last day of each calendar month following the date referred to in paragraph (i), up to one forty-eighth ($1/48^{th}$) of the total number of Vesting BSPCE-2021-3 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number; except for the last instalment, where the entire balance of the Vesting BSPCE-2021-3 not yet exercisable at that date, will become so).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-2021-3 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions:

- up to 50% of the BSPCE-2021-3 founders' share warrant (the "Performance BSPCE-2021-3"), in the event of the achievement of certain objectives determined by the Board of Directors and notified to each Beneficiary in the grant letter.

The BSPCE-2021-3 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-2021-3 founders' share warrants);
- 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);
- failure to exercise prior to the expiry of the term of validity of the BSPCE-2021-3 founders' share warrant.

(4) Each BSPCE-2021-4 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2021-4 founders' share warrant provide that the BSPCE-2021-4 may be exercised under the following conditions:

- for 33.33% of the BSPCE 2021-4 founders' share warrant (the "Vesting BSPCE-2021-4"), according to the following schedule:
  (i) the last day of the calendar month in which the date of the first anniversary of the Vesting Start Date falls, up to one quarter (1/4) of the total number of Vesting BSPCE-2021-4 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number); then
  (ii) the last day of each calendar month following the date referred to in paragraph (i), up to one forty-eighth ($1/48^{th}$) of the total number of Vesting BSPCE-2021-4 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number; except for the last instalment, where the entire balance of the Vesting BSPCE-2021-4 not yet exercisable at that date, will become so).
  As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-2021-4 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions;
- up to 66.67% of the BSPCE-2021-4 founders' share warrant (the "Performance BSPCEs-2021-4"), in the event of the achievement of certain objectives determined by the Board of Directors and notified to each Beneficiary in the award letter.

The BSPCE-2021-4 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-2021-4 founders' share warrants);
- 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);
- failure to exercise prior to the expiry of the term of validity of the BSPCE-2021-4 founders' share warrant.

(5) Each BSPCE-2021-5 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2021-5 founders' share warrant provide that the BSPCE-2021-5 may be exercised according to the following schedule:

(iii) the last day of the calendar month in which the date of the first anniversary of the Vesting Start Date falls, up to one third (1/3) of the total number of BSPCE-2021-5 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number); then

(iv) the last day of each calendar month following the date referred to in paragraph (i), up to one forty-eighth ($1/36^{th}$) of the total number of BSPCE-2021-5 founders' share warrant allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number; except for the last instalment, where the entire balance of the BSPCE-2021-5 not yet exercisable at that date, will become so).

As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-2021-5 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions.

The BSPCE-2021-5 founders' share warrants exercisable on a given date will become null and void in the following scenarios:

- 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);
- failure to exercise prior to the expiry of the term of validity of the BSPCE-2021-5 founders' share warrant.

(6) Each BSPCE-2021-6 founders' share warrant gives the right to subscribe (1) ordinary share. The terms and conditions of the BSPCE-2021-6 founders' share warrant provide that the BSPCE-2021-6 may be exercised under the following conditions:

- up to 20% of the BSPCE 2021-6 founders' share warrant (the "Vesting BSPCE-2021-6"), according to the following schedule:
  (i) the last day of the calendar month in which the date of the first anniversary of the Vesting Start Date falls, up to one quarter (1/4) of the total number of Vesting BSPCE-2021-6 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number); then
  (ii) the last day of each calendar month following the date referred to in paragraph (i), up to one forty-eighth ($1/48^{th}$) of the total number of Vesting BSPCE-2021-6 allocated to the Beneficiary (rounded down, if necessary, to the nearest whole number; except for the last instalment, where the entire balance of the Vesting BSPCE-2021-6 not yet exercisable at that date, will become so).
  As an exception to the above vesting schedule, the Board of Directors may unilaterally decide that all or some of the BSPCE-2021-6 share subscription warrants shall become exercisable early, it being specified that this decision may come with conditions:
- up to 80% of the BSPCE 2021-6 founders' share warrant (the "Performance BSPCE-2021-6"), in the event of the achievement of certain objectives determined by the Board of Directors and notified to each Beneficiary in the award letter.

The BSPCE-2021-6 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-2021-6 founders' share warrants);
- 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);
- failure to exercise prior to the expiry of the term of validity of the BSPCE-2021-6 founders' share warrant.

As at the date of approval of the Universal Registration Document, the total number of BSPCE founders' share warrants is **3,284,362** granting entitlement to **3,284,362** new Company shares.

Only a portion of the BSPCE founders' share warrants of the various plans presented above are exercisable on the date of the Universal 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.

6.1.4.3. Convertible bonds

On 6 December 2019, the Board of Directors of Affluent Medical issued a total of 4,000,000 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 CBs are 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 was then required to repay the convertible bonds and 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 repayment of around €4.1 million was made in the amount of €3.0 million in 2021. The balance was repaid at the end of January 2022.

The aforementioned pledges will be released as part of this repayment.

6.1.4.4. Allocation of bonus shares

On 20 July 2021, the Board of Directors decided to set up a bonus share allocation plan for some of its employees.

Changes in the bonus share allocation plan in force at 31 December 2021 are as follows:

Plan	Plan 2021-1
Date of the General Meeting that authorised the allocation of bonus shares	6 April 2021
Date of grant	20 July 2021
Vesting period	1 year

Plan	Plan 2021-1
Lock-up period	2 years
Total number of bonus shares allocated	4,050
Of which subject to performance conditions	0
Of which allocated to corporate officers	0
Number of shares acquired in 2021	0
Number of shares cancelled in 2021	350
Total number of outstanding shares as at 31 December	3,700

6.1.4.5. Summary of dilutive instruments

The table below presents a summary of dilutive instruments as at the date of approval of the Universal Registration Document:

	BSAs	BSPCEs	CBs	AGA	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	**287,487**	**3,284,362**	**0***	**3,700**	**3,575,549**

*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 Universal Registration Document, the potential dilution that may result from the exercise or the definitive allocation of all dilutive instruments is 16.45% of the share capital on a fully diluted basis.

6.1.5. Capital authorised but not issued

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 of validity	Common cap	Use of
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	Board of Directors Deliberations of 9 June 2021 Share capital increase of €2,906,978 par value through the issue of 2,906,978 shares.
Authorisation to be given to the Board of Directors to reduce the share capital by cancelling treasury shares, subject to a condition precedent	Up to a limit of 10% of the share capital per 24-month period		18 months	N/A	

Transaction	Cap (nominal amount)	Methods for determining the issue price/exercise price	Term of validity	Common cap	Use of
(24th resolution)					
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 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) 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	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 of validity	Common cap	Use of
- 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: €6,100,000 within the limit of 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 and/or securities giving rights to equity securities, with the cancellation of preferential subscription rights under the authorisation, subject to the 26th and 28th	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 of validity	Common cap	Use of
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	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 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, executives or employees of these entities in the case of legal entities;	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 of validity	Common cap	Use of
- executives, corporate officers or employees of the Company or its subsidiaries; (36th resolution)					
Authorisation to the Board of Directors to allocate bonus 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	Board of Directors Deliberations of 20 July 2021 Allocation of 4,050 ordinary shares subject to a continued presence condition.
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)		18 months	Common cap to the 35th to the 38th resolutions	Board of Directors Deliberations of 20 July 2021 Issue of 475,000 BSPCE founders' share warrants that may give rise to a capital increase of €475,000 par value through the issue of 475,000 shares. Deliberations of 20 September 2021 Issue of 506,500 BSPCE founders' share warrants that may give rise to a capital increase of €506,500 par value through the issue of 506,500 shares.
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 €6,100,000. 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 €60,000,000.

(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;

6.1.6. Information about the Company's capital that is under option or agreed conditionally or unconditionally to be put under option

Not applicable.

6.1.7. Changes in share capital

6.1.7.1. 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[58]	€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
11 June 2021	Share capital increase in cash	2,906,978	22,093,032.80	2,906,978	18,163,802	€1	€18,163,802

6.1.7.2. Changes of the allocation of the share capital in the past three financial years

Shareholders	Position as at 31 December 2021		Position as at 31 December 2020		Position as at 31 December 2019	
	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	11,851,753	65.25%	10,674,399	69.96%	7,735,621	65.01%
Other financial investors (including observers)	4,117,697	22.67%	4,361,344	28.59%	3,953,876	33.23%

[58] 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.

Founders, executives and members of the Board of Directors and committees	220,611	1.21%	220,611	1.45%	210,000	1.76%
Individual	1,888,956	10.40%	470	0.00%	470	0.00%
Employees	0	0.00%	0	0.00%	0	0.00%
Self-auditing	84,785	0.47%	0	0.00%	0	0.00%
TOTAL	**18,163,802**	**100.00%**	**15,256,824**	**100.00%**	**11,899,967**	**100.00%**

6.2. Memorandum of association and bylaws

6.2.1. 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.

6.2.2. Provisions of the bylaws or other provisions related to members of corporate governance and management bodies

It is reminded that the General Meeting of Shareholders of 24 May 2022 will be asked to set the age limit of the Chairman of the Board of Directors at 85 years, in order to ensure consistency with the age limit of Board members and the continuation of the current term of office of the Chairman and Chief Executive Officer.

The Company is governed by a Board of Directors.

6.2.2.1. 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 members are determined by laws and regulations.

Board members 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 Board members may be made by the Extraordinary General Meeting.

Board members may be individuals or legal entities, whether or not Company shareholders. Board members 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 Board member 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

Board members shall be appointed for a term of three (3) years and may always be reappointed. The duties of a Board member 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 Board member expires.

No Board member may be appointed if they are over the age of eighty-five (85), and if their appointment would result in the number of Board members over the age of 85 exceeding one third of the members of the Board.

The number of Board members 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 Board member 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 Board member 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 Board members falls below the legal minimum, the remaining Board members shall immediately call an Ordinary General Meeting in order to make up the number of Board members.

12.4 Compensation of Board members

The Annual General Meeting may allocate a fixed annual amount to the Board members 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.

Board members may not receive any compensation from the Company, whether permanent or not, in respect of their directorship, other than those provided for by law. Exceptional compensation for the assignments or offices entrusted to Board members 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 Board members' shares

Board members 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 Board members are invited. They have the same right to information as the Board members.

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, observers 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 directorship 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 Board member 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 and executes its decisions. He/she shall oversee the effectiveness of the Company's corporate governance structure and in particular ensure that the Board members are 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 directorship, but the termination of his/her directorship 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 (5) business days prior to the meeting of the Board on the first call and at least two (2) business days before the meeting of the Board on the second call, with the exception, where all Board members are present (if necessary by videoconference or telecommunication) or represented or have waived the notice periods (it being specified that a Board member'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 Board members with information relating to the decisions on which the Board of Directors is being called upon to vote. Except in cases where all Board members 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 Board member delegated to act as chairman), or failing that, by a Board member chosen by the Board of Directors.

Any Board member may authorise another Board member, 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 Board member may not hold more than one proxy at any given meeting.

Internal regulations that may be adopted by the Board of Directors may provide, in particular, within the limits established by law, for Board members 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 Board members as well as, where applicable, the Statutory Auditors and any representatives of the Social and Economic Committee, all the information required for decisions on the consultation agenda.

The Board members 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 Board member 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 Board members 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 Board members 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 Board members 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 Board member 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 Board members 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 Board members 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.

6.2.2.2. 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 Board member, 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 Board member 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 shareholders' meetings 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 CEO

On the proposal of the Chief Executive Officer, the Board of Directors may appoint one or more Deputy CEO as provided by law. The Deputy CEO must be natural persons. They may be chosen from among the Board members or from outside the Board. The number of Deputy CEO 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 Deputy CEO. With regard to third parties the Deputy CEO(s) has (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 Deputy CEO may be older than seventy-five years of age. If a Deputy CEO in office reaches that age, he/she will be deemed to have resigned.

The Deputy CEO 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 Deputy CEO shall keep their offices and allocations until a new Chief Executive Officer is appointed, unless otherwise decided by the Board.

16.4 Delegations of power

The Board of Directors may assign permanent or temporary assignments to its corporate officers, whether Board members or not, delegate authority to them and set the compensation it deems appropriate.

6.2.3. Rights, entitlements and restrictions attached to the Company's shares

6.2.3.1. 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.

6.2.3.2. 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.

6.2.3.3. 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.

6.2.3.4. 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.

6.2.3.5. Restrictions on voting rights

Not applicable.

6.2.3.6. 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.

6.2.3.7. 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.

6.2.3.8. Buyback by the Company of its own shares

Please refer to section 19.1.3 of this Universal Registration Document.

6.2.4. 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.

6.2.5. 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. 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 Board member 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 General 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.

6.3. 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.

6.3.1. 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 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.

6.3.2. Special 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.

7. MATERIAL AGREEMENTS

7.1. 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 Mainland 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[59]) by Shanghai Zuquan Investment Management Company Limited;
- 7.2 million RMB (*i.e.* approximately €0.9 million[61]) by the relevant Subsidiary (Epygon or MyoPowers);

it being specified that any additional expenses will be borne by Shanghai Zuquan Investment Management Company Limited.

7.2. Agreements related to research and development for the MIVANA Project

7.2.1. 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.

[59] Based on the RMB/EUR exchange rate prevailing on the date of the signing of the joint ventures.

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.

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.

7.2.2. 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 Universal Registration Document, three of the four key milestones of the MIVANA Project had been completed:

- Kephalios and Epygon received respectively €820,000 and €753,537 in grants, *i.e.* a total of €1,573,537;
- Kephalios and Epygon received respectively €892,000 and €1,655,000 in repayable advances, *i.e.* a total of €2,547,000.

The completion of the fourth key milestone 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 Universal 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).

7.3. Bpifrance agreement to provide funding for the Artus "Industrial Project for the Future" PIAVE initiative under the Investments for the Future Programme

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 "**PIAVE Artus 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 PIAVE Artus Project of €23.0 million.

In exchange, MyoPowers has pledged to Bpifrance Financement that this funding will only be used for the PIAVE Artus Project and to fund expenditures in industrial research, experimental development and investment.

As at the date of approval of the Universal Registration Document, the first two of the four key stages of the PIAVE Artus Project had been completed. On this occasion, MyoPowers received €117 thousand in grants and €6,188 thousand in repayable advances.

The completion of the next two key milestones of the PIAVE Artus Project are planned between the financial year 2022 and 2025.

Repayments of the advances received by MyoPowers as part of the PIAVE Artus Project are expected to start from the financial year 2023 and extend until 2026 (refer to section 3.4.4. of the Universal 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.

7.4. 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 €8,000,000 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.* 4,000,000 bonds) ("**Tranche A**") issued on 29 October 2018 and fully subscribed;

- €4,000,000 (*i.e.* 4,000,000 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. As at 31 December 2021, non-convertible bonds issued to Kreos totalled €1,370 thousand (of which €1,370 thousand in current financial liabilities) (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.

8. DOCUMENTS AVAILABLE

Copies of the Universal 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) website of the French Financial Markets Authority (*Autorité des marchés financiers* – AMF) (www.amf-france.org).

During the term of validity of the Universal 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 reporting;
- valuations and statements prepared by an expert at the Company's request, some of which are included or referred to in the Universal Registration Document; and
- the historical financial reporting included in the Universal 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. Regulated information within the meaning of the provisions of the AMF General Regulations is also available on the Company's website (www.affluentmedical.com).

9. 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 endoprosthesis 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)	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 celioscopies 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.
Plication	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)	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.
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.
Urinary retention	Inability to fully or partially empty the bladder.
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.

10. CONCORDANCE TABLE AND RECONCILIATION TABLE

23.1 Concordance table

Commission Delegated Regulation (EU) 2019/980 of 14 March 2019 supplementing Regulation (EU) 2017/1129 – Annex 1		Universal Registration Document
No.	**Section**	**Reference (Chapter/Section)**
1	**PERSONS RESPONSIBLE, THIRD PARTY INFORMATION, EXPERTS' REPORTS AND COMPETENT AUTHORITY APPROVAL**	**Chapter 1**
1.1	Persons responsible for the information contained in the Universal Registration Document	**1.1**
1.2	Declaration of the persons responsible for the Universal Registration Document	**1.2**
1.3	Person acting as an expert	**1.3**
1.4	Statement regarding third-party information	**1.4**
1.5	Statement concerning the approval of the Universal Registration Document by the competent authority	**1.5**
2	**STATUTORY AUDITORS**	**2**
2.1	Name and address of the Company's Statutory Auditors	**2.1 and 2.2**
2.2	Statutory auditors who resigned, were dismissed or were not reappointed during the period covered by the historical financial information	**2.3**
3	**RISK FACTORS**	**3**
4	**INFORMATION ABOUT THE COMPANY**	**4**
4.1	Company name and commercial name	**4.1**
4.2	Company's place of registration, registration number and Legal Entity Identifier (LEI)	**4.2**
4.3	Date of incorporation and term of the Company	**4.3**
4.4	Registered office and legal form of the Company, legislation governing its activities, country in which it is incorporated, address and telephone number of its registered office and website	**4.4**
5	**BUSINESS OVERVIEW**	**5**
5.1	Principal activities	**5.1**
5.1.1	Type of transactions carried out by the Company and its main activities	**5.1.1** **5.1.2**

5.1.2	Significant new product or service launched on the market	**5.2.2.2** **5.2.3.2** **5.2.3.3** **5.2.4.2**
5.2	Principal markets	**5.2.2.1** **5.2.3.1** **5.2.4.1**
5.3	Significant events in the development of the Company's business	**5.2.1**
5.4	Strategy and objectives	**5.1.2** **5.2.2.2** **5.2.3.2** **5.2.3.3** **5.2.4.2** **5.3.1** **5.3.2** **5.3.4** **5.3.5** **5.3.6**
5.5	Degree of dependence of the Company on patents or licenses, industrial, commercial or financial contracts or new manufacturing processes	**5.3.3**
5.6	Information on which the Company's statement of its competitive position is based	**5.2.2.2** **5.2.3.2** **5.2.3.3** **5.2.4.1**
5.7	Investments	**5.4**
5.7.1	Significant investments made by the Company during each financial year of the period covered by the historical financial information, up to the date of the Universal Registration Document	**5.4.1**
5.7.2	Significant investments by the Company that are in progress or for which firm commitments have already been made	**5.4.2**
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**
5.7.4	Environmental issues that could influence the Company's use of its tangible assets	**5.4.4**
6	**ORGANISATIONAL STRUCTURE**	**6**
6.1	Brief description of the Group and the Company's position within it	**6.1**
6.2	List of significant subsidiaries of the Company	**6.2**
7	**OPERATING AND FINANCIAL REVIEW**	**7**
7.1	Financial position	**7.1**

7.1.1	Fair presentation of the evolution and results of the Company's activities, as well as its position for each financial year and interim period for which historical financial information is required	**7.1.1 to 7.1.3**
7.1.2	Information on the probable future development of the Company's activities and its research and development activities	**7.1.1 to 7.1.3**
7.2	Operating income	**7.2**
7.2.1	Significant factors, including unusual or infrequent events or new developments, that materially affect the Company's operating revenue	**7.2.1**
7.2.2	Reason for significant changes in net revenue or net income	**7.2.1.1**
8	**CAPITAL RESOURCES**	**8**
8.1	Information on the issuer's capital (short-term and long-term)	**8.1**
8.2	Sources and amounts of the Company's cash flows and description of these cash flows	**8.2**
8.3	Provide information on the issuer's financing needs and structure	**8.3**
8.4	Information concerning any restrictions on the use of capital that have materially affected, or could materially affect, directly or indirectly, the Company's business	**8.4**
8.5	Information regarding the expected sources of funding that will be required to honour the Company's significant investments that are in progress or for which firm commitments have already been made	**8.5**
9	**REGULATORY ENVIRONMENT**	**9**
10	**TREND INFORMATION**	**10**
10.1	Description (i) of 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 Universal Registration Document, and (ii) any material changes 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 Universal Registration Document, or provide an appropriate negative statement	**10.1**
10.2	Trends, uncertainties, constraints, commitments or events of which the Company is aware and which is reasonably likely to have a material impact on the Company's outlook, at least for the current financial year	**10.2**
11	**PROFIT FORECASTS OR ESTIMATES**	**11**
12	**ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND SENIOR MANAGEMENT**	**12**

12.1	Name, professional address, position within the Company and main activities exercised outside the Company of (a) members of the corporate governance, management or supervisory bodies, (b) General Partners, in the case of *a société en commandite par actions*, (c) founders, if it is a company founded less than five years ago and (d) chief executive officers whose name can be mentioned to prove that the Company has appropriate expertise and experience to run its own business. Nature of any family ties between these persons. For each person who is a member of a corporate governance, management or supervisory body and for each person referred to in points (b) and (d), detailed information on their relevant management expertise and experience and (a) name of companies and limited partnerships in which the person has been a member of a corporate governance, management or supervisory body or General Partner, at any time during the last five years, (b) details of any convictions for fraud during the last five years at least, (c) details of any bankruptcy, receivership, liquidation or receivership of undertakings in the last five years at least, and (d) details of any claims and/or official public sanction pronounced by statutory or regulatory authorities as well as any disqualification ordered by a court of law to serve as a member of a corporate governance or management body or supervision of an issuer or to intervene in the management or conduct of the business of an issuer for at least the last five years.	**12.1**
12.2	Conflicts of interest, commitments relating to appointments, restrictions on disposals of Company shares	**12.2**
13	**REMUNERATION AND BENEFITS**	**13**
13.1	Amount of compensation paid and benefits in kind granted by the Company and its subsidiaries	**13.1**
13.2	Total amount provisioned or otherwise recognised by the Company or its subsidiaries for the payment of pensions, retirement or other benefits	**13.2**
14	**OPERATING PROCEDURES OF CORPORATE GOVERNANCE AND MANAGEMENT BODIES**	**14**
14.1	Date of expiry of current mandate and period during which the person remained in office	**12.1.1** **14.1**
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, or an appropriate statement attesting to the absence of such benefits	**14.2**
14.3	Information on the Company'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**
14.4	Statement as to whether or not the Company complies with the corporate governance regime applicable to it	**14.5**
14.5	Potential material impacts on corporate governance, including future changes in the composition of the corporate governance and management bodies and committees	**N/A**
15	**EMPLOYEES**	**15**

15.1	Number of employees at the end of the period covered by the historical financial reporting, and breakdown of employees by major category of activity and by site	**15.1**
15.2	Shareholdings and stock options	**15.2** **15.3**
15.3	Agreement providing for employee shareholding in the Company's share capital	**15.4**
16	**MAJOR SHAREHOLDERS**	**16**
16.1	Name of any person who is not a member of a corporate governance, management or supervisory body holding, directly or indirectly, a percentage of the share capital or voting rights of the Company that must be notified under the applicable national legislation and the amount of the interest held, or, failing this, an appropriate statement indicating the absence of such persons	**16.1** **16.2**
16.2	Different voting rights, or appropriate statement indicating the absence of such voting rights	**16.3**
16.3	Direct or indirect ownership or control of the Company	**16.4**
16.4	Agreement, known to the Company, the implementation of which could, at a later date result in a change of control over it	**16.5** **16.6**
17	**RELATED PARTY TRANSACTIONS**	**17**
18	**FINANCIAL INFORMATION CONCERNING THE ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES**	**18**
18.1	Historical financial information	**18.1**
18.1.1	Audited historical financial information for the last three financial years and audit report prepared for each of these financial years	**18.1.1**
18.1.2	Change of accounting reference date	**18.1.2**
18.1.3	Accounting standards	**18.1.3**
18.1.4	Change in accounting framework	**18.1.4**
18.1.5	Audited financial information including the balance sheet, income statement, statement of changes in equity, cash flow statement, accounting methods and explanatory notes	**18.1.5**
18.1.6	Consolidated financial statements	**18.1.1**
18.1.7	Date of latest financial information	**18.1.5**
18.2	Interim and other financial information	**18.2**

18.3	Audit of historical annual financial information	**18.3**
18.3.1	Historical annual financial reporting must be independently audited.	**18.3**
18.3.2	Other information contained in the Universal Registration Document audited by the statutory auditors	**N/A**
18.3.3	Sources and details of the absence of audit for unaudited financial information	**N/A**
18.4	Pro forma financial information	**18.6**
18.5	Dividend policy	**18.7**
18.5.1	Dividend policy or appropriate statement indicating the lack of dividend policy	**18.7.1**
18.5.2	Dividend per share	**18.7.2**
18.6	Legal and arbitration proceedings	**18.8**
18.7	Significant change in the issuer's financial position	**18.9**
19	**ADDITIONAL INFORMATION**	**19**
19.1	Share capital	**19.1**
19.1.1	Amount of share capital issued, total authorised share capital of the Company, number of shares issued and fully paid up, number of shares issued but not fully paid up, par value per share and reconciliation of the number of shares outstanding at the date of opening and closing date of the financial year	**19.1.1**
19.1.2	Number and main characteristics of shares not representing capital	**19.1.2**
19.1.3	Number, book value and par value of shares held by the Company, itself or on its behalf, or by its subsidiaries	**19.1.3**
19.1.4	Convertible securities, exchangeable securities or securities with warrants	**19.1.4**
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**
19.1.6	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	**19.1.6**
19.1.7	History of share capital for the period covered by the historical financial information	**19.1.7**
19.2	Memorandum of association and bylaws	**19.2**
19.2.1	Register and entry number in the register; Corporate purpose	**19.2.1**
19.2.2	Rights, entitlements and restrictions attached to each class of existing shares	**19.2.2**

19.2.3	Provisions of the Company's memorandum of association, bylaws, charter or regulation that would have the effect of delaying, deferring or preventing a change in its control	**19.3**
20	**MATERIAL CONTRACTS**	**20**
21	**DOCUMENTS AVAILABLE**	**21**

Commission Delegated Regulation (EU) 2019/980 of 14 March 2019 supplementing Regulation (EU) 2017/1129 – Annex 2		**Universal Registration Document**
No.	**Section**	**Reference (Chapter/Section)**
1	**INFORMATION TO BE DISCLOSED ABOUT THE COMPANY**	**Chapter 1**
1.1	Information required in accordance with the disclosure requirements applicable to the Universal Registration Document for equity securities set out in Appendix 1	
1.2	Statement indicating that the Universal 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 supplemented by amendments, where applicable, and a securities note and the approved summary and specifying, where applicable, that the Universal Registration Document has been filed with the competent authority without prior approval.	

23.2 Concordance table

This Universal Registration Document includes all the elements of the management report of the Company and the Group as required by the following articles of the French Commercial Code:

L. 225-100, L. 225-100-1, L. 22-10-35 as created by Order no. 2020-1142 of 16 September 2020 creating, within the French Commercial Code, a division specific to companies whose securities are admitted to trading on a regulated market (the "Order"), L. 232-1 II, L. 233-16, L. 233-26 and R. 225-102 as well as L. 225-102-1 and L. 22-10-36 as created by the Order (I). It also contains all the information contained in the annual financial report referred to in Articles L. 451-1-2 of the French Monetary and Financial Code and Article 222-3 of the General Regulation of the AMF (II).

In order to facilitate the reading of the aforementioned management report and the annual financial report, the following concordance table makes it possible to identify the headings constituting them.

The concordance table also makes it possible to identify the information required in the Board of Directors' corporate governance report prepared under Articles L. 225-37, L. 22-10-8 and L. 22-10.-9 as created by the Order, L. 225-37-4, L. 22-10-10 and L. 22-10-11 as created by the Order, of the French Commercial Code (III).

Lastly, the concordance table shows the other documents or reports prepared by the Board of Directors as well as the reports prepared by the Statutory Auditors (IV).

No.	Section	Reference texts	Reference (Chapter/Section)
I	**MANAGEMENT REPORT**		
1	**Group position and business**		
1.1	Position of the company during the past financial year and objective and exhaustive analysis of the evolution of the business, results and financial position of the company and the group, in particular its debt position, with regard to volume and business complexity	Articles L. 225-100-1, I., paragraph 1, L. 232-1, II, L. 233-6 and L. 233-26 of the French Commercial Code	Chapters 7 and 8
1.2	Key financial performance indicators	Article L. 225-100-1, I., paragraph 2	Chapters 7 and 8
1.3	Key non-financial performance indicators relating to the specific activity of the company and the group, in particular information relating to environmental and personnel issues	Article L. 225-100-1, I., paragraph 2	Chapters 7 and 8
1.4	Significant events between the closing date of the financial year and the date on which the management report is prepared	Articles L. 232-1, II. and L. 233-26 of the French Commercial Code	Note 27 of the notes to the consolidated financial statements presented in section 18.1.1.1
1.5	Identity of the main shareholders and holders of voting rights at General Meetings, and changes made during the financial year	Article L. 233-13 of the French Commercial Code	Chapter 16
1.6	Existing branches	Article L. 232-1, II of the French Commercial Code	N/A
1.7	Significant equity investments in companies with registered office in France	Article L. 233-6 paragraph 1 of the French Commercial Code	N/A
1.8	Disposals of cross-shareholdings	Articles L. 233-29, L. 233-30 and R.233-19 of the French Commercial Code	N/A
1.9	Foreseeable changes in the position of the Company and Group and future prospects	Articles L. 232-1, II. and L. 233-26 of the French Commercial Code	Chapters 10 and 11
1.10	Research and development activities.	Articles L. 232-1, II. and L. 233-26 of the French Commercial Code	5.1 and 5.2

1.11	Table showing the Company's results for each of the last five financial years	Article R. 225-102 of the French Commercial Code	18.10.2
1.12	Information on supplier and customer payment terms	Article D. 441-4 of the French Commercial Code	10.18.1
1.13	Amount of inter-company loans granted and Statutory Auditor's statement	Articles L. 511-6 and R. 511-2-1-3 of the French Monetary and Financial Code	N/A
2	**Internal control and risk management**		
2.1	Description of the main risks and uncertainties facing the Company	Article L. 225-100-1, I., 3 ° of the French Commercial Code	Chapter 3
2.2	Information on the financial risks related to the effects of climate change and measures taken by the Company to reduce them by implementing a low-carbon strategy in all components of its activity	Article L. 22-10-35, paragraph 1 of the French Commercial Code	N/A
2.3	Main characteristics of the internal control and risk management procedures implemented by the Company and the Group, detailing in particular those relating to the preparation and processing of accounting and financial information	Article L. 22-10-35, paragraph 2 of the French Commercial Code	14.6
2.4	Information on the objectives and policy concerning the hedging of each main category of transactions and on exposure to price, credit, liquidity and cash risks, including the use of financial instruments	Article L. 225-100-1., paragraph 4 of the French Commercial Code	Note 25 of the notes to the consolidated financial statements presented in section 18.1.1.1
2.5	Anti-corruption system	Law No. 2016-1691 of 9 December 2016 known as "Sapin 2"	N/A
2.6	Monitoring plan and report on its effective implementation	Article L. 225-102-4 of the French Commercial Code	N/A
3	**BOARD OF DIRECTORS' REPORT ON CORPORATE GOVERNANCE**		
Information on compensation			
3.1	Compensation policy for corporate officers detailed in Article R. 225-29-1 of the French Commercial Code	Article L. 22-10-8, I., paragraph 2 of the French Commercial Code Article R. 22-10-14 of the French Commercial Code	13.1.1

3.2	Compensation and benefits of any kind paid during the financial year or allocated in respect of the financial year to each corporate officer	Article L. 22-10-9, I., paragraph 1 of the French Commercial Code Article R. 22-10-15 of the French Commercial Code	13.2
3.3	Relative proportion of fixed and variable compensation	Article L. 22-10-9, I., paragraph 2 of the French Commercial Code	13.1.1.2 13.2.1.2
3.4	Use of the option to request the repayment of variable compensation	Article L. 22-10-9, I., paragraph 3 of the French Commercial Code	13.1.1.2
3.5	Commitments of any kind made by the Company for the benefit of its corporate officers, corresponding to elements of compensation, indemnities or benefits due or likely to be due as a result of the assumption, termination or change of their duties, or after they are exercised	Article L. 22-10-9, I., paragraph 4 of the French Commercial Code	13.2.1.1
3.6	Compensation paid or allocated by a company included in the scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code	Article L. 22-10-9, I., paragraph 5 of the French Commercial Code	13.2.1.2
3.7	Ratios between the level of compensation of each executive corporate officer and the average and median compensation of the Company's employees	Article L. 22-10-9, I., paragraph 6 of the French Commercial Code	13.2.1.2
3.8	Annual change in compensation, the Company's performance, the average compensation of the Company's employees and the aforementioned ratios over the five most recent financial years	Article L. 22-10-9, I., paragraph 7 of the French Commercial Code	13.2.1.2
3.9	Explanation of how the total compensation complies with the adopted compensation policy, including how it contributes to the long-term performance of the company and the way in which the performance criteria have been applied	Article L. 22-10-9, I., paragraph 8 of the French Commercial Code	N/A
3.10	How the vote of the last Ordinary General Meeting provided for in I of Article L. 22-10-34 of the French Commercial Code was taken into account	Article L. 22-10-9, I., paragraph 9 of the French Commercial Code	N/A
3.11	Deviation from the procedure for implementing the compensation policy and any exceptions	Article L. 22-10-9, I., paragraph 10 of the French Commercial Code	N/A
3.12	Application of the provisions of the second paragraph of Article L. 225-45 of the French Commercial Code (suspension of	Article L. 22-10-9, I., paragraph 11 of the French Commercial Code	N/A

	payment of directors' compensation in the event of non-compliance with the gender balance of the Board of Directors)		
Governance information			
3.15	List of offices and positions held in any company by each corporate officer during the past financial year	Article L. 225-37-4, paragraph 1 of the French Commercial Code	12.1.4
3.16	Agreements entered into between a corporate officer or a significant shareholder and a subsidiary of the Company	Article L. 225-37-4, paragraph 2 of the French Commercial Code	17.2
3.17	Summary table of current delegations granted by the General Meeting to increase share capital	Article L. 225-37-4, paragraph 3 of the French Commercial Code	19.1.5
3.18	Methods for exercising the General Management of the Company	Article L. 225-37-4, paragraph 4 of the French Commercial Code	14.1.1
3.19	Composition, conditions for preparing and organising the work of the Board of Directors	Article L. 22-10-10, paragraph 1 of the French Commercial Code	12.1.1 14.1.5
3.20	Application of the principle of balanced representation of women and men on the Board	Article L. 22-10-10, paragraph 2 of the French Commercial Code	12.1.1
3.21	Any limitations that the Board of Directors places on the powers of the Chief Executive Officer	Article L. 22-10-10, paragraph 3 of the French Commercial Code	14.1.2
3.22	Reference to a corporate governance code and application of the "comply or explain" principle	Article L. 22-10-10, paragraph 4 of the French Commercial Code	14.5.1
3.23	Specific procedures relating to shareholder participation in the General Meeting or reference to the provisions of the Articles of Association that provide for them	Article L. 22-10-10, paragraph 5 of the French Commercial Code	19.2.5
3.24	Procedure for assessing current agreements - Implementation	Article L. 22-10-10, paragraph 6 of the French Commercial Code	12.3
3.25	Elements likely to have an impact in the event of a public tender offer or exchange offer	Article L. 22-10-11 of the French Commercial Code	
	Structure of the Company's share capital		Chapter 16
	Statutory restrictions on the exercise of voting rights and share transfers, clauses of agreements brought to the attention of the		19.2.3

	Company pursuant to Article L. 233-11 of the French Commercial Code		
	Direct or indirect shareholdings in the Company's share capital of which it is aware pursuant to Articles L. 233-7 and L. 233-12 of the French Commercial Code		Chapter 16
	List of holders of any securities with special rights of control and description thereof		N/A
	Control mechanisms provided for in any employee shareholding system, when the rights of control are not exercised by the latter		N/A
	Agreements between shareholders of which the Company is aware and which may result in restrictions on the transfer of shares and the exercise of voting rights		N/A
	Rules applicable to the appointment and replacement of members of the Board of Directors and to the amendment of the Company's bylaws		19.2.2.1
	Powers of the Board of Directors, in particular the issue or buyback of shares		19.1.3/19.1.5
	Agreements entered into by the Company that are amended or terminated in the event of a change of control(1)		Chapter 20
	Agreements providing for compensation for members of the Board of Directors or employees if they resign or are dismissed without real and serious cause or if their employment is terminated due to a public offer		13.1.1
4	**Shareholding and capital**		
4.1	Structure, change in the Company's share capital and crossing of thresholds	Article L. 233-13 of the French Commercial Code	16.1/19.1
4.2	Acquisition and disposal by the Company of its own shares	Articles L. 225-211 and R. 225-160 of the French Commercial Code	19.1.3
4.3	Statement of employee profit-sharing on the last day of the financial year (proportion of capital represented)	Article L. 225-102, paragraph 1 of the French Commercial Code	15.3 and 19.1.4

4.4	Statement of any adjustments for securities giving access to the share capital in the event of share buybacks or financial transactions	Articles R. 228-90 and R. 228-91 of the French Commercial Code	N/A
4.5	Transactions carried out by executives and related persons on the Company's shares	Article L. 621-18-2 of the French Monetary and Financial Code	16.2
4.6	Amount of dividends distributed over the last three financial years	Article 243 bis of the French General Tax Code	18.7.2
5	**Statement of non-financial performance**		**N/A**
6	**Other information**		
6.1	Additional tax information	Articles 223 quater and 223 quinquies of the French General Tax Code	18.10.4
6.2	Injunctions or financial penalties for anti-competitive practices	Article L. 464-2 of the French Commercial Code	N/A
II	**ANNUAL FINANCIAL REPORT**		
1	Annual financial statements		18.4
2	Consolidated financial statements		18.1.1
3	Statutory Auditors' report on the parent company financial statements		18.5
4	Statutory Auditors' report on the consolidated financial statements		18.3
5	Management report		See I of this concordance table, in particular the headings 4, 5, 6, 7, 15 and 16, and III, 13 of this table
6	Report of the Board of Directors on corporate governance prepared in accordance with the last paragraph of Article L. 225-37 of the French Commercial Code		See III of this concordance table
7	Statement by the persons responsible for the annual financial report		1.2

8	Statutory Auditors' fees		Note 26 of the notes to the consolidated financial statements presented in 18.1.1.1
9	Statutory Auditors' report on corporate governance prepared in accordance with Article L. 225-235 of the French Commercial Code		18.5

(1) Unless such disclosure, except in cases of legal disclosure, would seriously harm the Company's interests.